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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

No. 17-4014

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.

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

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[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*

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 nationally." 42 U.S.C. § 1395ff(f)(1)(B). In the absence of a national coverage determination, local Medicare contractors may issue a "local

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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.

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.

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[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.

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[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.

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

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[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.

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 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

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

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 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]

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[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."

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.

"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)

Abernathy v. Wandes, 713 F.3d 538, 552 (10th Cir. 2013). We decline to address Intermountain's separation of powers argument.

(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

[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.

reimbursable under Medicare, and in particular, who reviewed reimbursement claims for Dr. Sorensen during his decade there.[9]

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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[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 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.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

No. 2:16-CV-00304-JNP-EJF

UNITED STATES OF AMERICA, ex rel.
GERALD POLUKOFF,

Plaintiff/Relator,

v.

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

Defendants.

MEMORANDUM DECISION AND ORDER GRANTING MOTIONS TO DISMISS

Before the court are three motions to dismiss brought by (1) Intermountain Healthcare, Inc. and Intermountain Medical Center (collectively, IHC) [Docket 168]; (2) Doctor Sherman Sorensen and the

Sorensen Cardiovascular Group (collectively, Dr. Sorensen) [Docket 172]; and (3) St. Mark's Hospital [Docket 190]. The court GRANTS the motions and dismisses the complaint with prejudice.

BACKGROUND

The relator in this lawsuit, Doctor Gerald Polukoff, alleges in his complaint that Doctor Sherman Sorenson performed unnecessary medical procedures and then fraudulently billed the federal government for some of these procedures. Dr. Polukoff also alleges that two hospitals, IHC and St. Mark's, fraudulently billed the government for costs associated with these unnecessary procedures.

The medical procedure at the heart of this case is a patent foramen ovale (PFO) closure. The foramen ovale is a small opening in the wall separating the two upper chambers of the heart found in a fetus as it develops in the womb. In about 75% of the population, the opening closes soon after birth. In the other 25% of the population, the opening never closes. Except in rare cases, this condition is asymptomatic. But an adult with a PFO has an increased risk of suffering a stroke because blood clots that would otherwise have lodged in the lungs during pulmonary circulation may instead leak through the PFO, enter the systemic circulatory pathway, and lodge in the brain. A PFO may be closed through a percutaneous surgical procedure.

Opinions regarding the use of a PFO closure to prevent strokes have varied over the past decade. In 2006, the American Heart Association/American Stroke Association (AHA/ASA) issued guidelines

regarding the use of a PFO closure to decrease the odds of a stroke. These guidelines stated that "PFO closure may be considered for patients with recurring cryptogenic stroke despite taking optimal medical therapy." [Docket 90, ¶ 83]. In 2011, the AHA/ASA updated its recommendation, noting that "insufficient data exists to make a recommendation about PFO closure in patients with first stroke and PFO." [Docket 90, ¶ 84] In 2014, the AHA/ASA updated its recommendations again, noting that for "patients with a cryptogenic ischemic stroke or TIA and PFO without evidence for deep vein thrombosis (DVT) available data do not support a benefit for PFO closure." [Docket 90, ¶ 85]

Medicare has not issued a National Coverage Determination (NCD) for PFO closures. [Docket 90, ¶ 91]. Thus Medicare has not taken an official position on when it will or will not pay for this procedure. Healthcare providers, however, 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." [Docket 90, ¶ 56] Furthermore, 42 U.S.C. § 1395y(a) provides that "no payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Dr. Sorensen performed PFO closures from December 2002 through December 2011. [Docket 90, ¶ 2]. He performed these procedures with much greater frequency than other physicians throughout

the country. [Docket 90, ¶¶ 3, 93]. Part of the reason that Dr. Sorensen performed more PFO closures than other doctors is that he believed that it was best for the patient not to wait until he or she suffered one or two strokes before performing the procedure. [Docket 90, ¶¶ 123, 145]. Thus, Dr. Sorensen would perform PFO closures as a preventative measure for patients who had not yet suffered a stroke, but who had an elevated risk of a stroke. [Docket 90, ¶¶ 123, 145]. Dr. Sorensen also performed PFO closures to treat chronic migraines. [Docket 90, ¶¶ 137, 144].

On March 30, 2011, IHC adopted internal guidelines for PFO closures. [Docket 90, ¶ 87]. These guidelines stated that a PFO closure may be considered for "patients with a single well-documented significant stroke or systemic emboli in a high risk patient who has been comprehensively evaluated for alternative cause of embolic stroke." [Docket 90, ¶ 88]. The IHC guidelines required an independent neurology consult or other tests to confirm either the occurrence of a stroke or an embolism before performing a PFO closure. [Docket 90, ¶ 88]. The guidelines also provided that the procedure may only be performed to treat migraines in a clinical trial setting. [Docket 90, ¶ 90].

On June 11, 2011, IHC suspended Dr. Sorensen's medical privileges for 14 days because he had performed PFO closures that did not conform to IHC's internal policies. [Docket 90, ¶¶ 115, 117, 119–21]. After returning from his suspension, Dr. Sorensen again performed PFO closures that did not comply with IHC's guidelines. [Docket 90, ¶ 122] In

September, 2011, IHC initiated a procedural process to permanently suspend Dr. Sorensen's medical privileges. IHC and Dr. Sorensen entered into a settlement agreement, but soon thereafter, IHC notified Dr. Sorensen that he was in violation of the agreement. After IHC threatened to suspend him and report him to the National Practitioner Database, Dr. Sorensen resigned from IHC. [Docket 90, ¶ 122]. Thereafter, Dr. Sorensen performed PFO closures exclusively at St. Mark's until he retired in December, 2011.

Dr. Polukoff began working with Dr. Sorensen's practice on August 17, 2011, shortly before Dr. Sorensen resigned his privileges at IHC. [Docket 90, ¶ 123]. Dr. Polukoff worked with Dr. Sorensen for about four months until Dr. Sorensen retired in December 2011. Dr. Polukoff observed Dr. Sorensen perform PFO closures at St. Mark's, including procedures on patients who had not suffered a prior stroke. Dr. Polukoff avers that Dr. Sorensen falsely stated on medical records that the medical basis for the procedure was a history of strokes. [Docket 90, ¶ 123]. He also claims that Dr. Sorensen made false statements on medical records in an attempt to disguise PFO closures as a different medical procedure, a repair of an atrial septal defect. [Docket 90, ¶ 138].

While he was employed by Dr. Sorensen, Dr. Polukoff was looking into the possibility of purchasing Dr. Sorensen's practice. As part of this investigation, Dr. Polukoff obtained billing documents and a hard drive containing approximately eight years of billing records for Dr.

Sorensen's practice. [Docket 90, ¶ 141]. These billing records included patient names, dates of service, and amounts billed. These records did not include Dr. Sorensen's medical notes. [Docket 90, ¶ 141].

Dr. Polukoff filed this *qui tam* lawsuit under the FCA against Sorensen, IHC, St. Mark's, and St. Mark's parent company, HCA, Inc. After investigating the complaint, the government elected not to intervene in this action.

Dr. Polukoff originally filed his complaint in the Middle District of Tennessee. A court in that district dismissed all claims against HCA, the only party with a presence in that district. Upon dismissing HCA from the suit, the Tennessee district court determined that venue in the Middle District of Tennessee was no longer proper and transferred the case to the District of Utah. In this court, the remaining defendants filed motions to dismiss under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

ANALYSIS

All of Dr. Polukoff's claims in this case derive from the FCA, which was enacted during the Civil War to curb fraud against the federal government. *See Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996 (2016). Broadly speaking, liability under the FCA requires a knowing lie to the government in order to receive a payment that it would not have otherwise remitted. *See id.* (The FCA's "focus remains on those who present or directly induce the submission of false or fraudulent claims."). The FCA imposes penalties against any

person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"; (3) "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"; or (4) conspires to commit any of these violations. 31 U.S.C. § 3729(a)(1)(A)–(C), (G). The Act permits individuals to sue on behalf of the government to enforce the statute. *Id*. § 3730(b).

Dr. Polukoff alleges that Dr. Sorensen violated the FCA by performing medically unnecessary PFO closures and then billing the government for these procedures through Medicare and Medicaid. Dr. Polukoff also claims that IHC and St. Mark's also fraudulently billed the government for hospital costs associated with these procedures.

The defendants have moved to dismiss the complaint on three grounds. First, IHC argues that this court should dismiss the complaint with prejudice because Dr. Polukoff initially filed this case in the wrong court. Second, all of the defendants assert that the complaint should be dismissed because Dr. Polukoff has not pled his claims with particularity as required by Rule 9(b). And third, all of the defendants contend that Dr. Polukoff has failed to plead an objectively false claim submitted to

the government. The court will address each of these arguments in turn.

I. Forum Shopping

IHC argues that Dr. Polukoff's complaint should be dismissed with prejudice because his decision to file his complaint in the Central District of Tennessee constituted bad faith forum shopping. This court, however, need not delve into whether Mr. Polukoff acted in good faith or not when he chose to file in Tennessee because IHC's argument misapplies the relevant transfer statute.

A district court's authority to transfer or dismiss a case for improper venue is found in 28 U.S.C. § 1406(a). Under this statute, "[t]he district court of a district in which is filed a case laying venue in the wrong division or district shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought." This statutory provision specifically permits the court in which the complaint was originally filed to decide whether the interests of justice require either dismissal or transfer. If the original court elects to transfer a case, nothing in the statute permits the receiving court to countermand the original court's decision and dismiss the case, much less dismiss the case with prejudice.

Thus, the decision of whether to transfer or dismiss Mr. Polukoff's case rested with the Tennessee district court. Although IHC could have addressed its argument to that court, this court lacks statutory authority to invalidate the Tennessee court's decision to transfer rather than dismiss this

case. Moreover, even if this court had the authority to do so, it would exercise its discretion to accept the transfer rather than dismiss this case with prejudice as IHC requests.

II. Rule 9(b)

Rule 9(b) of the Federal Rules of Civil Procedure requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Because violations of the FCA constitute a fraud on the government, the heightened pleading requirements of Rule 9(b) apply to actions under the Act. *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726 (10th Cir. 2006). "At a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where and how' of the alleged fraud." *Id.* at 726–27 (citation ommitted).

In determining whether the complaint satisfies Rule 9(b), the court first addresses a dispute between the parties regarding the appropriate legal standard when applying this rule to FCA claims. The court then applies what it believes to be the proper legal standard to the factual allegations levied against each defendant to determine whether the requirements of Rule 9(b) have been meet.

A. The appropriate standard under *Sikkenga* and *Lemmon*

The defendants rely heavily upon *Sikkenga* for their argument that Dr. Polukoff has not satisfied Rule 9(b). In that case, the Tenth Circuit noted that "[u]nderlying schemes and other wrongful activities that result in the submission of fraudulent claims

are included in the 'circumstances constituting fraud and mistake' that must be pled with particularity under Rule 9(b)." *Sikkenga*, 472 F.3d at 727 (citation omitted). "However, unless such pleadings are 'linked to allegations, stated with particularity, of the actual false claims submitted to the government,' they do not meet the particularity requirements of Rule 9(b)." *Id.* (citation omitted). Quoting First Circuit precedent, the *Sikkenga* court concluded that a relator asserting an FCA claim must plead with particularity details regarding the bills submitted to the government for payment:

> [A] relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or the bills submitted, their identification numbers, the amount of money charged to the government, the particular goods and services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied for each allegation included in a complaint. However, like the Eleventh Circuit, we believe that "some of this information, for at least some of

> the claims must be pleaded in order to satisfy Rule 9(b).

Id. at 727–28 (alteration in original) (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232–33 (1st Cir. 2004)).

Citing *Sikkenga*, the defendants argue that Dr. Polukoff has not alleged sufficient detail regarding the bills submitted to the government for PFO closures. Dr. Sorensen argues that the 60-page list found in the operative complaint that contains dates of service, the procedure code, and amounts billed by Dr. Sorensen is inadequate because Dr. Polukoff did not allege specific details of bills submitted to the government. IHC and St. Mark's also argue that Dr. Polukoff has not alleged any details regarding bills that they submitted to the government for costs related to the PFO closures.

Dr. Polukoff, on the other hand, argues that a more recent Tenth Circuit case holds that billing details are not always required to satisfy 9(b). He cites *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010), which held that under Rule 9(b) "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.* at 1172 (emphasis added). Thus, the *Lemmon* court rejected an argument proffered by the defendant that Rule 9(b) had not been satisfied because the complaint sometimes failed to match an alleged violation of the FCA to "a specific payment request," reasoning that "[t]he complaint must

provide enough information to describe a fraudulent scheme to support a plausible inference that false claims were submitted." *Id.* at 1173.

In so holding, *Lemmon* cites cases from the Fifth and Seventh Circuits explicitly rejecting the notion that specific allegations regarding the bills submitted to the government are essential to satisfy Rule 9(b).[10] *Id.* at 1172 (citing *United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 190 (5th Cir.2009) and *United States ex rel. Lusby v. Rolls–Royce Corp.,* 570 F.3d 849, 854–55 (7th Cir.2009). In *Lusby*, the Seventh Circuit held that specific allegations regarding the contents of invoices submitted to the government were not required; reasonable inferences concerning the requests for payment were sufficient. 570 F.3d at 854–55. Moreover, in *Grubbs* the Fifth Circuit reasoned that

> [s]tating "with particularity the circumstances constituting fraud" does not necessarily and always mean stating the contents of a bill. The particular circumstances constituting the fraudulent presentment are often harbored in the scheme. . . . Standing alone, raw bills—even

[10] *Lemmon* also cites a First Circuit case, *United States ex rel. Duxbury v. Ortho Biotech Prod., L.P.*, 579 F.3d 13 (1st Cir. 2009). After the First Circuit issued *Karvelas*, which influenced the *Sikkenga* court, that circuit moderated its requirement that relators provide billing particulars. The First Circuit has distinguished *Karvelas* by holding that relators need not plead billing particulars when the relator alleges that a third party submitted the bills. *Duxbury*, 579 F.3d at 29; *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007).

> with numbers, dates, and amounts— are not fraud without an underlying scheme to submit the bills for unperformed or unnecessary work. It is the scheme in which particular circumstances constituting fraud may be found that make it highly likely the fraud was consummated through the presentment of false bills.

565 F.3d at 190. *Grubbs* went on to hold that "to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.*

The standard adopted in *Lemmon* is not compatible with some of the language found in *Sikkenga*. In *Sikkenga*, the Tenth Circuit held that at least some of the details concerning the dates and contents of invoices submitted to the government were required to plead an FCA claim with particularity. 472 F.3d at 727–28. *Lemmon*, on the other hand, held that a relator need only plead the particulars of the underlying fraudulent scheme and "provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." 614 F.3d at 1172. Under *Lemmon*, therefore, the contents of the fraudulent invoice are not essential to plead an FCA claim; the existence of the request for payment may be inferred from the fraudulent scheme itself. *Id.* at 1173. Thus, *Lemmon*

tacitly overruled language from *Sikkenga* requiring specific allegations regarding the bills submitted to the government. *See United States ex rel. Blyn v. Triumph Grp., Inc.*, No. 2:12-CV-922-DAK, 2016 WL 1664904, at *7 (D. Utah Apr. 26, 2016) (applying the *Lemmon* standard and citing *United States ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 126 (D.C. Cir. 2015), which adopted the rule announced in *Lemmon* and in other circuit courts); *United States ex rel. Fowler v. Evercare Hospice, Inc*., No. 11-CV-00642-PAB-NYW, 2015 WL 5568614, at *9, *11 (D. Colo. Sept. 21, 2015) (applying the *Lemmon* standard).

The court, therefore, must determine whether Dr. Polukoff has pled the who, what, when, where, and how of a fraudulent scheme perpetrated by each of the defendants. 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." *Lemon*, 614 F.3d at 1172.

B. The Application of the Particularity Requirement to Dr. Polukoff's Complaint

1) Dr. Sorensen

Dr. Polukoff has pled the who, what, when, where, and how of an allegedly fraudulent scheme perpetrated by Dr. Sorensen. The complaint satisfies the "who," "what," and "how" requirements by alleging that Dr. Sorensen, both in his individual capacity and as the principal of the Sorensen Cardiovascular Group, performed PFO closures on patients who had not suffered a prior stroke and

then billed the government for these purportedly unnecessary medical procedures. The complaint further specifies the "when" and the "where" of the scheme by alleging that the surgeries occurred at the Intermountain Medical Center and St. Mark's Hospital and that they occurred between December 2002 and December 2011. Dr. Polukoff further alleged specific dates for hundreds of unnecessary PFO closures and related examinations performed between 2007 and 2011.[11] [Docket 90, ¶ 143–44]. Thus, the complaint adequately pleads the specifics of a purportedly fraudulent scheme to defraud the government in violation of the FCA.

In addition, the complaint provides an adequate basis for a reasonable inference that false claims were submitted to the government. Indeed the complaint lists thousands of procedures that were billed to the government along with the amount billed. [Docket 90, ¶ 143–44]. Therefore the allegations in the complaint against Dr. Sorensen satisfy the requirements of Rule 9(b).

2) IHC and St. Mark's

Dr. Polukoff's claims against the hospital defendants, IHC and St. Mark's, are different in kind from his claims against Dr. Sorensen. Dr. Polukoff does not allege that IHC or St. Mark's decided

[11] Dr. Polukoff was not required to allege the precise date of every purportedly fraudulent procedure Dr. Sorensen performed to survive a motion to dismiss. *See Lemmon*, 614 F.3d at 1173 ("The federal rules do not require a plaintiff to provide a factual basis for every allegation. . . . Rather, to avoid dismissal under Rules 9(b) and 8(a), plaintiffs need only show that, taken as a whole, a complaint entitles them to relief.").

whether or not to perform a PFO closure on patients. Instead, Dr. Sorensen exercised his judgment as to whether a particular patient should receive the procedure. Then the procedure would be performed at either IHC or St. Mark's, which would bill the government for costs associated with the procedure. Thus Dr. Polukoff's theory of liability against IHC and St. Mark's must be predicated on actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information that Dr. Sorensen was performing PFO closures on patients who had an elevated risk of strokes but had not yet suffered a stroke. *See* 31 U.S.C. § 3729(b)(1)(A). The essence of his claim against the hospital defendants is that their managing agents knew that Dr. Sorensen was performing allegedly medically unnecessary procedures in their facilities, but billed the government for costs associated with these procedures anyway.

Because both IHC and St. Mark's are corporations, this knowledge must be held by a managing agent of either of these corporate entities. In order to plead a fraudulent scheme with the particularity required by Rule 9(b), therefore, Dr. Polukoff must allege which individuals within these corporations knew about Dr. Sorensen's criteria for performing a PFO closure and when they knew it. General allegations that the corporate entity itself "knew" about Dr. Sorensen's surgeries is not sufficient. *See Sonnenblick-Goldman Co. v. ITT Corp.*, 912 F. Supp. 85, 90 (S.D.N.Y. 1996) (holding that a complaint that failed to specify which agents of a corporation made fraudulent statements did not

satisfy Rule 9(b)). Although "knowledge[] and other conditions of a *person's mind* may be alleged generally," FED. R. CIV. P. 9(b) (emphasis added), this does not excuse Dr. Polukoff from identifying individuals within a corporation and alleging the knowledge or state of mind held by those individuals.

Under this standard, Dr. Polukoff has not adequately pled a fraudulent scheme perpetrated by IHC. Although he alleged that an internal investigation conducted around June 2011 revealed that Dr. Sorensen had performed PFO closures on patients who had not suffered strokes, over the next three months IHC took action to stop Dr. Sorensen from performing the procedure on pre-stroke patients, which ultimately led Dr. Sorensen to relinquish his medical privileges at the hospital. [Docket 90, ¶¶ 115–122]. IHC's efforts to curb Dr. Sorensen's use of PFO closures is not evidence of a fraudulent scheme. The complaint also alleges that the director of IHC's catheterization laboratory made objections against Dr. Sorensen. [Docket 90, ¶ 122]. But the complaint fails to specify what the objections were, to whom the objections were directed, and when they were made. Thus, vital information regarding who knew what and when they knew it is missing. Likewise, allegations that a professor at the University of Utah issued written warnings to unknown individuals also lacks the requisite specificity. [Docket 90, ¶ 122] Because it is impossible to discern the who, what, when, where, and how of a knowing fraudulent scheme perpetrated by IHC, Rule 9(b) has not been met.

Dr. Polukoff, however, has alleged with particularity a fraudulent scheme orchestrated by St. Mark's. In the complaint, he alleges that when Dr. Sorensen was suspended from practicing at IHC, Dr. Polukoff discussed the suspension with the CEO of St. Mark's and his physician liaison. [Docket 90, ¶ 133]. Thus, Dr. Polukoff has alleged which agents of St. Mark's knew about Dr. Sorensen's practice of performing PFO closures on pre-stroke patients and when they knew it. These allegations are specific enough to plead a fraudulent scheme in which St. Marks knowingly permitted Dr. Sorensen to perform allegedly medically unnecessary procedures in its facilities in order to profit from the attendant hospital charges. Because St. Mark's presumably billed the government for hospital expenses incurred by Medicaid and Medicare patients who received PFO closures performed by Dr. Sorensen, there is "an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Lemon*, 614 F.3d at 1172.

C. Leave to Amend

As noted above, the court concludes that the particularity requirement of Rule 9(b) has been satisfied for the claims against Sorensen and St. Mark's, but not for the claims against IHC. Thus, this court would normally determine whether to grant Dr. Polukoff leave to amend his complaint. But, as discussed below, the court also concludes that the complaint fails to state a claim against any of the defendants because it does not allege that the defendants submitted objectively false claims for payment. Because the court ultimately dismisses the

complaint on this ground, it need not determine whether to grant Dr. Polukoff an opportunity to cure the Rule 9(b) deficiencies in his claims against IHC.

III. Objective Falsity

A. The Objective Falsity Standard

Dr. Polukoff does not allege that the defendants billed the government for phantom services that were never provided—i.e. a "factually false" claim. *See United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008) ("In a run-of-the- mill 'factually false' case, proving falsehood is relatively straightforward: A relator must generally show that the government payee has submitted 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'" (citation omitted)). Instead, he asserts that the defendants' claims for payment were legally false. In other words, he alleges that the defendants have "'certifie[d] compliance with a statute or regulation *as a condition* to government payment,' yet knowingly failed to comply with such statute or regulation." *Id.* (citation omitted).

Dr. Polukoff concedes that Medicare has not issued a NCD regarding PFO closures and has not provided specific guidance on when it will or will not pay for the procedure. He instead points to two closely related conditions for payment and then alleges that the defendants falsely claimed that they had complied with these conditions. First, Dr. Polukoff alleges that healthcare 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." [Docket 90, ¶ 56] Second, 42 U.S.C. § 1395y(a) provides that "no payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 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 by Dr. Sorensen were medically reasonable and necessary and that this representation was false. *See United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 982 (10th Cir. 2005) (unpublished) (an FCA cause of action requires "(1) a claim for payment from the government, (2) that is false or fraudulent").

In an unpublished opinion, *United States ex rel. Morton v. A Plus Benefits, Inc.*, the Tenth Circuit has provided guidance on the standard for determining whether a representation is false. *Morton* held that "the FCA requires proof of an objective falsehood." *Id.* Thus, liability "must be predicated on an objectively verifiable fact." *Id.* at 983. "Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." *Id.* (citation omitted). The *Morton* court cautioned that it was "not prepared to conclude that in all instances, merely because the verification of a fact relies upon clinical medical judgments . . . the fact cannot form the basis of an FCA claim." *Id.* But it held that an allegation in a

complaint that medical care provided to a prematurely born infant was "therapeutic" rather than "custodial" was inherently ambiguous and therefore not subject to proof of objective falsehood. *Id.* Because this medical determination was not "predicated on an objectively verifiable fact," *Morton* concluded that the district court correctly dismissed the FCA complaint under Rule 12(b)(6). *Id.* at 983–84.

Authority from other circuits confirms the objective falsehood standard employed in *Morton*. *See United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) ("To satisfy this first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood."); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J., concurring) ("Where there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim."); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[I]mprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA."); *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) (holding that where an FCA claim was based upon an alleged violation of a "statute's imprecise and discretionary language[,] . . . Even viewing [the relator's] evidence in the most favorable light, that evidence shows only a disputed

legal issue; that is not enough to support a reasonable inference that the allocation was *false* within the meaning of the False Claims Act."); *United States, ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 676–77 (N.D. Miss. 2011) (holding that the falsity requirement had not been met as a matter of law where the FCA claim rested "not on an objective falsehood, as required by the FCA, but rather on [the government's] subjective interpretation of Defendants' regulatory duties."); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) ("[C]laims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government.").

A court in the Northern District of Alabama recently concluded in a similar case involving a doctor's clinical judgment that a "mere difference of opinion between physicians, *without more*, is not enough to show falsity." *United States v. AseraCare Inc*, 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016). That court reasoned that if it found

> that all the Government needed to prove falsity in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician, hospice providers would be subject to potential FCA liability any time the Government could find a medical expert who disagreed with the certifying physician's clinical judgment. The court refuses to go down that road.

Id. at 1285.

B. The Application of the Objective Falsity Standard

In order to prevail on his FCA claim, therefore, Dr. Polukoff must show that the defendants knowingly made an objectively false representation to the government that caused the government to remit payment. The crux of Dr. Polukoff's theory in this case is that the defendants represented to the government that the PFO closures performed by Dr. Sorensen were medically reasonable and necessary and that this representation was objectively false.

These representations, however, cannot 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. *Morton*, 139 F. App'x at 983. Moreover, liability may not be premised on subjective interpretations of imprecise statutory language such as "medically reasonable and necessary." *See Wilson,* 525 F.3d at 376–77; *Southland*, 326 F.3d at 684; *Lamers*, 168 F.3d at 1018; *Hagood*, 81 F.3d at 1477.[12] Dr. Polukoff alleges that some of the PFO closures performed were medically unreasonable and unnecessary because they were performed on patients with an elevated

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[12] Moreover, because the Supreme Court has ruled "that the False Claims Act is a punitive statute, it is both a violation of administrative law, as well as a violation of due process, to apply a truly ambiguous regulation to assess a sanction against a regulated party." 1 JOHN T. BOSE, CIVIL FALSE CLAIMS AND *QUI TAM* ACTIONS § 2.03[B][1] (2016) (footnote omitted).

risk of stroke but who had not yet suffered a stroke[13] or to treat chronic subjective medical opinions that cannot be proven to be objectively false.[14]

Dr. Polukoff relies heavily upon recommendations issued by the AHA/ASA for when a PFO closure should be performed to bolster his claim that some of the procedures performed by Dr. Sorensen were not medically reasonable or necessary.[15] In so doing, Dr. Polukoff equates the

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[13] Dr. Polukoff concedes in his complaint that a PFO may reduce the risk of a stroke. [Docket 90, ¶ 81]. He argues, however, that a PFO closure is not medically reasonable or necessary if performed as a preventative measure on patients with an elevated risk of stroke rather than waiting for one or two strokes to occur before performing the procedure.

[14] Dr. Polukoff also alleged that on two occasions, he observed Sorensen create a PFO by puncturing the atrial septum during a procedure. [Docket 90, ¶ 124] As there appears to be no conceivable medical reason to create a PFO, any certification that these two procedures were medically reasonable or necessary could potentially be proven to be objectively false. But the operative complaint never alleges that these two procedures were performed on Medicare or Medicaid patients or that any of the defendants ever submitted a claim for payment to the government for these procedures. This allegation, therefore, cannot support a claim for liability under the FCA.

[15] The Dr. Polukoff's also alleges that Dr. Sorensen falsely recorded on medical charts that patients had a history of strokes in order to disguise the fact that he was performing PFO closures on pre-stroke patients. But these allegations do not support FCA liability because there is no allegation that these medical charts were ever forwarded to the government in support of a claim for payment. Thus, there was no false representation made to the government that could have affected the decision to pay the claims.

AHA/ASA standards with the medical necessity standard imposed by Medicare. But this is a false equivalence. "Medicare does not require compliance with an industry standard as a prerequisite to payment. Thus, requesting payment for [medical procedures] that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *accord Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001) *abrogated on other grounds by Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1999–2001 (2016) ("The term 'medical necessity' does not impart a qualitative element mandating a particular standard of medical care, and [the relator] does not point to any legal authority requiring us to read such a mandate into the form."). Thus, even if Dr. Polukoff could show that Dr. Sorensen did not comply with the relevant AHA/ASA standards, this does not support a claim that Dr. Sorenson's certification that the PFO closures were medically necessary was objectively false.[16]

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[16] Moreover, it is less than clear whether Dr. Sorensen breached the standard adopted by the AHA/ASA. The 2014 standard has no application here because Dr. Sorensen retired in 2011. And the 2006 and 2011 standards do not explicitly advise against performing pre-stroke PFO closures. In 2006, the AHA/ASA advised that "PFO closure may be considered for patients with recurring cryptogenic stroke despite taking optimal medical therapy." Ralph L. Sacco, MD, et al., *Guidelines For Prevention of Stroke in Patients With Ischemic Stroke or Transient Ischemic Attack*, AHA/ASA GUIDELINES (2006), http://stroke.ahajournals.org/content/37/2/577.full [Docket 90, ¶ 83]. In 2011, the AHA/ASA updated its recommendation,

The government, of course, can promulgate a regulation that clarifies the conditions under which it will or will not pay for a PFO closure. *See United States ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *1 (E.D.N.Y. May 13, 2014) ("Deciding what is "reasonable and necessary" is delegated in the first instance to the Secretary of Health and Human Services ("HHS"), and HHS may decide whether to exclude certain types of treatments by promulgating national coverage determinations ("NCDs")."); 42 U.S.C. § 1395ff(a)(1) (The Secretary shall promulgate regulations . . . with respect to benefits . . . ."). But in the absence of an objective standard created by the government, Dr. Polukoff can only rely upon the subjective and ambiguous "reasonable and necessary" standard. Any attempt to prove that the defendants have violated this standard by seeking payment for PFO closures must necessarily rest on evidence of medical opinions and subjective standards of care rather

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noting that "insufficient data exists to make a recommendation about PFO closure in patients with first stroke and PFO." Karen L. Furie, MD, et al*., Guidelines for Prevention of Stroke in Patients With Stroke or Transient Ischemic Attack*, AHA/ASA GUIDELINES (2011), http://stroke.ahajournals.org/content/42/1/227.full [Docket 90, ¶ 84]. Neither version of these guidelines addresses the use a PFO closure to treat migraines. Although the 2006 and 2011 recommendations may give rise to a permissible inference that a prior stroke is a prerequisite to a PFO closure, the AHA/ASA never explicitly states that a patient with an elevated risk of strokes should not receive the procedure. In the absence of a clear prohibition, even if Dr. Sorensen had represented that he had complied with AHA/ASA guidelines, such a representation would not be objectively false.

than objectively false representations. But as the Tenth Circuit held in *Morton*, the punitive provisions of the FCA—including treble damages and attorney fees—cannot be applied absent an objectively false representation. Therefore, Mr. Polukoff's FCA claims fail as a matter of law and the court dismisses all causes of action asserted against the defendants.

C. Leave to Amend

In his oppositions to the motions to dismiss, Mr. Polukoff has requested leave to amend his complaint in the event that his complaint is dismissed. Amendments that are not permitted as a matter of course under Rule 15(a)(1) of the Federal Rules of Civil Procedure require written consent from the opposing party or leave of the court. FED. R. CIV. P. 15(a)(2). "The court should freely give leave when justice so requires." *Id.* "Refusing leave to amend is generally only justified upon a showing of undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment." *Bylin v. Billings*, 568 F.3d 1224, 1229 (10th Cir. 2009) (citation omitted).

The court denies Mr. Polukoff's request for leave to amend. The fundamental legal defect in Mr. Polukoff's complaint is that it does not identify an objectively false representation made by any of the defendants. The court concludes that in the face of this legal impediment to the theory of liability advanced by the operative complaint, leave to amend would be futile. The problem with Mr. Polukoff's complaint is not that it lacks specificity or that

certain factual allegations are missing. The defect lies in the fact that his central theory of liability is that the defendants lied when they represented to the government that the certain PFO closures were medically "reasonable and necessary." Because this standard is inherently ambiguous, these representations cannot be objectively false. *See* 1 JOHN T. BOSE, CIVIL FALSE CLAIMS AND *QUI TAM* ACTIONS § 2.03[B][1] (2016) ("[T]he existence of more than one legitimate interpretation of statute or regulation also determines the objective validity or falsity of the claim [for payment].").

Moreover, Mr. Polukoff has already had an opportunity to amend his complaint in response to the charge that he failed to plead an objectively false claim. Both IHC and Dr. Sorensen raised the objective falsity argument in motions to dismiss filed in the latter half of 2015. [Docket 68, pp. 17–23; 87, pp. 13–14]. Dr. Polukoff then amended his complaint in response to the motions to dismiss. [Docket 90]. In fact, Dr. Polukoff requested and received an extension of time in which to amend his complaint by right so that he could "amend his complaint once, if at all, in light of the various responsive pleadings filed by Defendants, instead of potentially multiple times." [Docket 72, p. 2; Docket 78].

Mr. Polukoff also has recently filed another motion for leave to amend his complaint in light of the current motions to dismiss and the hearing on these motions. [Docket 204] The proposed amendments consist mainly of assertions that the American Academy of Neurology currently advises against the routine use of PFO closures and that

several private insurance companies do not cover the procedure absent a prior history of strokes. [Docket 204-1, ¶¶ 95–97]. Most of these recommendations and insurance coverage policies postdate Dr. Sorensen's 2011 retirement and are irrelevant. But even the three insurance coverage policies that were in effect while Dr. Sorensen was practicing would not affect the court's analysis laid out above. The question is not whether some private insurance policies would have covered the medical procedures performed by Dr. Sorensen, but whether the government would pay for the procedures. In the absence of objective standards similar to those promulgated by the insurance coverage policies listed in the proposed second amended complaint, the defendants could not make objectively false representations to the government.

In sum, neither the 2015 amendments to the complaint nor the recent proposed amendments remedy the legal defect in Mr. Polukoff's FCA claims. Mr. Polukoff's inability to cure his failure to plead an objectively false representation made by any of the defendants strengthens the court's conviction that amendment would be futile.

CONCLUSION

The court GRANTS the motions to dismiss filed by IHC [Docket 168], Dr. Sorensen [Docket 172], and St. Mark's [Docket 190] and dismisses the amended complaint with prejudice. The court, therefore, DENIES the Amended Motion for Leave to File Second Amended Complaint filed by Dr. Polukoff. [Docket 204]. In light of the dismissal, the motions to

stay discovery filed by the defendants [Docket 170, 173, 175] are moot.

Signed January 19, 2017.

BY THE COURT

/s/ Jill N. Parrish

Jill N. Parrish

United States District Court Judge

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

No. 17-4014

UNITED STATES OF AMERICA EX REL.,
GERALD POLUKOFF,

Plaintiff - Appellant,

v.

ST. MARK'S HOSPITAL, et al.,

Defendants - Appellees,

and

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

Defendant.

UNITED STATES OF AMERICA,

Amicus Curiae and Intervenor.

ORDER

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

Appellees' petition for rehearing is denied.

The petition for rehearing en banc was transmitted to all of the judges of the court who are in regular active service. As no member of the panel and no judge in regular active service on the court requested that the court be polled, that petition is also denied.

Entered for the Court
/s/ Elisabeth A. Shumaker
ELISABETH A. SHUMAKER, Clerk