[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 16-10532

D.C. Docket No. 1:10-cv-21094-KMW

UNITED STATES OF AMERICA, Ex Rel.
GERRY PHALP AND MATT PEOPLES,

Plaintiffs-Appellants,

versus

LINCARE HOLDINGS, INC. and LINCARE, INC.,
d/b/a Diabetics Experts of America,

Defendants-Appellees.

Appeal from the United States District Court
For the Southern District of Florida

(May 26, 2017)

Before MARCUS and BLACK, Circuit Judges, and COHEN,* District Judge.

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* Honorable Mark H. Cohen, United States District Judge for the Northern District of Georgia, sitting by designation.

COHEN, District Judge:

Plaintiffs Gerry Phalp and Matt Peoples (collectively "Relators") brought a *qui tam* action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), alleging that Defendants submitted claims to Medicare without adequate authorization from the relevant Medicare beneficiaries and claims that were the product of unsolicited telemarketing calls to Medicare beneficiaries. Relators appeal summary judgments granted to Defendants with respect to each issue.

We affirm the district court with one modification. Although the district court applied an erroneous scienter standard, the evidence proffered by Relators as to Defendants' state of mind with respect to the assignment of benefits forms was insufficient to survive summary judgment under the proper standard. The district court did not err in granting summary judgment on Relators' claims that Defendants violated Medicare's unsolicited telephone contact rules.

I. BACKGROUND

A. Facts

Relators are former salespersons for Lincare, Inc. ("Lincare"), which does business as Diabetic Experts of America ("Diabetic Experts"). Defendants are Relators' former employer and related entities. Lincare supplies Medicare patients suffering from chronic obstructive pulmonary disease with oxygen, respiratory, and other therapy services. Diabetic Experts is a fictional name Lincare registered

in 2004 to sell diabetic-testing supplies.[1] Lincare Holdings, Inc. ("Holdings") is a holding company for its wholly-owned subsidiary, Lincare, Inc., and other subsidiaries. Additionally, Holdings supports the information systems of Lincare and Diabetic Experts by providing, among other things, a database which contains the telephone numbers for Diabetic Experts' customers.

During the relevant time period, Diabetic Experts was in the practice of supplying Medicare patients with diabetic-testing supplies. Specifically, Diabetic Experts would place calls to individuals to whom Lincare previously had provided Medicare-covered items related to chronic obstructive pulmonary disease. Diabetic Experts would offer these individuals a free diabetic-testing monitor and sell them diabetic-testing supplies, including blood-testing strips.[2] After selling diabetic-testing strips to these individuals, Diabetic Experts would submit claims to Medicare using authorizations, or assignments of benefits ("AOBs"), previously provided by the Medicare beneficiaries to Lincare in connection with Lincare's provision of items related to chronic obstructive pulmonary disease. Diabetic Experts did not obtain AOBs that were specifically related to diabetic testing

[1] The district court concluded that Lincare and Diabetic Experts are a single supplier for the purposes of the Medicare statutes, regulations, and supplier standards at issue. This ruling is not contested on appeal.

[2] The district court's finding that a Medicare beneficiary is unable to reuse the blood-testing strips is not contested on appeal.

supplies. Instead, Diabetic Experts submitted the AOBs given to Lincare that were generic in nature and provided that the Medicare beneficiaries agreed: (1) to rent or purchase "certain medical equipment, products, supplies, prescription drugs and/or associated services" from "Lincare and its affiliates;" (2) that Lincare would provide "HME [home medical equipment] and Supplies" or "DME [durable medical equipment];" and (3) to assign Medicare benefits to Lincare.

B. Procedural Background

Relators alleged in their Second Amended Complaint ("Complaint") that Defendants violated the FCA by submitting reimbursement claims to Medicare that were non-compliant with Medicare regulations in two respects: (1) the reimbursement claims submitted by Defendants were based upon improper generic authorizations given to Lincare in connection with the provision of items related to chronic obstructive pulmonary disease and failed to include a new authorization when Defendants requested reimbursement for diabetic blood-testing strips; and (2) the claims submitted to Medicare arose out of telemarketing calls with beneficiaries that violated Medicare's unsolicited telephone contact rules. The Complaint included six examples of claims submitted by Defendants to Medicare on behalf of six different Medicare beneficiaries which were alleged to be illustrative of Defendants' unlawful conduct.

Defendants moved for summary judgment. They contended that the claims filed on behalf of these exemplars complied with the applicable Medicare regulations and could not form the basis of any FCA claim. The district court issued an order on July 13, 2015 (the "July Summary Judgment Order"), granting Defendants' motion for summary judgment on the six exemplars, but recognized the possibility that its order may not be dispositive of the entire case. United States ex rel. Phalp v. Lincare Holdings, Inc., 116 F. Supp. 3d 1326, 1361 (S.D. Fla. 2015). Subsequently, Relators cited evidence of three additional exemplars which were alleged to be illustrative of Defendants' practice of unlawfully telemarketing Medicare beneficiaries. The district court issued a second order on January 11, 2016 (the "January Summary Judgment Order"), granting Defendants' motion for summary judgment on the three additional exemplars. United States ex rel. Phalp v. Lincare Holdings, Inc., No. 10-CV-21094, 2016 WL 3961840 (S.D. Fla. Jan. 11, 2016). Relators appeal portions of those two orders to this Court.

1. The July Summary Judgment Order

The district court held that the evidence was insufficient to create a genuine issue of material fact with regard to scienter—that is, whether the defendants "knew or should have known that its policies or practices violated the applicable statutes and implementing regulations." The district court analyzed Relators' "best evidence" of scienter, which consisted of two emails. One dealt with an entirely

different compliance issue. In the second email, Lincare personnel wrote that "they '[m]ay need to reconsider [their] process for Patient Agreements,'" but the email postdated the relevant transactions by several months. The court concluded that these two emails did not "allow a reasonable jury to conclude that Diabetic Experts knowingly submitted false claims."

Citing United States ex rel. Hixson v. Health Mgt. Sys., Inc., 613 F.3d 1186, 1191 (8th Cir. 2010), the district court stated that when a defendant claims that the governing law is ambiguous, "[t]o prevail under the False Claims Act, 'relators must show that there is no reasonable interpretation of the law that would make the allegedly false statement true.'" The district court expanded on this line of reasoning, stating that "a defendant's 'reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA.'" Based on this reasoning, as "an alternative and independent ground" for granting summary judgment in favor of Defendants,[3] the court concluded "as a matter of law that, with regard to the six exemplars, no reasonable jury could find for Relators on the questions of whether Defendants submitted false claims or made or used false records with the requisite scienter."

[3] The district court also made various findings concerning whether a new AOB was required to submit claims for diabetic testing strips and whether such strips should be classified as "supplies" or "equipment" under Medicare regulations. It is unnecessary for this Court to determine whether the district court's or Relators' interpretation of multiple provisions of the Medicare regulatory scheme is the correct one, given this Court's conclusion that Relators' evidence was insufficient to establish scienter under the FCA.

2. The January Summary Judgment Order

At the conclusion of the July 13 Summary Judgment Order, the district court invited the parties to submit a status report indicating what, if any, claims remained in the case. Relators supplemented the record with evidence of three additional exemplars, who were previous clients of Lincare's wholly owned subsidiaries, Med4Home and Reliant. Relators alleged that Diabetic Experts' telemarketing of these beneficiaries was in violation of Medicare's prescription against unsolicited telephone contact. See 42 U.S.C. § 1395m(a)(17)(A). Relators argued that, unlike Diabetic Experts' relationship with Lincare, Med4Home and Reliant could not be considered the same supplier as Diabetic Experts for purposes of Medicare regulations.

On January 11, 2016, the district court entered its order granting summary judgment in favor of Defendants. The court found that the three additional exemplars presented by Relators fell within the exception to the anti-telemarketing prescription that applies where the beneficiary gives written permission to the Medicare supplier. See 42 C.F.R. § 424.57(c)(11)(i) ("The supplier must . . . agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless . . . [t]he individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to

be rented or purchased.").[4] The court subsequently granted summary judgment for Defendants on Relators' remaining claims.

II. STANDARD OF REVIEW

"We review a district court's grant of summary judgment *de novo*, viewing all of the facts in the record in the light most favorable to the non-movant." Haynes v. McCalla Raymer, LLC, 793 F.3d 1246, 1249 (11th Cir. 2015) (quotation and citation omitted). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact" such that "the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

"We review a district court's decision to rule on a summary-judgment motion before all discovery disputes have been resolved for abuse of discretion." Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1050 (11th Cir. 2015) (citation omitted). In order to prevail on appeal, "a party must be able to show substantial harm to its case from the denial of its requests for additional discovery," Leigh v. Warner Bros., Inc., 212 F.3d 1210, 1219 (11th Cir. 2000), and that the party timely informed the district court of the outstanding discovery, Cowan v. J.C. Penney Co., Inc., 790 F.2d 1529, 1532 (11th Cir. 1986). Moreover, the party "must specifically demonstrate how postponement of a ruling on the motion [for summary judgment

[4] The court also rejected Relators' argument that even if their exemplars did not demonstrate FCA violations, Relators could survive summary judgment based on facts known to them personally from their time as employees of Lincare affiliates. We agree with the district court that Relators' evidence failed to create a genuine dispute of material fact, and confine our discussion to Relators' exemplars.

would have] enable[d] him, by discovery or other means, to rebut the movant's showing of the absence of a genuine issue of fact." Reflectone, Inc. v. Farrand Optical Co., 862 F.2d 841, 843 (11th Cir. 1989) (quotation marks and citation omitted).

III. DISCUSSION

A. Relators Failed to Offer Evidence That Defendants Acted With the Requisite Scienter to Establish a Violation of the FCA.

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." 31 U.S.C. § 3729(a)(1)(A-B).[5] The FCA authorizes private citizens to bring actions on behalf of the United States. Id. § 3730(b). Relators in this case brought claims under two subsections of the FCA, § 3729(a)(1)(A) and (B). To establish a cause of action under § 3729(a)(1)(A), a relator must prove three elements: (1) a false or fraudulent claim, (2) which was presented, or caused to be presented, for payment or approval, (3) with the knowledge that the claim was false. 31 U.S.C. § 3729(a)(1)(A). To prove a claim

[5] On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA and re-designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B). We need not decide whether the earlier or amended version of the FCA is applicable because we conclude that the district court properly granted summary judgment to Defendants on Relators' claims based on the alleged violation of the Medicare regulations under either version of the statute. Moreover, the 2009 amendment does not materially affect the issues on appeal.

under § 3729(a)(1)(B), a relator must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim. 31 U.S.C. § 3729(a)(1)(B).

In this case, Relators' theory of FCA liability is a "false certification theory," whereby Defendants are alleged to have falsely certified that they "complied with a [Medicare] statute or regulation the compliance with which is a condition for Government payment." United States v. Amin Radiology, No. 5:10-CV-583-Oc-PRL, 2015 WL 403221, at *3 (M.D. Fla. Jan. 28, 2015) (quotation and citation omitted)), aff'd sub nom. U.S. ex rel. Florida v. Amin Radiology, 649 F. App'x 725 (11th Cir. 2016). This case is not one in which the plaintiff seeks to enforce Medicare regulations, but is a lawsuit brought under and governed by the FCA. U.S. ex rel. Clausen, 290 F.3d at 1311 ("The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.") (citation omitted). Accordingly, the "fact that there may have been a violation of the laws governing Medicare . . . is not enough, standing alone, to sustain a cause of action under the False Claims Act." Amin Radiology, 2015 WL 403221, at *3 n.3; see also Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1328 (11th Cir. 2009) (concluding that "[i]mproper practices standing alone are insufficient to state a

claim under either § 3729(a)(1) or (a)(2) absent allegations that a specific fraudulent claim was in fact submitted to the government.").

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." 31 U.S.C. § 3729(a)(1)(A-B). With regard to scienter, a relator must show that the defendant acted "knowingly," which the FCA defines as either "actual knowledge," "deliberate ignorance," or "reckless disregard." 31 U.S.C. § 3729(b). "Congress added the 'reckless disregard' provision to the FCA in 1986" in order "to ensure that 'knowingly' captured the 'ostrich' type situation whether an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted." Urquilla-Diaz, 780 F.3d at 1058 (internal quotations partially omitted) (quoting S. REP. 99-345, at 21, reprinted in 1986 U.S.C.C.A.N. 5266, 5288)). "Although proof of a specific intent to defraud is not required, the statute's language makes plain that liability does not attach to innocent mistakes or simple negligence." Id. (citation and quotation omitted).

> Liability attaches to only those who act in gross negligence—those who fail to make such inquiry as would be reasonable and prudent to conduct under the circumstances. In other words, Congress did not intend to turn the False Claims Act, a law designed to punish and deter fraud, into a vehicle either punishing honest mistakes or incorrect claims submitted through mere negligence or imposing a

> burdensome obligation on government contractors rather than a limited duty to inquire.

Id. (internal punctuation, quotation, and citations omitted).

In the July Summary Judgment Order with regard to the initial six exemplars, the district court concluded that Relators failed to produce sufficient evidence that Defendant submitted false claims with the requisite level of scienter because "a defendant's reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." The district court's conclusion that a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation that would have permitted its conduct is erroneous. Although ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter. Instead, a court must determine whether the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation. See United States v. R&F Props. of Lake Cty., Inc., 433 F.3d 1349, 1358 (11th Cir. 2005) (finding a question of fact as to the defendants' understanding of a regulation precluded summary judgment despite ambiguity in the regulation).

Furthermore, under the district court's legal interpretation, a defendant could avoid liability by relying on a "reasonable" interpretation of an ambiguous regulation manufactured *post hoc*, despite having actual knowledge of a different

authoritative interpretation. However, scienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable. See United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1053-54 (8th Cir. 2002) (holding that scienter is established if a defendant knowingly disregards the proper interpretation of an ambiguous regulation); see also S. REP. 99-345, at 6-7 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5271-72 (clarifying that instead of an actual knowledge standard, the Senate Judiciary Committee intended to adopt a standard which recognizes "that those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate.").

Applying the correct standard, this Court finds that Relators failed to present sufficient evidence of scienter to defeat Defendants' motion for summary judgment. As explained above, Relators' "best evidence" of scienter consisted of two emails: one dealt with an entirely different compliance issue and the other postdated the relevant transactions by several months. The district court correctly concluded that neither email would permit "a reasonable jury to conclude that Diabetic Experts knowingly submitted false claims."

Relators have not identified any error in this analysis and instead have emphasized evidence of an email exchange from November 2008 between Lincare employees inquiring whether Lincare could share AOBs with Diabetic Experts.

There is nothing about this exchange, which merely discussed Defendants' then-existing policy, to suggest that any of Defendants' employees believed or had reason to believe they were violating Medicare regulations.

Relators also argue that the plain language of 42 C.F.R. § 424.36(a) and the 2008 amendments thereto constituted notice to Defendants that any authorization should have included the specific service being provided and, as such, establish the requisite scienter in this case. There is nothing in the plain language of 42 C.F.R. § 424.36(a) that would put Defendants on notice that Diabetic Experts' use of AOBs given to Lincare were not compliant with Medicare regulations.

Accordingly, the district court did not err in concluding that summary judgment to Defendants was appropriate because Relators did not provide sufficient evidence of scienter.

B. The District Court Did Not Err in Concluding That Defendants' Telemarketing Practice Did Not Violate Medicare's Prohibition on Unsolicited Telephone Contacts.

Medicare regulations prohibit a supplier from contacting a Medicare beneficiary by phone unless one of the following three exceptions applies:

> (i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.
>
> (ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

> (iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

42 C.F.R. § 424.57(c)(11).

In its July Summary Judgment Order, the district court found that Lincare sold durable medical equipment covered by the Medicare regulations to the six exemplar beneficiaries within the fifteen months leading up the calls in question made by Diabetic Experts. Based on this fact, the district court correctly found that the calls made by Diabetic Experts fell squarely within the third exception to Medicare's prescription against making unsolicited telephone contact, which permits calls to beneficiaries "[i]f the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, [and] the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact." 42 C.F.R. § 424.57(c)(11)(iii).

With regard to the three additional exemplars at issue in the January Summary Judgment Order, the district court found that "each of the New Exemplars contains consent to contact by 'supplier and its affiliates.'" The district court correctly concluded that these consents meant that the calls placed by Defendants fell within the first exception to the proscription on telemarketing

beneficiaries where the beneficiary gives written permission to the Medicare supplier.[6] 42 C.F.R. § 424.57(c)(11)(i).

Relators have not presented any argument that requires this Court to disturb the lower court's ruling. Relators' contention that there was evidence that the first six exemplars did not consent to being contacted misses the import of the district court's July Summary Judgment Order, which relied upon the third, instead of the first, exception to § 424.57(c)(11).

Additionally, the Court finds without merit Relators' assertion that the district court abused its discretion in denying discovery on the "no consent" AOBs and by ruling on Defendants' summary judgment motion while Relators had a pending motion related to the discovery. The record reveals that any pending discovery requests related to damages and there is no indication that the information sought would have had any bearing on the outcome of the district court's ruling. See Relators' Mot. for Leave to File Suppl. to Mot. for Partial Summ. J. (indicating that pending discovery motion was limited to damages discovery).

[6] Specifically, the district court correctly found "that Diabetic Experts' practice of calling customers of its affiliate who had consented to contact by affiliates as represented by the New Exemplars are not violations of the statute that could create an objectively false claim when presented to the government."

IV. CONCLUSION

We affirm the district court's orders granting summary judgment to Defendants. Although the district court incorrectly stated that a defendant can preclude a finding of scienter by identifying a reasonable interpretation of an ambiguous regulation that would have permitted its conduct, Relators nevertheless failed to present sufficient evidence of scienter to survive summary judgment under the correct standard. The district court also did not err in granting summary judgment on Relators' claim that Defendants violated Medicare's proscription against unsolicited telemarketing calls.

AFFIRMED AS MODIFIED.