United States Court of Appeals
For the Eighth Circuit

No. 15-2420

United States ex rel. Linda Donegan, as Administrator
of the Estate of John Timothy Donegan

Relator - Appellant

v.

Anesthesia Associates of Kansas City, PC

Defendant - Appellee

United States of America

Amicus Curiae

Appeal from United States District Court
for the Western District of Missouri - Kansas City

Submitted: February 10, 2016
Filed: August 12, 2016

Before RILEY, Chief Judge, LOKEN and BENTON, Circuit Judges.

LOKEN, Circuit Judge.

John Timothy Donegan, a Certified Registered Nurse Anesthetist ("CRNA"), commenced this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C.

§ 3729-33.[1] The FCA's *qui tam* provisions authorize relators -- private citizens acting as whistleblowers -- to sue on behalf of the United States to recover damages for the submission of materially false claims for government payments. See United States ex rel. Newell v. City of St. Paul, 728 F.3d 791, 794 (8th Cir. 2013), cert. denied, 134 S. Ct. 1284 (2014). "The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment." United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5, 688 F.3d 410, 414 (8th Cir. 2012) (quotation omitted).

Donegan alleged that his former employer, Anesthesia Associates of Kansas City, P.C. ("AAKC"), violated 31 U.S.C. § 3729(a)(1)(A) and (B) by submitting claims for Medicare reimbursement of anesthesia services at the "Medical Direction" rate. The claims were knowingly false, Relator alleged, because AAKC anesthesiologists were not present in the operating room during patients' "emergence" from anesthesia, and therefore AAKC did not comply with the Medicare conditions of payment for submitting such claims. See 42 C.F.R. § 415.110(a)(1). The United States declined to intervene. The district court[2] granted AAKC summary judgment, concluding that Relator failed to establish that AAKC knowingly submitted false claims; the court declined to consider a theory of liability not asserted in Relator's amended complaint. Relator appeals these rulings. We granted the United States leave to appear as *amicus curiae* supporting neither party. Reviewing the grant of summary judgment *de novo*, and the failure to consider an unpleaded theory for abuse of discretion, we affirm.

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[1]Donegan passed away while the lawsuit was pending in the district court. His estate was substituted as *qui tam* Relator. This opinion will use the term Relator when referring to the *qui tam* plaintiff-appellant.

[2]The Honorable David Gregory Kays, Chief Judge of the United States District Court for the Western District of Missouri.

I. The "Emergence" Claim.

The Centers for Medicare and Medicaid Services ("CMS"), part of the Department of Health and Human Services, administers the Medicare and Medicaid programs. 42 U.S.C. §§ 1302, 1395hh. In reimbursing anesthesiology services, CMS regulations distinguish between four levels of services provided by anesthesiologists and CRNAs: Personally Performed, Medical Direction, Medical Supervision, and Not Medically Directed. 42 C.F.R. §§ 414.46, 414.60. The Medical Direction category at issue in this case applies when an anesthesiologist directs a qualified individual such as a CRNA in up to four concurrent anesthesia cases. 42 C.F.R. § 414.46(d)(ii); 42 C.F.R. § 415.110(a). To obtain reimbursement for Medical Direction, the Medicare regulations require the anesthesiologist to complete seven steps:

> (1) For each patient, the physician --
>
> > (i) Performs a pre-anesthetic examination and evaluation;
> > (ii) Prescribes the anesthesia plan;
> > (iii) Personally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence;
> > (iv) Ensures that any procedures in the anesthesia plan that he or she does not perform are performed by a qualified individual as defined in operating instructions;
> > (v) Monitors the course of anesthesia administration at frequent intervals;
> > (vi) Remains physically present and available for immediate diagnosis and treatment of emergencies; and
> > (vii) Provides indicated post-anesthesia care.

42 C.F.R. § 415.110(a)(1). The anesthesiologist must document "in the patient's medical record" that each step was completed, "specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable." 42 C.F.R. § 415.110(b).

AAKC employed CRNA Donegan at Menorah Medical Center ("MMC") in Overland Park, Kansas, from 2006 until January 2012. In MMC surgeries, the CRNA stays in the operating room with the patient throughout the procedure. The anesthesiologist concurrently directs or supervises anesthesia services in up to four operating rooms. MMC's practice is consistent with reimbursement for Medical Direction, provided its anesthesiologists comply with the required seven steps.

This appeal turns on compliance with "Step Three," which requires that the anesthesiologist "[p]ersonally participates in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence. 42 C.F.R. § 415.110(a)(1)(iii). At MMC, the anesthesiologist is present to insert the endotracheal tube that will be used to administer general anesthesia ("induction"). After the surgery, the CRNA removes the tube ("extubation") and delivers the patient to the recovery room, called the Post-Anesthesia Care Unit ("PACU"), where the CRNA transfers patient care to a PACU nurse. The anesthesiologist may visit the patient after surgery in the operating room or during transfer to the PACU. But the record reflects that in many if not most cases, the AAKC anesthesiologist's post-surgery visit occurred while the patient was recovering in the PACU.

Donegan's detailed FCA Amended Complaint alleged that AAKC failed to comply with Step Three of the Medical Direction requirements because its anesthesiologists were "virtually never present with patients during 'emergence,'" alleging that "the broadest definition of 'emergence'" is that it ends when the patient is turned over to the PACU staff. Relator claimed that AAKC knowingly violated the FCA by seeking reimbursement at the Medical Direction rate despite its non-compliance with this regulatory requirement.

After extensive discovery, the parties filed cross motions for summary judgment. The district court granted AAKC summary judgment, concluding that Relator cannot establish that AAKC submitted knowingly false or fraudulent claims

because (i) the term "emergence" in Step Three of the regulation has not been defined by CMS and is ambiguous; (ii) AAKC's definition of "emergence" as a process that includes the patient's recovery time in the PACU was objectively reasonable; and (iii) AAKC's reasonable interpretation of the ambiguous regulation "belies the scienter necessary to establish a claim of fraud under the FCA," quoting United States ex rel. Ketroser v. Mayo Found., 729 F.3d 825, 832 (8th Cir. 2013). On appeal, Relator challenges all three components of the district court's analysis.

We review the grant of summary judgment in FCA cases *de novo*, evaluating "whether the record, viewed in a light most favorable to the non-moving party, shows that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Schell v. Bluebird Media, LLC, 787 F.3d 1179, 1184 (8th Cir. 2015) (quotation omitted). The issue is whether Relator submitted sufficient evidence that AAKC's alleged practice of billing at the Medical Direction rate when the anesthesiologist did not participate in emergence in the operating room "constituted the knowing submission of a false or fraudulent claim or statement within the meaning of 31 U.S.C. § 3729(a)(1)(A) or (B)." Ketroser, 729 F.3d at 829. The statute defines "knowing" as "actual knowledge" or acting "in deliberate ignorance [or] reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

1. The brief of the United States as amicus curiae confirms what the district court observed: "CMS has not issued guidance on the meaning of" the term emergence in Step Three of the Medical Direction regulation, 42 C.F.R. § 415.110(a)(1)(iii). Nor has the term been defined by a controlling source, such as a Department of Health and Human Services national or binding local Coverage Determination, see 42 U.S.C. § 1395ff(c)(3)(B)(ii), or by the American Society of Anesthesiologists and the American Association of Nurse Anesthetists, professional bodies that establish anesthesia standards of care. See 72 Fed. Reg. 66,580, 66,885

(Nov. 27, 2007). On this record, given the term's obvious lack of a plain meaning, we agree with the district court that the regulation is ambiguous on this essential question.

2. Concerned by regulatory silence and the vagueness of the term, AAKC's Professional Practice Committee defined emergence in its 2001 Corporate Compliance Plan "to include the recovery room." In discovery, medical experts *for both parties* agreed that "emergence" is a medical term that refers to a post-surgery recovery process that can extend into the recovery room. AAKC's expert Dr. Helgeson wrote, "It is generally understood by anesthesiologists and CRNAs that emergence from general anesthesia is a process and has no discrete point in time. . . . Typically, there is no specific point in time where emergence is complete," but it continues at least while the patient is "still recovering from the anesthetic." Relator's experts, Dr. McAlary and Dr. Young, agreed that emergence as understood medically is a process that can extend into the PACU. On this record, we conclude that AAKC's interpretation -- that emergence as referenced in Step Three includes the patient's continued recovery in the PACU -- is objectively reasonable. This is an issue of law. See United States ex rel. Purcell v. MWI Corp., 807 F.3d 281, 288 (D.C. Cir. 2015).

In support of its contrary argument, Relator relies heavily on our decision in Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1056 (8th Cir.), cert. denied, 537 U.S. 944 (2002) ("Allina"). In that case, we reversed the grant of summary judgment on the relators' Medical Direction claim because there was a material fact dispute whether defendant anesthesiologists participated in emergence. The issue addressed in our Allina opinion was the proper interpretation of the term emergence in the regulation. Here, the question is whether AAKC's reasonable interpretation of the ambiguous regulation precludes a finding that it *knowingly* submitted false or fraudulent claims, even if CMS or a reviewing court would interpret the regulation differently. Relator simply failed to submit evidence refuting AAKC's strong showing that its interpretation was objectively reasonable. Relator's experts expressed their opinions that emergence as referred to in Step Three

should end before an AAKC patient is transferred to the PACU. But Relator's contention that the Medicare regulations be interpreted in this fashion is "a claim of regulatory noncompliance," not "an FCA claim of knowing fraud." Ketroser, 729 F.3d at 831-32; see United States ex rel. Norbeck v. Basin Elec. Power Coop., 248 F.3d 781, 793 (8th Cir. 2001), cert. denied, 534 U.S. 1115 (2002) ("The audit team's deliberate choice of this assumption cannot be fraud if they honestly believed it was a correct assumption.").

3. The remaining question is whether the district court correctly concluded that AAKC's reasonable interpretation of the ambiguous regulation precludes a determination that AAKC was guilty of knowingly submitting false claims in violation of the FCA. The district court accurately noted our prior ruling that an FCA defendant's reasonable interpretation of an ambiguous regulation "belies the scienter necessary to establish a claim of fraud under the FCA." Ketroser, 729 F.3d at 832. The United States as *amicus* protests that the district court "adopted the sweeping rule that a defendant's reasonable interpretation of an ambiguous regulation precludes FCA liability, regardless of the defendant's state of mind."

The word "belies" is not so sweeping. It lies in harmony with the principle that summary judgment is not proper on the issue of FCA scienter *if* a Relator (or the United States) produces sufficient evidence of government guidance that "warn[ed] a regulated defendant away from an otherwise reasonable interpretation" of an ambiguous regulation. Purcell, 807 F.3d at 290, applying the Supreme Court's interpretation of "reckless disregard" in Safeco Ins. Co. v. Burr, 551 U.S. 47, 69-70 (2007). This principle was the basis for our reversal of summary judgment on the Personally Performed FCA claim in Allina: a Medicare agency memorandum "made it clear that anesthesiologists were not to leave a patient during a personally performed procedure." 276 F.3d at 1054. Here, Relator submitted no relevant evidence that, at the time AAKC submitted the reimbursement claims at issue, the government had warned AAKC that the agency interpreted Step Three differently. Accord United

States v. K & R Ltd. v. Mass. Hous. Fin. Agency, 530 F.3d 980, 982 (D.C. Cir. 2008). Relator relies on a 1997 report prepared for relators in Allina by a former Section Chief of CMS's predecessor. However, a report prepared nearly two decades ago by a former agency official for use in another case is not the kind of official government warning that would be sufficient evidence of reckless disregard.

Relator further argues that summary judgment was improper because AAKC had a duty to ask CMS or its local contractors whether its interpretation of "emergence" was proper. We disagree. As the agency had not clarified an obvious ambiguity in its Step Three regulation for decades, AAKC's "failure to obtain a legal opinion or prior [CMS] approval cannot support a finding of recklessness." K & R Ltd., 530 F.3d at 983-84.

II. The New Theory Issue.

Relator argues the district court erred in refusing to consider a theory first articulated in Relator's summary judgment papers -- that AAKC violated Step Three because its anesthesiologists were not present during extubation, one of the "most demanding aspects of the anesthesia plan." Relator argues that its Amended Complaint alleged that anesthesiologists were not present at extubation, and that extubation is part of emergence and therefore need not be separately pleaded. But an FCA claim that an anesthesiologist was not present at extubation, a "demanding aspect" not specifically referenced in Step Three, is different than an FCA claim that an anesthesiologist was never present during "emergence," which is specifically referred to in Step Three. Whether due to careless pleading or an attempt to "lay in the weeds," Relator's litigation tactic deprived the United States of an opportunity to

consider this theory before declining to join in the action. The district court did not abuse its discretion in refusing to consider the theory.[3]

III. The Documentation Issue.

Relator argues that AAKC violated 42 C.F.R. § 415.110(b), which requires the anesthesiologist to "document[] in the patient's medical record that the conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she . . . was present during the most demanding procedures, including induction and emergence where applicable."

For each anesthesia procedure, AAKC anesthesiologists and CRNAs complete a two-page Anesthesia Services Form. The CRNA separates the original top page when the patient is transferred to the PACU and submits the carbonless copy second page to AAKC's billing office. Donegan testified that he and other CRNAs were always instructed to check the "Medical Direction" box at the top of the forms. AAKC anesthesiologists were directed to change this designation if they were supervising more than four cases and thus did not qualify for Medical Direction. The top page of the form remained in the patient's medical record at MMC.

The form includes four lines where the anesthesiologist reflects by initialing that he or she was: (1) "present at induction"; (2) "monitoring at frequent intervals"; (3) "immediately available"; and (4) "present for emergence." In discovery, Relator

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[3]Relator's further contention that the district court abused its discretion by granting AAKC's motion to strike unidentified portions of Relator's summary judgment briefs and evidence is without merit. Even if the district court improperly excluded some evidence, which cannot be determined from the record on appeal, the alleged evidentiary error did not "affect[] the substantial rights of the appellant." Schmidt v. City of Bella Villa, 557 F.3d 564, 569 (8th Cir. 2009) (quotation omitted).

sought production of Medical Direction reimbursement claims since July 1, 2002, and the carbonless copies of the Anesthesia Services Form for those claims, but not the original top pages from patient medical records. Out of approximately 13,000 Medical Direction reimbursement claims for general anesthesia services, 724 had an unsigned emergence line on the carbonless copy of the Anesthesia Services Form. Relator moved for partial summary judgment on the 724 claims and appeals the district court denial of that motion. Relator argues that this is conclusive evidence that AAKC failed to comply with Step Three and failed to comply with the record-keeping requirements of 42 C.F.R. § 415.110(b) with respect to those claims.

As the district court recognized, the regulation required AAKC to document anesthesiologist presence at emergence "in the patient's medical record," not in AAKC's billing records. When an anesthesiologist visited a patient in the PACU, after the CRNA had sent the carbonless copy of the form to the billing office, one would expect the anesthesiologist to initial the emergence line on the top copy of the form, which became part of the patient's medical record. Therefore, Relator was not entitled to partial summary judgment on the 724 claims because it made no effort to obtain the top copies of the Anesthesia Services Forms from MMC patient records. AAKC reviewed fifty of those patient files and found that anesthesiologists completed the emergence line in nineteen of them. The district court concluded that Relator at most produced evidence that AAKC "may have negligently submitted 31 of 13,000 Medical Direction claims, which is not an FCA violation." We agree. "[T]he FCA does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." Ketroser, 729 F.3d at 829 (quotation omitted).

The judgment of the district court is affirmed.
