[DO NOT PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 24-12998

Non-Argument Calendar

UNITED STATES OF AMERICA, ex rel. et al.,

Plaintiffs,

BARBARA SENTERS,

Plaintiff-Appellant,

versus

QUEST DIAGNOSTICS INC.,

Defendant-Appellee,

JOHN DOE FLORIDA CORPORATIONS 1-1000, et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Georgia
D.C. Docket No. 1:10-cv-02202-AT

Before JILL PRYOR, BRASHER, and WILSON, Circuit Judges.

PER CURIAM:

In this qui tam action, Barbara Senters (Relator) appeals the district court's dismissal of her fourth amended complaint (FAC). The district court found that Relator failed to plead with particularity that a false claim had been submitted. After careful review, we affirm.

I. Background

Quest Diagnostics sells diagnostic laboratory tests to a variety of different type of medical entities, including hospitals and medical practices. Relator started working for Quest in 2005 as a human resources generalist. In 2007, Relator was promoted to a compliance officer for the Southeastern Business Unit, which cover multiple states including Georgia. Part of Relator's job included making sure that Quest was billing the government, namely Medicare and Medicaid, for tests eligible for reimbursement. In July 2010, after uncovering an alleged fraudulent billing scheme,

Relator sued Quest under seal on behalf of the United States and the State of Georgia, alleging that Quest violated the False Claims Act (FCA), 31 U.S.C. § 3729, the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168.1, and the Georgia Medical Assistance Act, O.C.G.A. § 49-4-146.1.

As Relator alleged, the scheme involved custom lab panels created by Quest's sales representatives to be implemented in doctors' offices by Quest employees. Relator further alleges that in creating these custom panels, Quest made it difficult for doctors to know which tests were included in the custom panel and thus difficult to understand what tests were ordered. As a result, when the physicians selected the custom panels, they unknowingly ordered tests that were not determined to be medically necessary for their patients, and then Quest billed the government for those unnecessary tests.

Because Quest, not the doctor's offices or hospitals, submits the claim for reimbursement to the government, it must submit a Center for Medicare & Medicaid Services Form 1500 (CMS Form 1500). CMS Form 1500 requires a provider, here Quest, to expressly certify that the claim being submitted "complies with all Medicare and/or Medicaid laws, regulations" and that the services listed on the form "were medically indicated and necessary for the health of the patient." To submit the CMS Form 1500, Quest had to submit a Medicare Enrollment Application, Form CMS-855B, which requires that Quest agree to abide by federal laws and

regulations along with certifying that Quest would not "knowingly present . . . a false or fraudulent claim for payment by Medicare."

In July 2011, Relator's action was administratively closed pending the United States's decision on whether to intervene. Very little activity occurred on the district court docket, but investigations occurred. In October 2020, the United States declined to intervene. In February 2021, Relator filed a third amended complaint (TAC) that was not under seal. In the TAC, the crux of Relator's claim was that Quest submitted false claims and false statements that lab tests were medically necessary and eligible for reimbursement and that Quest certified on its CMS Form 1500 that it complied with all Medicare laws for payment.

Quest moved to dismiss. The district court granted the motion because under Federal Rule of Civil Procedure 9(b), it found that Relator had not pled with particularity that "a specific fraudulent claim was in fact submitted to the government." But based on Relator's representations that she had 75 hours of investigative recording that would allow her to plead her claims with more detail, the district court granted Relator leave to file the FAC.

Unlike in the TAC, Relator alleged in the FAC that Quest submitted requests for payment of services, that Quest did not know whether the lab tests were medically necessary, and that despite this lack of knowledge, Quest certified on its CMS Form 1500 that it complied with all Medicare laws for payment. Quest again moved to dismiss.

The district court granted Quest's motion to dismiss, finding that "Relator fail[ed] to plead the falsity element with particularity and so fail[ed] to plead that an actual *false* claim was submitted to the government." In relying on the express certification theory, the court explained that "Relator must plead a representative false claim in which the services rendered were not 'medically indicated and necessary for the health of the patient' and where the claim was submitted to the government for payment." And Relator failed to do so because the FAC does not provide any particular details about the only representative claim submitted to the government. Instead, Relator used inferences because of the alleged "shady nature of the scheme." At the end, the district court explained that "this case must come to a close" and did not give Relator leave to amend.[1] Relator timely appealed.

II. Standard of Review

"We review a dismissal with prejudice for failure to state a claim under the False Claims Act *de novo*." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1050 (11th Cir. 2015). We take the allegations in the complaint as true and draw all reasonable inferences in Relator's favor. *Id.*

III. Analysis

On appeal, Relator argues that the district court erred in dismissing the FAC because it alleged with the requisite particularity

[1] Relator did not file a separate motion for leave to amend, but she asked for leave in her response to Quest's motion to dismiss.

a false claim violation under 31 U.S.C. § 3729. Relator also argues that the district court should have allowed Relator to amend her complaint. We address each argument in turn.

A. Dismissal of FAC

"The FCA imposes liability on any person who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017) (quoting 31 U.S.C. § 3729(a)(1)(A)–(B)). Section 3729(a)(1) imposes liability for various acts, and relevant for our purposes, it imposes liability for *presentment* and *false statements*. 31 U.S.C. § 3729(a)(1)(A)–(B).

"To state a § 3729(a)(1)(A) *presentment* claim, a complaint must allege (1) a false claim, (2) that the defendant presented, or caused to be presented, for payment or approval, (3) with knowledge that the claim was false. *United States ex rel. 84Partners, LLC v. Nuflo, Inc.*, 79 F.4th 1353, 1359 (11th Cir. 2023) (emphasis added). "To state a § 3729(a)(1)(B) *false-statement* claim, a complaint must allege (1) the defendant made, or caused to be made, a false statement, (2) the defendant knew the statement was false, and (3) the statement was material to a false claim." *Id.* (emphasis added). "[A]n essential element that must be alleged in a False Claims Act complaint is the actual presentment or payment of a *false* claim." *Id.* at 1360 (emphasis added). "Standing alone, a

fraudulent scheme, no matter how egregious, is not enough; there must be an actual false claim." *Id.*

When alleging an FCA violation, a relator's complaint must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006). Rule 9 (b) requires that a party "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." "[T]he particularity standard in qui tam actions requires the relator to allege the actual submission of a false claim." *Olhausen v. Arriva Med., LLC*, 124 F.4th 851, 860 (11th Cir. 2024) (per curiam) (internal quotation marks omitted and alteration adopted). "It is not enough to plead generally that false claims were submitted, nor may a relator merely "point to 'improper practices of the defendant' to support 'the inference that fraudulent claims were submitted' because 'submission cannot be inferred from the circumstances.'" *Id.* at 860–61 (alterations adopted). Rather, a relator must "allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (per curiam).

Here, Relator asserts that the FAC contained an exemplar sample of a false claim that shows a violation under 31 U.S.C. § 3729, under three theories of liability: (1) express false certification theory, (2) implied false certification theory, and (3) fraudulent inducement theory. Relator expends considerable ink on these different theories. But she misses the mark. No matter which theory

she pursues, her FAC rises and falls with the fact that she failed to plead with particularity that a *false* claim was submitted to the government.

As an example, Relator's exemplar sample for Patient Y shows that the doctor ordered a custom panel and that panel was submitted to the government for reimbursement using the CMS Form 1500, which required a certification that the services listed on the form "were medically indicated and necessary for the health of the patient." Then Relator alleges that Quest did not know if the services were medically necessary. But that is a blanket allegation with no particular facts to show why the custom panel for Patient Y was not medically necessary and why, therefore, any certification to the contrary was false. Like the district court noted, "Relator provided no factual allegations to indicate that doctors later discovered, or even now believe, that they were tricked or confused into ordering medically unnecessary tests or tests that they did not intend to order."

Relator tries to work around this issue by pointing to personal knowledge about the alleged fraudulent claims, including Patient Y's custom panel. *See United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1230 (11th Cir. 2012) ("[W]e are more tolerant toward complaints that leave out some particularities of the submissions of a false claim if the complaint also alleges personal knowledge or participation in the fraudulent conduct."). We recognize that Relator's job gave her access to the claims being submitted to the government and that she reviewed the claims

billed to the government, but Relator must still provide particular facts about a representative false claim. Previously, we found that relators with "managerial positions" who attended "monthly financial review meetings" could not satisfy the Rule 9(b) particularity requirements because "the relators failed to explain how their access to possibly relevant information translated to knowledge of actual tainted claims presented to the government." *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1277–78 (11th Cir. 2018).

Relator's complaint suffers from the same flaw. The FAC alleged that Relator had access to Quest's billing system and confirmed from her review of those systems that Quest was submitting claims to the government, but she does not allege any facts that show those label panels "were medically indicated and necessary for the health of the patient." Those allegations cannot satisfy Rule 9(b)'s particularity requirement because even with "direct knowledge of the defendants' billing and patient records," Relator "failed to provide any specific details regarding either the dates on or the frequency with which the defendants submitted false claims, the amounts of those claims, or the patients whose treatment served as the basis for the claims." *United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1302 (11th Cir. 2010) (per curiam). Nor did Relator claim to have observed the submission of an actual false claim; nor did she personally participate in submitting false claims. *See Matheny*, 671 F.3d at 1230. Thus, Relator's access and knowledge does not help Relator satisfy the heightened particularity requirement.

Although we construe all facts in favor of Relator, we "decline to make inferences about the submission of fraudulent claims because such an assumption would strip all meaning from Rule 9(b)'s requirements of specificity." *Corsello*, 428 F.3d at 1013 (internal quotation marks omitted and alteration adopted).

B. Leave to Amend

Relator did not file a motion asking for leave to file a fifth amended complaint but asked in her response to Quest's motion to dismiss. The district court did not address this request but dismissed the case with prejudice. On appeal, Relator argues that the district court erred in entering a dismissal with prejudice because the district court did not make a finding of delay or willful conduct such that lesser sanctions were not appropriate. But as Quest notes, the district court did not dismiss the case as a sanction for litigation misconduct. The district court dismissed the case with prejudice because the case had been happening for over fourteen years with several complaints where Relator ultimately failed to plead a false claim with particularity as required. The district court did not err. *See Corsello*, 428 F.3d at 1014.

IV. Conclusion

The district court's dismissal of the FAC with prejudice is affirmed.

AFFIRMED.