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United States Court of Appeals
Tenth Circuit

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Elisabeth A. Shumaker
Clerk of Court

PUBLISH

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

UNITED STATES OF AMERICA EX REL. GERALD POLUKOFF,

Plaintiff - Appellant,

v.

ST. MARK'S HOSPITAL; INTERMOUNTAIN HEALTHCARE, INC.; SHERMAN SORENSEN, M.D.; SORENSEN CARDIOVASCULAR GROUP; INTERMOUNTAIN MEDICAL CENTER,

Defendants - Appellees,

and

HCA, INC., a/k/a HCA,

Defendant.

UNITED STATES OF AMERICA,

Amicus Curiae and Intervenor.

No. 17-4014

Appeal from the United States District Court
for the District of Utah
(D.C. No. 2:16-CV-00304-JNP-EJF)

Tejinder Singh, Goldstein & Russell, P.C., Bethesda, Maryland (Thomas C. Goldstein, Goldstein & Russell, P.C., Bethesda, Maryland; Rand P. Nolen, George M. Fleming,

Sylvia Davidow, Gregory D. Brown, David Hobbs, and Jessica A. Kasischke, Fleming, Nolen & Jez, LLP, Houston, Texas, with him on the briefs), appearing for Appellant.

J. Scott Ballenger, Latham & Watkins LLP, Washington DC (Alexandra P. Shechtel, Latham & Watkins LLP, Washington DC; Katherine A. Lauer, Latham & Watkins LLP, San Diego, California; Andrew A. Warth, W. David Bridgers, and Wells Trompeter, Waller Lansden Dortch & Davis LLP, Nashville, Tennessee, with him on the brief), appearing for Appellee St. Mark's Hospital.

Matthew L. Knowles, McDermott Will & Emery LLP, Boston, Massachusetts (M. Miller Baker, McDermott Will & Emery LLP, Washington, DC; Shamis Beckley and Alexander J. Kritikos, McDermott Will & Emery LLP, Boston, Massachusetts; Alan C. Bradshaw, Sammi V. Anderson, and Christopher M. Glauser, Manning Curtis Bradshaw & Bednar, PLLC, Salt Lake City, Utah; Daniel S. Reinberg and Asher D. Funk, Polsinelli PC, Chicago, Illinois, with him on the brief), appearing for Appellee Intermountain Healthcare, Inc. and Intermountain Medical Center.

Blaine J. Benard, Holland & Hart LLP, Salt Lake City, Utah, and Gregory Goldberg, Holland & Hart LLP, Denver, Colorado, on the brief for Appellees Sherman Sorensen M.D., and Sorensen Cardiology Group.

Sarah Carroll, Attorney, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC (Chad A. Readler, Acting Assistant Attorney General, United States Department of Justice, Washington, DC; John W. Huber, United States Attorney for the District of Utah, Salt Lake City, Utah; Douglas N. Letter and Michael S. Raab, Attorneys, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC), appearing for Intervenor and Amicus Curiae United States of America.

Before **TYMKOVICH**, Chief Judge, **BRISCOE** and **HARTZ**, Circuit Judges.

BRISCOE, Circuit Judge.

This is a *qui tam* action alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–33, involving fraudulent reimbursements under the Medicare Act, 42 U.S.C. §§ 1395–1395ccc. Plaintiff Gerald Polukoff, M.D., is a doctor who worked with Defendant Sherman Sorensen, M.D. After observing some of Dr. Sorensen's medical

practices, Dr. Polukoff brought this FCA action, on behalf of the United States, against Dr. Sorensen and the two hospitals where Dr. Sorensen worked (collectively, "Defendants"). Dr. Polukoff alleges Dr. Sorensen performed thousands of unnecessary heart surgeries and received reimbursement through the Medicare Act by fraudulently certifying that the surgeries were medically necessary. Dr. Polukoff further alleges the hospitals where Dr. Sorensen worked were complicit in and profited from Dr. Sorensen's fraud. The district court granted Defendants' motions to dismiss, reasoning that a medical judgment cannot be false under the FCA. Exercising jurisdiction pursuant to 28 U.S.C. § 1291, we REVERSE and REMAND for further proceedings.

I

A. Statutory Background

"The FCA 'covers all fraudulent attempts to cause the government to pay out sums of money.'" *United States ex rel. Conner v. Salina Regional Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008) (quoting *United States ex rel. Boothe v. Sun Healthcare Grp., Inc.*, 496 F.3d 1169, 1172 (10th Cir. 2007)). Specifically, any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); [or]
>
> . . .
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or

> knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty [and treble damages].

31 U.S.C. § 3729(a)(1). The FCA defines the "knowingly" scienter requirement as follows:

> (A) mean[s] that a person, with respect to information—
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require[s] no proof of specific intent to defraud . . . .

Id. § 3729(b)(1).

There are two options to remedy a violation of the FCA. "First, the Government itself may bring a civil action against the alleged false claimant." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000). "Second, as is relevant here, a private person (the relator) may bring a *qui tam* civil action 'for the person and for the United States Government' against the alleged false claimant, 'in the name of the Government.'" *Id.* (quoting 31 U.S.C. § 3730(b)(1)). If a relator files a *qui tam* civil action, the government may intervene and take over the case. 31 U.S.C. § 3730(b)(2). "If the government elects not to proceed with the action," the relator "shall have the right to conduct the action." *Id.* § 3730(c)(3). Depending on the specific circumstances of the

qui tam suit, the government and the relator divide any proceeds derived from the suit. *Id.* § 3730(d).

The FCA is applicable to many statutes that provide for federal reimbursement of expenses. One such statute is the Medicare Act,[1] which imposes requirements for reimbursement of medical expenses. As relevant here, the Medicare Act states that "no payment may be made . . . for any expenses incurred for items or services" that "are not *reasonable and necessary* for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added). Physicians and medical providers who seek reimbursement under the Medicare Act must "certify the *necessity* of the services and, in some instances, recertify the continued need for those services." 42 C.F.R. 424.10(a) (Oct. 1, 2013) (emphasis added); *see also* 42 U.S.C. §§ 1395f(a), 1395n(a) (listing the various certifications).

The Secretary of Health and Human Services decides "whether a particular medical service is 'reasonable and necessary' . . . by promulgating a generally applicable rule *or* by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (emphasis added). The *former* course involves a "national coverage determination" that announces "whether or not a particular item or service is covered

[1] The amended complaint also references the "TRICARE/CHAMPUS Program." App'x at 521–22. This healthcare program benefits retired military personnel and dependents of both active and retired military personnel. *Id.* at 521; *see also Baptist Physician Hosp. Org., Inc. v. Humana Military Healthcare Servs., Inc.*, 368 F.3d 894, 895 (6th Cir. 2004). The amended complaint alleges that Defendants "submitted Requests for Reimbursement to TRICARE/CHAMPUS that were based on their submissions to Medicare." App'x at 522. We do not distinguish this program from Medicare and Medicaid in our analysis because Defendants failed to argue for any relevant distinction.

nationally." 42 U.S.C. § 1395ff(f)(1)(B). In the absence of a national coverage determination, local Medicare contractors may issue a "local coverage determination" that announces "whether or not a particular item or service is covered" by that contractor. *Id.* § 1395ff(f)(2)(B).

The *latter* course allows "contractors [to] make individual claim determinations, even in the absence of [a national or local coverage determination], . . . based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). In making an individual claim determination about whether to reimburse a medical provider, "[c]ontractors shall consider a service to be reasonable and necessary if the contractor determines that the service is: [(1)] Safe and effective; [(2)] Not experimental or investigational . . .; and [(3)] Appropriate." Centers for Medicare & Medicaid Services ("CMS"),[2] *Medicare Program Integrity Manual* § 13.5.1 (2015) (describing local coverage determinations); *see also id.* § 13.3 (incorporating § 13.5.1's standards for individual claim determinations). One factor that contractors consider when deciding whether a service is "appropriate" is whether it is "[f]urnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member." *Id.* § 13.5.1.

[2] CMS is an agency within Health and Human Services, *see Protocols, LLC v. Leavitt*, 549 F.3d 1294, 1295 (10th Cir. 2008), and this agency administers the Medicare Act, *see United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 705 & n.1 (10th Cir. 2006).

B. Factual Background

"At the motion-to-dismiss stage, we must accept all the well-pleaded allegations of the complaint as true and must construe them in the light most favorable to the plaintiff." *Albers v. Bd. of Cty. Comm'rs of Jefferson Cty.*, 771 F.3d 697, 700 (10th Cir. 2014) (quotation omitted). As a result, we rely on Dr. Polukoff's amended complaint.[3]

1. The PFO closure procedure

This case involves two very similar cardiac conditions: patent foramen ovale ("PFO") and atrial septal defect ("ASD"). Both PFOs and ASDs involve a hole between the upper two chambers of the heart, but they have different causes. Most people are born with a PFO, as it helps blood circulate throughout the heart while in the womb, but for 75% of the population, the hole closes soon after birth. ASDs, on the other hand, are an abnormality. Regardless, both PFOs and ASDs allow blood to flow in the wrong direction within the upper chambers of the heart. In rare cases, they can lead to a variety of dangerous complications, including stroke. Physicians can "close" ASDs and PFOs through ASD and PFO closures (collectively, "PFO closures"), a percutaneous surgical procedure involving cardiac catheterization. In layman's terms, physicians insert a thin tube into a blood vessel to access the heart, rather than performing open heart surgery.

The amended complaint makes specific reference to industry guidelines published by the American Heart Association and American Stroke Association (the "AHA/ASA

[3] Although Dr. Polukoff filed a motion (and later, an amended motion) for leave to file a second amended complaint, the district court denied the amended motion. Thus, Dr. Polukoff's amended complaint is the operative complaint.

Guidelines") in 2006 and 2011, related to PFO closures.[4] The 2006 AHA/ASA Guidelines observed that "[s]tudies have found an association between PFO and cryptogenic stroke."[5] App'x at 2077. They noted "conflicting reports concerning the safety and efficacy of surgical PFO closure" to treat cryptogenic stroke, but after reviewing several studies, also noted that each reported "no major complications." *Id.* The 2006 AHA/ASA Guidelines concluded: "Insufficient data exist to make a recommendation about PFO closures in patients with a first stroke and a PFO. PFO closure may be considered for patients with recurrent cryptogenic stroke despite optimal medical therapy . . . ." *Id.* at 2079. In other words, the 2006 AHA/ASA Guidelines advised that (1) for patients with two or more cryptogenic strokes, PFO closures may be considered; (2) for patients with only one cryptogenic stroke, there was insufficient data to make a recommendation; and (3) for patients without a single cryptogenic stroke, the AHA/ASA Guidelines did not contemplate the potential for PFO closures.

The 2011 AHA/ASA Guidelines are similarly inconclusive. In a table titled "Recommendations for Stroke Patients With Other Specific Conditions," the guidelines stated: "There are insufficient data to make a recommendation regarding PFO closure in patients with stroke and PFO . . . ." *Id.* at 2125. The 2011 AHA/ASA Guidelines did, however, observe that recent "studies provide[d] new information on options for closure

[4] The amended complaint also references the 2014 AHA/ASA Guidelines. Those guidelines, however, were published after all relevant conduct occurred in this case, and thus are irrelevant.

[5] A "cryptogenic stroke" describes a stroke for which the cause is unknown.

of PFO and generally indicate[d] that short-term complications with these procedures are rare and for the most part minor." *Id.* at 2126.

Relying on the AHA/ASA Guidelines, the amended complaint alleges "[t]here has long been general agreement in the medical community that PFO closure is not medically necessary, except in the limited circumstances where there is a confirmed diagnosis of a recurrent cryptogenic stroke or TIA,[6] despite optimum medical management." *Id.* at 524.

2. The Defendants' conduct

Dr. Sorensen practiced medicine as a cardiologist in Salt Lake City, Utah. He was the principal shareholder of Sorensen Cardiovascular Group ("SCG"). Dr. Sorensen, through SCG, provided cardiology services at two hospitals: (1) Intermountain Medical Center and (2) St. Mark's Hospital ("St. Mark's"). Intermountain Medical Center is part of a large network of hospitals in Utah principally owned by Intermountain Healthcare, Inc., a not-for-profit corporation (collectively, with Intermountain Medical Center, "Intermountain"). St. Mark's, on the other hand, is a for-profit corporation owned by HCA, Inc. Dr. Polukoff is a practicing cardiologist who worked with Dr. Sorensen at both St. Mark's and Intermountain.

Dr. Sorensen started providing cardiology services at Intermountain in December 2002. Later, in 2008, he began working at St. Mark's as well. Part of his practice included performing a relatively high number of PFO closures. For example, "[t]he

[6] A "TIA" is a "transient ischemic attack," which is a brief interruption of blood flow to the brain that causes stroke-like symptoms.

Cleveland Clinic reported that it had performed 37 PFO closures in 2010; during that same time period [Dr.] Sorensen's billing records indicate that he had performed 861." *Id.* at 542. The amended complaint alleges that Dr. Sorensen performed so many PFO closures because of "his medically unsupported belief that PFO closures would cure migraine headaches or prevent strokes." *Id.* In addition, "Dr. Sorensen knew that Medicare and Medicaid would not pay for PFO closures to treat migraines, so he chose to represent that the procedures had been performed based upon indications set forth in the AH[A]/ASA stroke guidelines—the existence of confirmed recurrent cryptogenic stroke." *Id.*

The amended complaint describes Dr. Sorensen's medical notes and reasons for the large number of PFO closures:

> Dr. Sorensen's notes in his patients' medical records indicate that [Dr.] Sorensen fully understands, but rejects, the standard of care for PFO/ASD closures set forth in the [AHA/ASA] Guidelines described above. For example, Dr. Sorensen notes that closures are considered medically necessary only for recurrent cryptogenic strokes or TIA, secondary to paradoxical embolization despite medical therapy, but argues that while "[w]e do have experience with the two strokes first and then closure approach, we found this very unsatisfactory as a very high number of patients were disabled and disability is not reversed by closure." Dr. Sorensen notes that "[w]e therefore follow a preventative strategy and risk stratify the patient. . . ." Dr. Sorensen notes that he considers waiting for a stroke or TIA to reoccur before proceeding to closure is "unethical."

Id. at 607.

In early 2011, several doctors at Intermountain objected to Dr. Sorensen's approach to PFO closures, claiming Dr. Sorensen was violating Intermountain's internal guidelines for PFO closures. In March 2011, in response to the objections, Intermountain

adopted new internal guidelines for PFO closures that mirrored the AHA/ASA Guidelines. In May 2011, Intermountain conducted an investigation into Dr. Sorensen's practice and internally released an audit of the 47 PFO closures Dr. Sorensen performed in April 2011. The audit concluded that "the guidelines had been violated in many of the 47 cases reviewed." *Id.* at 535.

On June 27, 2011, following the internal investigation, Intermountain suspended Dr. Sorensen's cardiac privileges. The suspension was effective until July 11, 2011. On July 12, 2011, Dr. Sorensen returned to Intermountain, but continued to violate the hospital's internal guidelines for PFO closures. Intermountain discovered the continued violations, and subsequently entered into a settlement agreement with Dr. Sorensen to avoid his permanent suspension. Intermountain later found that Dr. Sorensen had violated the terms of the settlement agreement and moved to permanently suspend Dr. Sorensen, but Dr. Sorensen tendered his resignation in September 2011.

After Dr. Sorensen left Intermountain, he moved his entire practice to St. Mark's. St. Mark's knew of Dr. Sorensen's suspension from Intermountain, but courted his moving his practice anyway. St. Mark's allowed Dr. Sorensen to continue his cardiology practice until he retired from medical practice altogether a few months later, on December 9, 2011.

Dr. Polukoff—the relator in this case—worked at both Intermountain and St. Mark's, but not directly for Dr. Sorensen until 2011. On June 11, 2011, Dr. Polukoff signed an employment agreement with SCG to learn PFO closures from Dr. Sorensen, and on August 17, 2011, actually began working for Dr. Sorensen at St. Mark's. While

working for Dr. Sorensen, Dr. Polukoff "personally observed [Dr.] Sorensen perform medically unnecessary PFO closures on patients at St. Mark's." *Id.* at 536. He alleges to have "observed [Dr.] Sorensen *create* a PFO by puncture of the atrial septum in patients who were found to have an intact septum during surgery." *Id.*

The amended complaint further alleges that St. Mark's and Intermountain "signed or caused to be executed provider agreements with Medicare that permitted each Defendant to submit claims and accept payment for services." *Id.* at 518. Both hospitals "allowed and encouraged Dr. Sorensen to perform and submit claims to federal health benefit programs for PFO and ASD procedures despite clear compliance red flags, including, but not limited to, the fact that Dr. Sorensen was performing these procedures at a rate that far exceeded that of any other institution or physician." *Id.* at 507.

C. Procedural Background

On December 6, 2012, Dr. Polukoff filed this *qui tam* action under seal in the United States District Court for the Middle District of Tennessee against: (1) Dr. Sorensen; (2) Sorensen Cardiovascular Group; (3) Intermountain Healthcare, Inc.; (4) St. Mark's Hospital; and (5) HCA, Inc. On June 15, 2015, the government filed its notice of election to decline intervention. On June 19, 2015, the district court unsealed the *qui tam* complaint. All Defendants moved to dismiss the action.

Dr. Polukoff then filed an amended complaint against all Defendants previously named, and added Intermountain Medical Center. The amended complaint alleged four separate violations of the FCA, corresponding to four separate subsections of the FCA. *Id.* at 611–14 (citing 31 U.S.C. § 3729(a)(1)(A)–(C), (G)). All Defendants moved to

dismiss the amended complaint. The district court dismissed the claims against HCA, and concluded that, without HCA, venue in the United States District Court for the Middle District of Tennessee was no longer proper. Consequently, the district court transferred the case to the United States District Court for the District of Utah, without ruling on the motions to dismiss as to the remaining Defendants—Dr. Sorensen (both as an individual and the Sorensen Cardiovascular Group); Intermountain (both the individual hospital and the nonprofit that owned it); and St. Mark's.

The remaining Defendants filed renewed motions to dismiss. Oral arguments were scheduled for November 10, 2016. The day before oral arguments, Dr. Polukoff filed a motion for leave to file an amended complaint. The district court heard oral arguments as scheduled. Before the district court ruled on the motions to dismiss, Dr. Polukoff filed an amended motion for leave to file a second amended complaint on January 18, 2017. The next day, the district court granted Defendants' motions to dismiss, with prejudice, and denied Dr. Polukoff's motion for leave to amend.

As relevant to this appeal, the district court first addressed Defendants' Rule 9(b) argument that Dr. Polukoff had failed to plead with particularity. The district court determined that the proper standard was "whether Dr. Polukoff has pled the who, what, when, where and how of a fraudulent scheme perpetrated by each of the defendants." *Id.* at 2519. "In addition, the court must decide whether the operative complaint provides 'an adequate basis for a reasonable inference that false claims were submitted as part of that scheme.'" *Id.* (quoting *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010)). The court concluded that Dr. Polukoff had adequately

pled his claims against Dr. Sorensen and St. Mark's but not against Intermountain because he failed to identify a "managing agent" involved in the conspiracy at Intermountain. *Id.* at 2519–22.

The court then turned to Defendants' Rule 12(b)(6) argument. Relying on language from this court's unpublished decision in *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980 (10th Cir. 2005), the district court concluded that "Dr. Polukoff must show that the defendants knowingly made an objectively false representation to the government that caused the government to remit payment." App'x at 2526. It observed that "Dr. Polukoff's FCA causes of action rest upon his contention that the defendants represented (either explicitly or implicitly) that the PFO closures performed by Dr. Sorensen were medically reasonable and necessary and that this representation was false." *Id.* at 2524. But, because "[o]pinions, medical judgments, and 'conclusions about which reasonable minds may differ cannot be false' for the purposes of an FCA claim," *id.* at 2526 (quoting *Morton*, 139 F. App'x at 983), Dr. Sorensen's representations to the government could not be false absent "a regulation that clarifies the conditions under which it will or will not pay for a PFO closure," *id.* at 2528. Thus, Dr. Polukoff's "FCA claims fail[ed] as a matter of law and the court dismisse[d] all causes of action asserted against the defendants." *Id.* at 2529. The court further determined that "leave to amend would be futile," *id.*, so it dismissed the amended complaint with prejudice.

Dr. Polukoff timely appealed. The government filed an amicus brief in his support. All three Defendants— Dr. Sorensen, St. Mark's, and Intermountain—filed

response briefs. Of particular note, in Intermountain's brief, it argued that the *qui tam* provisions of the FCA violate Article II of the U.S. Constitution. The government intervened thereafter, pursuant to 28 U.S.C. § 2403(a), to respond to Intermountain's constitutional argument in an additional brief as intervenor.

II

The district court relied upon Rules 12(b)(6) and 9(b) to dismiss Dr. Polukoff's amended complaint with prejudice. We address the district court's holdings in turn.[7]

A. Rule 12(b)(6)

We first address the district court's conclusion that, absent a specific regulation addressing the necessity of the treatment, a physician's medical judgment concerning the necessity of a treatment could not be "false or fraudulent" under the FCA. As a result of this conclusion, the district court dismissed Dr. Polukoff's amended complaint under Rule 12(b)(6), believing it failed to state a claim as a matter of law, and then denied leave to amend, believing amendment would have been futile. We disagree.

[7] Intermountain argues, for the first time on appeal, that "at least where the Government has not intervened, a private relator's prosecution of an FCA case on behalf of the Government violates the separation of powers." Intermountain Br. at 54. Intermountain concedes it "did not assert a constitutional challenge below." *Id.* at 54 n.11. We consider this argument forfeited. "It is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below." *Singleton v. Wulff*, 428 U.S. 106, 120 (1976). "[W]here the ground presented here has not been raised below we exercise this authority [to consider the newly raised argument] 'only in exceptional cases.'" *Heckler v. Campbell*, 461 U.S. 458, 468 n.12 (1983) (quoting *McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430, 434 (1940)). "[T]he decision regarding what issues are appropriate to entertain on appeal in instances of lack of preservation is discretionary." *Abernathy v. Wandes*, 713 F.3d 538, 552 (10th Cir. 2013). We decline to address Intermountain's separation of powers argument.

"We review the district court's dismissal under Rule 12(b)(6) de novo." *Lemmon*, 614 F.3d at 1167. "Although we generally review for abuse of discretion a district court's denial of leave to amend a complaint, when this 'denial is based on a determination that amendment would be futile, our review for abuse of discretion includes de novo review of the legal basis for the finding of futility.'" *Cohen v. Longshore*, 621 F.3d 1311, 1314 (10th Cir. 2010) (quoting *Miller ex. Rel. S.M. v. Bd. of Educ. of Albuquerque Pub. Schs.*, 565 F.3d 1232, 1250 (10th Cir. 2009)).

"Enacted in 1863, the False Claims Act 'was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). "'[A] series of sensational congressional investigations' prompted hearings where witnesses 'painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war.'" *Id.* (quoting *United States v. McNinch*, 356 U.S. 595, 599 (1958)).

Today, the FCA generally prohibits private parties from "knowingly" submitting "a false or fraudulent claim" for reimbursement. 31 U.S.C. § 3729(a)(1)(A). Unfortunately, "Congress did not define what makes a claim 'false' or 'fraudulent.'" *Escobar*, 136 S. Ct. at 1999. Without a definition from Congress, the Supreme Court has turned to common law. And "common-law fraud has long encompassed . . . more than

just claims containing express falsehoods." *Id.* Consequently, the Court favors a more expansive view of "false or fraudulent."

As we have held, "false or fraudulent" includes both factually false and legally false requests for payment. *See Lemmon*, 614 F.3d at 1168. "Factually false claims generally require a showing that the payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1168 (10th Cir. 2016) (quotation omitted). "Claims arising from legally false requests, on the other hand, generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment." *Id.* In this case, Dr. Polukoff does not allege Dr. Sorensen submitted *factually* false requests because his claims do not focus on an inaccuracy of the PFO closures performed. Instead, he claims the PFO closures do not comply with Medicare's "reasonable and necessary" requirement, meaning Dr. Sorensen submitted *legally* false requests for payment.

"Such claims of legal falsity can rest on one of two theories—express false certification, and implied false certification." *Id.* at 1169 (quotation and brackets omitted). "An express false certification theory applies when a government payee falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Conner*, 543 F.3d at 1217 (quotation omitted). "By contrast, the pertinent inquiry for implied-false-certification claims is not whether a payee made an affirmative or express false statement, but whether, through the act of

submitting a claim, a payee knowingly and falsely implied that it was entitled to payment." *Thomas*, 820 F.3d at 1169 (quotation and brackets omitted).

As relevant here, Dr. Polukoff brings express-false-certification claims against Dr. Sorensen. The amended complaint alleges Dr. Sorensen submitted express false certifications when he signed and submitted CMS Form 1500, which states: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient. . . ." App'x at 518.

The district court concluded that Dr. Polukoff's express-false-certification claims were not legally cognizable under the FCA. First, it held that "medical judgments and 'conclusions about which reasonable minds may differ cannot be false' for the purposes of an FCA claim." App'x at 2526 (quoting *Morton*, 139 F. App'x at 983). Second, the district court determined that a physician's certification that a PFO closure was "reasonable and necessary" could not be false under the FCA—given that it would constitute a medical judgment—absent "a regulation that clarifies the conditions under which [the government] will or will not pay for a PFO closure." *Id.* at 2528.

Morton is narrower than the district court suggests. First, *Morton* involved the application of the FCA to ERISA, not Medicare. Second, we explicitly cabined *Morton* to the facts in that case:

> We agree that liability under the FCA must be predicated on an objectively verifiable fact. Nonetheless, we are not prepared to conclude that in all instances, merely because the verification of a fact relies upon clinical medical judgments, or involves a decision of coverage under an ERISA plan, the fact cannot form the basis of an FCA claim. In this case, the nature of neither the scientific nor contract determinations inherent in the formation and evaluation of

> the allegedly "false" statement is susceptible to proof of truth or falsity.

139 F. App'x at 983. We did not create a bright-line rule that a medical judgment can never serve as the basis for an FCA claim.

It is possible for a medical judgment to be "false or fraudulent" as proscribed by the FCA for at least three reasons. First, we read the FCA broadly. *See United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (observing that the FCA "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government," and "refus[ing] to accept a rigid, restrictive reading"). Second, "the fact that an allegedly false statement constitutes the speaker's opinion does not disqualify it from forming the basis of FCA liability." *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 310 (1st Cir. 2010) (holding, in the Social Security benefits context, that "an applicant's opinion regarding the date on which he became unable to work" can give rise to FCA liability); *cf. Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1326 (2015) (suggesting, in the securities context, that a "false-statement provision . . . appl[ies] to expressions of opinion"). Third, "claims for medically unnecessary treatment are actionable under the FCA." *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (holding relator's complaint "sufficiently allege[d] that statements were known to be false, rather than just erroneous, because she assert[ed] that Defendants ordered the services knowing they were unnecessary"); *cf. Frazier ex rel. United States v. Iasis Healthcare Corp.*, 392 F. App'x 535, 537 (9th Cir. 2010) (affirming FCA claim was inadequately pled, but

suggesting an FCA claim could survive if the relator "provide[s] 'reliable indicia' that [the defendant] submitted claims for medically unnecessary procedures").

As the government states in its amicus brief, "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." Amicus Br. at 14. 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. The manual instructs contractors to "consider a service to be reasonable and necessary" if the procedure is:

- Safe and effective;
- Not experimental or investigational . . .; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

CMS, *Medicare Program Integrity Manual* § 13.5.1; *see also id.* § 13.3 (incorporating § 13.5.1's definition of reasonable and necessary for individual claim determinations).

We thus 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. We understand the concerns that a broad definition of "false or fraudulent" might expose doctors to more liability under the FCA, but the Supreme Court has already addressed those concerns:

"Instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the [FCA]'s materiality and scienter requirements. Those requirements are rigorous." *Escobar*, 136 S. Ct. at 2002 (quotation marks and some brackets omitted).

In this case, Dr. Polukoff adequately alleges that Dr. Sorensen performed unnecessary PFO closures on patients and then knowingly submitted false certifications to the federal government that the procedures were necessary, all in an effort to obtain federal reimbursement. Specifically, Dr. Polukoff alleges: (1) Dr. Sorensen performed an unusually large number of PFO closures, App'x at 542 ("The Cleveland Clinic reported that it had performed 37 PFO closures in 2010; during that same time period [Dr.] Sorensen's billing records indicate that he had performed 861."); (2) these procedures violated both industry guidelines and hospital guidelines, *id.* at 524–26, 535; (3) other physicians objected to Dr. Sorensen's practice, *id.* at 535; (4) Intermountain eventually audited Dr. Sorensen's practice, and concluded that its "guidelines had been violated in many of the 47 cases reviewed," *id.*; and (5) "Dr. Sorensen knew that Medicare and Medicaid would not pay for PFO closures to treat migraines, so he chose to represent that the procedures had been performed based upon indications set forth in the AH[A]/ASA stroke guidelines—the existence of confirmed recurrent cryptogenic stroke," *id.* at 542. Under these specific factual allegations, Dr. Polukoff has pleaded enough to state a claim as a matter of law and survive Rule 12(b)(6) dismissal against Dr. Sorensen.

We further hold the amended complaint adequately states express-false-certification claims against St. Mark's and Intermountain, both of which allegedly "billed for the hospital charges associated with" PFO closures. *Id.* at 542–43. More specifically, the amended complaint alleges St. Mark's and Intermountain both requested reimbursements for these procedures by submitting annual Hospital Cost Reports. The reports require hospitals to certify: "I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." *Id.* at 516. By submitting a Hospital Cost Report, then, St. Mark's and Intermountain expressly certified that every procedure for which they sought reimbursement complied with Medicare's requirements. Because the complaint adequately alleges that Dr. Sorensen's surgeries and any procedure associated therewith was not, in fact, "reasonable and necessary," the complaint adequately alleges that St. Mark's and Intermountain submitted false claims for reimbursement to the government through their Hospital Cost Reports.

Moreover, Dr. Polukoff adequately alleges St. Mark's and Intermountain submitted these false certifications "knowingly." As to St. Mark's, Dr. Polukoff alleges that he personally told the CEO about the circumstances surrounding Dr. Sorensen's suspension from Intermountain for performing unnecessary PFO closures. Nonetheless, according to Dr. Polukoff, St. Mark's continued to recruit Dr. Sorensen's business:

> Contemporaneously with his suspension from Intermountain, St. Mark's executive management knew that [Dr.] Sorensen had been suspended for performing medically unnecessary PFO closures. Dr. Polukoff personally discussed the suspension with the CEO of St. Mark's Hospital, Steve Bateman, and his physician liaison, Nikki

> Gledhill. Despite the fact that St. Mark's knew that [Dr.] Sorensen was performing medically unnecessary PFO closures, and knew that [Dr.] Sorensen had been suspended from Intermountain for performing medically unnecessary PFO closures, St. Mark's Hospital continued to court [Dr.] Sorensen's septal closure business and provide a platform and assistance to [Dr.] Sorensen.

Id. at 540–41.

As to Intermountain, Dr. Polukoff alleges that, "at all times relevant to this case, Intermountain knew that septal closures were rarely indicated." *Id.* at 535. This is because, "[f]or years Intermountain ignored the loud objections from its own medical staff and leadership, including the Director of the Catheterization Laboratory, Dr. Revenaugh, and the Medical Director for Cardiovascular Services at Intermountain Healthcare, Dr. Lappe, as well as written warnings and complaints from Professor Andrew Michaels of the University of Utah." *Id.* Because Dr. Sorensen performed an excessively large number of profitable PFO closures for Intermountain, Dr. "Sorensen was given his own catheterization lab room at Intermountain and provided with a handpicked staff of Intermountain employees." *Id.* at 610. "No other cardiologist received this type of special treatment from Intermountain." *Id.*

The FCA requires a defendant submit a false claim "knowingly," which includes the submission of claims by an entity who "acts in deliberate ignorance of the truth or falsity of the information" or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). At a minimum, the amended complaint adequately alleges that St. Mark's and Intermountain acted with reckless disregard as to whether the PFO closures Dr. Sorensen was performing were medically necessary.

B. Rule 9(b)

All Defendants also challenged the amended complaint under Rule 9(b), arguing that Dr. Polukoff had failed to plead his claims with sufficient particularity. The district court denied the motions as to Dr. Sorensen and St. Mark's, but granted the motion as to Intermountain. Dr. Polukoff appeals, arguing his amended complaint pleaded allegations against Intermountain with sufficient particularity to survive a motion to dismiss under Rule 9(b). We agree with Dr. Polukoff.

Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "Concerning the failure to plead fraud with particularity under Rule 9(b), we . . . review a dismissal de novo." *Lemmon*, 614 F.3d at 1167.

The purpose of Rule 9(b) is "to afford defendant[s] fair notice of plaintiff's claims and the factual ground upon which [they] are based." *Id.* at 1172 (quotations omitted). "Thus, claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Id.* Practically speaking, FCA claims comply with Rule 9(b) when they "provid[e] factual allegations regarding the who, what, when, where and how of the alleged claims." *Id.* But, "in determining whether a plaintiff has satisfied Rule 9(b), courts may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control." *George v. Urban Settlement Servs.*, 833 F.3d 1242, 1255 (10th Cir. 2016). This reflects the principle that

"Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." *Williams v. Duke Energy Int'l, Inc.*, 681 F.3d 788, 803 (6th Cir. 2012) (quotation omitted).

The district court dismissed Dr. Polukoff's allegations against Intermountain under Rule 9(b) because "vital information regarding who knew what and when they knew it [was] missing." App'x at 2521–22. But, for many of the same reasons the amended complaint survived Rule 12(b)(6) against all Defendants, it survives Rule 9(b) as well. Rule 9(b) itself states: "Malice, intent, *knowledge*, and other conditions of a person's mind may be alleged *generally*." Fed. R. Civ. P. 9(b) (emphases added). Moreover, we excuse deficiencies that result from the plaintiff's inability to obtain information within the defendant's exclusive control. *See George*, 833 F.3d at 1255. Intermountain,[8] no doubt, knows which employees handle federal billing for procedures reimbursable under Medicare, and in particular, who reviewed reimbursement claims for Dr. Sorensen during his decade there.[9]

[8] This applies with equal force to St. Mark's. But, because the district court determined that Dr. Polukoff satisfied Rule 9(b)'s particularity requirements as to St. Mark's, we limit our discussion of Rule 9(b) to Intermountain.

[9] In discussing the legal background of Rule 9(b), the district court stated: "Because both [Intermountain] and St. Mark's are corporations, this knowledge must be held by a managing agent of either of these corporate entities." App'x at 2521. The district court then failed to cite any authority for its "managing agent" theory. To the extent the district court relied upon the "managing agent" theory, we disagree. "It is well established that a corporation is chargeable with the knowledge of its agents and employees acting within the scope of their authority." *W. Diversified Servs., Inc. v. Hyundai Motor Am., Inc.*, 427 F.3d 1269, 1276 (10th Cir. 2005); *see also United States*

III

Because Dr. Polukoff's amended complaint satisfies the pleading requirements of Rules 12(b)(6) and 9(b), we REVERSE and REMAND this case for further proceedings.

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ex rel. Jones v. Brigham & Women's Hosp., 678 F.3d 72, 82 n.18 (1st Cir. 2012) ("We have long held that corporate defendants may be subject to FCA liability when the alleged misrepresentations are made while the employee is acting within the scope of his or her employment."). Thus, under Rule 9(b), it suffices that *any* employee, acting within the scope of his or her employment, had knowledge.