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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA EX REL. ERIC JAMES STENSON, Plaintiff-Appellant, v. RADIOLOGY LIMITED, LLC, Defendant-Appellee.	No. 22-16571 D.C. No. 2:19-cv-00306-TUC-JGZ (EJM) MEMORANDUM[*]

Appeal from the United States District Court
for the District of Arizona
Jennifer Zipps, District Judge, Presiding

Argued and Submitted November 7, 2023
Phoenix, Arizona

Before: HAWKINS and COLLINS, Circuit Judges, and SEEBORG,[**] District Judge.
Partial Concurrence and Partial Dissent by Judge COLLINS.

Appellant-Relator Eric Stenson appeals the dismissal of his *qui tam* action alleging violations of the False Claims Act ("FCA"). *See* 31 U.S.C. § 3729(a)(1).

[*] This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

[**] The Honorable Richard Seeborg, Chief United States District Judge for the Northern District of California, sitting by designation.

Stenson also appeals the denial of his motion for leave to amend his first amended complaint ("FAC"). We have jurisdiction under 29 U.S.C. § 1291, and for the reasons below, we affirm in part and reverse in part.

Stenson, an Arizona-based information technology executive, sued Appellee-Defendant Radiology Limited, LLC ("Radiology Limited"), a radiology facility in Tucson, Arizona, alleging that it violated the FCA by submitting false claims to the Centers for Medicare and Medicaid Services ("CMS"). In the simplest terms, Stenson avers Radiology Limited charged CMS over six million dollars for diagnostic readings that did not qualify for Medicare reimbursement because they were conducted on non-medical grade Dell computer monitors.[1] The district court found these allegations failed to sufficiently state any of Stenson's five FCA claims and dismissed the FAC. The district court also denied Stenson's motion for leave to amend the FAC with prejudice, finding amendment would be "futile."

We review de novo the grant of a motion to dismiss for failure to state a claim for which relief can be granted. *Lee v. City of Los Angeles*, 250 F.3d 668, 679 (9th Cir. 2001); Fed. R. Civ. P. 12(b)(6). "In reviewing the dismissal of a complaint, we inquire whether the complaint's factual allegations, together with all reasonable inferences, state a plausible claim for relief." *United States ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054 (9th Cir. 2011).

[1] Hereinafter, "the Dell Monitors."

Although we need not accept conclusory statements of law, we presume that all factual allegations in the operative complaint to be true and view them in the light most favorable to Stenson. *Lee*, 250 F.3d at 679. Rule 12(b)(6) dismissal is proper when there is either a "lack of cognizable legal theory or the absence of sufficient facts alleged." *UMG Recordings, Inc. v. Shelter Cap. Partners, LLC*, 718 F.3d 1006, 1014 (9th Cir. 2013) (internal punctuation omitted) (quoting *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988)).

Because the FAC alleges fraud, Stenson must also plead claims with requisite "particularity under Federal Rule of Civil Procedure 9(b)." *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1116 (9th Cir. 2020) (internal punctuation omitted). That is, it must "state with particularity the circumstances constituting fraud or mistake, including the who, what, when, where, and how of the misconduct charged." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (internal quotation marks and alterations omitted). While Stenson need not "allege the details of every false claim submitted to the federal government for reimbursement," *United States ex rel. Solis v. Millennium Pharms., Inc.*, 885 F.3d 623, 628–29 (9th Cir. 2018), any allegations made on "information and belief" must state the factual basis for such belief, *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993). When read together, Rules 8(a) and 9(b) compel relators to allege "enough fact[s] to raise a reasonable expectation that

discovery will reveal evidence of [the misconduct alleged]." *Cafasso*, 637 F.3d at 1055 (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 556 (2007)).

I. Motion to Dismiss

The district court granted Radiology Limited's motion to dismiss after finding that Stenson failed to state a claim under the False Claims Act. The FCA was "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (emphasis added). A successful FCA claim "requires: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018) (internal punctuation omitted). The district court found that Stenson failed to plead the first two elements—falsity and materiality.

A. Falsity

To prove falsity, Stenson proceeded under a "false certification" theory, which required him to allege that Radiology Limited "falsely certifie[d] compliance with a statute or regulation as a condition to government payment." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1173 (9th Cir. 2016). There are two kinds of false certification: express and implied. Express false certification occurs when "the entity seeking payment [falsely] certifies compliance with a law, rule or

regulation as part of the process through which the claim for payment is submitted." *Rose*, 909 F.3d at 1017 (quoting *Lungwitz*, 616 F.3d at 998). Implied false certification, by contrast, "occurs when an entity has *previously* undertaken to expressly comply with a law, rule, or regulation [but does not], and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim." *Id.*

Each time Radiology Limited submits claims for reimbursement, it expressly certifies its compliance with applicable Medicare rules, regulations, and policies. Radiology Limited also impliedly certifies its compliance with applicable "Medicare laws, regulations[,] and program instructions" through its annual Medicare Enrollment Agreement. Thus, both false certification theories are implicated on appeal.

Stenson alleges that Radiology Limited falsely certified its compliance with CMS's policy of only reimbursing medical devices with a particular degree of approval from the Food and Drug Administration ("FDA"), and the general Medicare statute's requirement that claimed services be "reasonable and necessary." On appeal, he also alleges that Radiology Limited charged CMS for diagnostic readings using billing codes that falsely implied the use of more sophisticated technology. Only his allegations concerning the general Medicare statute are sufficiently pleaded in the FAC.

FDA Approval. To the extent that Stenson alleges that Radiology Limited's claims were false because the Dell Monitors lack specific approval from the FDA, dismissal was appropriate. "Claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) (citing *United States ex rel. Local 342 v. Caputo Co.,* 321 F.3d 926, 933 (9th Cir. 2003)).

CMS requires medical suppliers to obtain FDA approval before introducing their devices into the stream of commerce. *See Int'l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994 (9th Cir. 2012); *see also* Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 FR 55634-01. However, outside of the mammography context, CMS has no policies regarding the kinds of monitors that medical providers like Radiology Limited must use when conducting diagnostic readings. *Compare* 42 C.F.R. § 410.32(b)(2) (explaining that FDA-approved monitors must be used for mammographs) *with* 42 C.F.R. § 410.32(a), (b)(1) (explaining that only physicians can administer other kinds of diagnostic readings).

Radiology Limited cannot expressly or impliedly misrepresent its compliance with CMS rules and policies that do not apply to its allegedly fraudulent conduct. Thus, the FAC fails to plead falsity on this basis.

Misleading Billing Codes. Likewise, to the extent that the FAC alleges that Radiology Limited used misleading billing codes, it also fails to plead falsity. The FAC and Stenson's briefs fail to identify any controlling rule, regulation, or standard that Radiology Limited violates by submitting "misleading" billing codes. In the absence of controlling authority, there can be no violation.

General Medicare Statute. However, to the extent the FAC alleges that Radiology Limited falsely certified its compliance with the general Medicare statute, dismissal, at least at this stage, was not warranted. CMS regulations require that all reimbursed services be "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). And, in this Circuit, "a false certification of medical necessity can give rise to FCA liability." *Winter*, 953 F.3d at 1118. Medicare contractors determine whether services are reasonable and necessary by assessing whether the service is "(1) safe and effective; (2) not experimental or investigational, . . . and (3) appropriate." *See* Centers for Medicare & Medicaid Services, Medicare Program Integrity Manual § 13.5.1 (2015) (cleaned up) (describing protocols for local coverage determinations); *see also id.* § 13.3 (incorporating § 13.5.1's standards for individual claim determinations).

Even if no federal rule, regulation, or law requires radiologists to use FDA-approved devices outside of the mammography context, the general Medicare statute nevertheless requires all physicians to provide services that meet minimum efficacy

standards. Stenson alleges that by using less sophisticated, non-FDA approved monitors, Radiology Limited knowingly submits claims for diagnostic readings that fall below this federally mandated minimum standard of care.

This argument plausibly pleads falsity under Rule 12(b)(6), and we reject the idea that the existence of CMS regulations in the mammography context means that Radiology Limited has no obligation to use appropriate technology under the general Medicare statute's "reasonable and necessary" requirement. "CMS guidance makes clear that safety and efficacy determinations are based on 'authoritative evidence' or 'general[ ] accept[ance] in the medical community.'" *Dan Abrams Co. LLC v. Medtronic Inc.*, 850 Fed. Appx. 508, 509 (9th Cir. 2021). The FAC specifically alleges that the Dell Monitors are far less technologically sophisticated (and, therefore, less effective) than the picture archiving and communication systems ("PACs") typically used by radiologists.

Stenson's "reasonable and necessary" theory also meets the particularity requirement under Rules 9(b) and 8(a). The FAC makes a general argument that radiologists can detect cancer in images displayed on diagnostic-grade monitors but cannot detect cancer when the same images are displayed on lower-grade displays, like the Dell Monitors. This point is supported by sufficiently credible physician testimony and, thus, gives rise to a reasonable inference that the technological quality of radiologists' monitors has some bearing on the efficacy of their diagnostic

readings. The FAC applies this inference to the instant case by suggesting that when Radiology Limited conducted diagnostic readings on the Dell Monitors, it was "not actually providing the [claimed] services at all."

The FAC supports this allegation with sufficient particularity by pointing to minutes from an Arizona Medical Board meeting where a Radiology Limited physician was issued an advisory warning for failing to identify a 6mm mass in a patient's kidney. The FAC also notes that Dell does not market the Monitors for diagnostic use, nor does it endorse their use in medical settings unless they are equipped with PerfectLum software, which Radiology Limited does not use. Discovery might produce additional evidence of improper diagnoses. Additionally, experts might testify to the Dell Monitor's efficacy or conduct testing to establish that the Dell Monitors do not safely, effectively, or appropriately diagnose diseases. Thus, Stenson has sufficiently pleaded that Radiology Limited falsely certifies its compliance with the general Medicare statute by submitting claims for diagnostic readings conducted on the Dell Monitors. The existence of regulations in the mammography context does not impact that conclusion.

B. Materiality

Under the FCA, "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "The materiality standard is demanding." *United States ex rel.*

Campie v. Gilead Scis., Inc., 862 F.3d 890, 905 (9th Cir. 2017) (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016)). "[R]egulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Escobar*, 579 U.S. at 191. *See also Rose*, 909 F.3d at 1019. Instead, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 579 U.S. at 193 (alteration in original). Because Stenson failed to plead falsity on his FDA-approval and misleading-billing-code theories, we only consider whether he has sufficiently pleaded materiality as to his "reasonable and necessary" argument. We determine he has.

Compliance with the "reasonable and necessary" requirement is an essential part of the government's decision to reimburse Radiology Limited's claims—indeed, as Stenson notes, "by statute, CMS cannot pay a claim that violates it." *See* Dkt. 14 at 48 (quoting 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under part A or part B for any expenses incurred for items or services . . . which, . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury")). Nevertheless, without more, mere violations of the requirement are not necessarily material under the FCA. Under the Supreme Court's guidance in *Escobar*, we must also consider CMS's actual or likely response to Radiology Limited's claims for diagnostic readings had it known the readings were conducted on the Dell Monitors.

579 U.S. at 195 (explaining that materiality is not a bright-line rule and providing non-dispositive examples of evidence that might support materiality, such as proof the government routinely refuses to pay claims for the alleged violations.).

If the Dell Monitors are as inadequate as Stenson alleges, it seems likely that CMS would deny Radiology Limited's claims for at least some diagnostic readings. In the context of radiological diagnostic readings, the display technology used is "so central" to the medical service provided that conducting a reading on wholly inadequate technology is effectively the same as not providing the service at all. *Winter*, 953 F.3d at 1121 ("For a false statement to be material, a plaintiff must plausibly allege that the statutory violations are 'so central' to the claims that the government 'would not have paid these claims had it known of these violations.'"). Given that CMS routinely declines to reimburse medical providers for services they did not actually administer or administered below a federally prescribed quality of care, we are persuaded that the FAC sufficiently pleads materiality at this stage of litigation. *See, e.g.*, *United States v. Mackby*, 261 F.3d 821, 827 (9th Cir. 2001) (declining to reimburse claims for services administered without required physician supervision); *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1085–86 (N.D. Cal. 2020) (providers' use of false diagnostic billing codes was "material" where the codes were the only factor CMS used to determine the amount of a beneficiary's Medicare Advantage payments); *Winter*, 953 F.3d at 1112

(physician's false certifications concerning the medical necessity of patients' hospitalizations were material to CMS's decision to reimburse underlying claims).

In sum, we affirm the district court's dismissal of the FAC to the extent that it alleges that the Dell Monitors lack required FDA approval. However, we reverse its findings regarding the general Medicare statute's "reasonable and necessary" requirement. Although Stenson did not raise his argument concerning the misleading billing codes to the district court, he has not presented a viable theory of that claim on appeal. Thus, although this theory fails for the same reason as Stenson's FDA-approval theory, dismissal with prejudice would not be similarly proper.

II. Motion for Leave to Amend

Finally, we consider the district court's refusal to allow Stenson to amend the FAC. We review decisions regarding amendment for abuse of discretion but consider the futility of amendment de novo. *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 893 (9th Cir. 2010); *Foman v. Davis*, 371 U.S. 178, 182 (1962) (leave to amend should be freely given in the absence of undue delay, bad faith, repeated failure to cure deficiencies, prejudice, or futility).

The district court's futility determination was proper to the extent that Stenson alleged Radiology Limited violated the FCA by falsely certifying its compliance

with FDA regulations. However, Stenson's other theories are either sufficiently pleaded or might be established upon the pleading of additional facts.

Thus, we affirm the district court's denial of the motion for leave to amend in part and reverse in part. On remand, the district court should grant Stenson leave to amend the FAC to the extent that he wishes to proceed on grounds other than his FDA-approval theory.

AFFIRMED in part and REVERSED in part. **Each party shall bear their own costs on appeal.**

COLLINS, Circuit Judge, concurring in the judgment in part and dissenting in part:

To plead a claim under the False Claims Act ("FCA") with the particularly required by Federal Rule of Civil Procedure 9(b), a relator must plead, *inter alia*, "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1209 (9th Cir. 2019) (citation omitted). The district court here concluded that relator Eric Stenson failed to plead sufficient facts to establish that Defendant Radiology Ltd., LLC ("Radiology"), by using monitors not approved by the Food and Drug Administration ("FDA") in performing radiological services, thereby submitted false claims for reimbursement for such services under the Medicare program. The court also concluded that further amendment would be futile, and it therefore dismissed the complaint with prejudice. I agree that the operative complaint is inadequate, but I believe that the district court erred in declining to allow a further attempt at amendment. I therefore would affirm the dismissal of the operative complaint, but I would reverse the denial of leave to amend. Because the majority instead finds the current complaint to be adequate, I respectfully dissent in part.

I agree with the majority that Stenson's FCA claims fail as a matter of law to the extent that they rest on the theory that Radiology allegedly falsely certified

compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and the regulations promulgated under that Act by the FDA. Stenson has not identified any provision of law that required Radiology, as a condition of payment under Medicare, to certify that it, as a user of the challenged monitors, had *itself* complied with the provisions of the FDCA or with FDA regulations.

The question, instead, is whether Stenson adequately pleaded that Radiology falsely certified that radiology services that were performed using such unapproved monitors were eligible for reimbursement under the Medicare Act and the implementing regulations issued by the Centers for Medicare and Medicaid Services ("CMS"). Because Stenson has not pointed to any CMS regulation that specifically addresses the quality of monitors that are used for the particular radiological services at issue here, Stenson must rely on the more general specification in § 1862(a)(1)(A) of the Medicare Act that CMS will not reimburse any service that is not "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). Because Stenson's complaint made no effort to identify *any* particular claims that it alleged to be false, it instead had to plead sufficient facts concerning the general practices of Radiology to support a "strong inference" that a particular type of false claim was "actually submitted." *Godecke*, 937 F.3d at 1209. Stenson's complaint failed to do so.

Stenson argues that CMS regulations categorically establish that radiology services that *use* non-FDA-approved monitors are not "reasonable and necessary," but that is wrong. Stenson relies on the CMS regulation providing that "Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not 'reasonable' and 'necessary' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons." 42 C.F.R. § 405.207(a). To show that this regulation bars all claims for radiology services using non-FDA-approved monitors, Stenson could point to an across-the-board determination by CMS that such monitors are "noncovered device[s]" in that either CMS has determined that they are not "reasonable and necessary" or CMS has "excluded [them] from coverage for other reasons." *Id*.; *cf*. *also Int'l Rehab. Servs. v. Sebelius*, 688 F.3d 994, 998–999 (2012) (reviewing categorical determination by the Medicare Appeals Council that a particular device was not "reasonable and necessary" for treatment). Stenson has not identified any such CMS determination that would support this claim. Although the complaint alleges that CMS "require[s] that medical diagnostic displays be used by" Radiology, the only support provided for this legal assertion is a citation of an article published by the Society for Imaging Informatics in Medicine that summarizes best practices in accordance with standards established by the National Electrical Manufacturers Association and the

American Association of Physicians in Medicine. As the district court correctly noted, "[t]his article is not derived from a governmental agency," and therefore has no independent legally binding force. Nor does the article support a plausible inference that, as a factual matter, FDA-approved monitors are required in order to actually provide reasonable and necessary services. On the contrary, as the district court observed, the article expressly states that its recommendations concerning monitors do "not imply" that a monitor used for radiology services "has to be an FDA-listed display product in every instance."

Nor has Stenson otherwise pleaded sufficient facts to establish that, as a factual matter, services using such monitors must be classified as not "reasonable and necessary." In reaching a contrary conclusion, the majority relies on three facts alleged in the complaint, but even taken together, these allegations are insufficient to plausibly support such an inference.

First, the complaint alleges that the particular type of software that Radiology uses with its Dell monitors is not the one that the FDA has specifically cleared for use on such monitors under § 510(k) of the FDCA. But nothing in the complaint provides any basis for inferring that, even without FDA clearance, the different software program that Radiology uses is *not* of sufficient quality that radiology services performed using it can still be deemed "reasonable and necessary."

Second, the complaint alleges that, in 2018, the Arizona Medical Board issued an "Advisory Letter" to a Radiology doctor "for failing to identify a 6mm calculus near the ureteropelvic junction of the left kidney on a CT scan," but that says nothing about whether the error in that particular case was even due to the quality of the monitors used. Indeed, the complaint concedes that Stenson has "no knowledge as to how many patients' diagnoses were incorrect or incomplete as a result of Defendant using Dell Non-Diagnostic Monitors as opposed to FDA-approved diagnostic-grade monitors."

Third, the complaint states that Stenson himself put together a test scenario in which he asked a non-Radiology radiologist to examine, on a "non-diagnostic monitor setup," a "CT study" that, unbeknownst to the doctor, contained a known cancer mass, and that the doctor was unable to detect the mass. The complaint, however, wholly fails to plead any facts that would tie this example to Radiology's situation. In particular, there is no basis for plausibly inferring that the setup that Stenson contrived matches the conditions that Radiology uses or that Radiology would have used that particular setup under those circumstances.

Accordingly, the complaint does not plead any facts that would support a plausible inference that the monitors that Radiology uses are so inadequate that Radiology's use of them must have led to the submission of false claims. The complaint's allegations about Radiology's practices are simply too vague, and its

proffered inferences too speculative, to raise a "strong inference" that false claims of a particular type "were actually submitted." *Godecke*, 937 F.3d at 1209. The operative complaint was therefore properly dismissed.[1]

In denying leave to amend, the district court relied dispositively on the view that the complaint's viability "turn[ed] on the incorrect *legal* conclusion that radiologists must use a particular type of monitor to read general radiological images" and that, as a result, Stenson "*cannot* allege any additional facts that could save his complaint." This reasoning was flawed. Although the district court was correct in concluding that Stenson failed to identify any law or regulation that specifically required the use of an FDA-approved monitor as a *legal* matter, Stenson could also attempt to rely on the alternative theory that, as a *factual* matter, the monitors used by Radiology were so deficient for the particular purposes for which they were used that the services performed using them were not "reasonable and necessary" within the meaning of the Medicare Act. Accordingly, I would reverse the district court's denial of leave to amend.

For these reasons, I concur in the judgment in part and dissent in part.

[1] I decline to address Stenson's theory that Radiology's "claims were misleading because the billing codes [Radiology] used falsely implied that approved medical-grade displays were used in providing the services." This theory was not pleaded in the operative complaint, nor was it addressed in the district court's order.