

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

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

Plaintiffs,

v.

Case No. 8:13-cv-3150-T-33AEP

RS COMPOUNDING LLC d/b/a
ZOE SCRIPTS LABORATORY SERVICES,
LLC and d/b/a WESTCHASE
COMPOUNDING PHARMACY,
RENIER GOBEA, STEPHEN M. CADDICK,
Pharm D., and JOHN DOE
CORPORATIONS 1-10, all whose
true names are unknown,

Defendants.

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ORDER

This matter comes before the Court pursuant to Defendants RS Compounding LLC and Renier Gobeas Motion to Dismiss Relators First Amended Complaint (Doc. # 48), filed on September 20, 2017, and Defendant Stephen Caddicks Motion to Dismiss Relators First Amended Complaint (Doc. # 70), filed on October 11, 2017. Relator McKenzie Stepe responded on October 4 and 25, 2017. (Doc. ## 65, 73). For the reasons that follow, the Motions are granted and Stepes Amended Complaint is dismissed with leave to amend by December 7, 2017.

I. Background

Defendants Renier Gobeia and Stephen M. Caddick, Pharm. D., co-founded Defendant RS Compounding LLC in 2004. (Doc. # 39 at ¶ 35). RS Compounding, which does business as Zoe Scripts Laboratory Services, LLC, and Westchase Compounding Pharmacy, is a compounding pharmacy that “distribute[s] massive quantities of pre-made compounds for both humans and animals throughout the country in a fashion similar to a large pharmaceutical manufacturing company.” (Id. at ¶¶ 5, 7). Defendants market many types of creams and gels, some of which contain ketamine. (Id. at ¶ 8). These creams and gels are intended to treat various medical conditions, including peripheral neuropathy, carpal tunnel syndrome, phantom limb pain, sciatica, and arthritis. (Id. at ¶ 88). “At least 40% to 50% of Defendants’ sales and revenues are earned from Medicare and TRICARE reimbursements.” (Id. at ¶ 6).

Caddick is a licensed pharmacist, but Gobeia is not. (Id. at ¶¶ 35-36). Although Gobeia at one point sold his ownership interest to Caddick, Gobeia returned and purchased Caddick’s ownership interest in February of 2014. (Id. at ¶ 35). Thus, “Gobeia is the current owner and director of RS Compounding.” (Id.). Nevertheless, prior to his departure, Caddick “oversaw

all of RS Compounding's operations, including the training of RS Compounding's sales representatives." (Id. at ¶ 36).

Plaintiff relator McKenzie Stepe worked for RS Compounding as a sales representative in New York and New Jersey between November of 2011 and February of 2013. (Id. at ¶ 30). Through her work, Stepe alleges she became aware of various schemes committed by Defendants in order to increase reimbursements from the Government.

The first was a marketing scheme, which Defendants called the "1, 2, 3 strategy." (Id. at ¶ 9). This scheme involved pre-printed script pads, listing RS Compounding's various creams and gels, along with sales representatives' "coaching" physicians to prescribe the most highly reimbursed drugs. (Id. at ¶¶ 9-10). According to Stepe, "Defendants [] Goba and/or [] Caddick have instructed RS Compounding's sales representatives to fill in the physician's name, National Provider Identifier ('NPI') number, and to also write in '6' for the number of refills, regardless of actual patient need," on the pre-printed script pad. (Id. at ¶ 10). And, during Stepe's first year with RS Compounding, Defendants "required that their [script pads] contain prepopulated check marks for the most expensive compounds RS Compounding sold, thereby placing the burden on the

prescribing physicians to cross out the check mark and check off another product.” (Id. at ¶¶ 11, 18).

Stepe alleges that, as a result of these pre-printed script pads, “Defendants automatically ship refills to patients – often of the most expensive products if the physician did not cross out the check mark and check off a different compound – and seek TRICARE, Medicare, Medicaid, and private insurance reimbursements for those refills despite questionable (and unsupervised by a doctor) medical necessity.” (Id. at ¶ 18).

In addition to the pre-printed script pads, “[u]nder the ‘1, 2, 3 strategy,’ Defendants’ sales representatives ‘coach’ physicians to number three products on the pre-printed script.” (Id. at ¶ 14). Thus, for pre-printed script pads that did not include checkmarks by the most expensive drugs, Stepe alleges “[p]hysicians are coached to choose their top three preferences for each cream or gel based on the active ingredients.” (Id. at ¶ 67). Sales representatives “‘coach’ physicians to write number ‘1’ next to either NeuroMax, NeuroPlus-0 or KetaLIGHT,” which “provide[] the highest reimbursement rate” from the Government or private insurers. (Id. at ¶ 68). Next, sales representatives instruct physicians “to write a number ‘2’ next to either NeuroFlex or

FlexUltra," which "have the second-highest reimbursement rates of Defendants' drugs, if they are covered" by the patient's health plan. (Id. at ¶ 69). "Finally, Defendants instruct sales representatives to 'coach' physicians to write a '3' next to NeuroGel, which has the lowest reimbursement rate of Defendants' drugs." (Id. at ¶ 70). The importance of this numbering was emphasized to sales representatives like Stepe by RS Compounding's Vice President of Sales and Marketing, Jon Taylor. He "instructed [them] to 'fill out a sample prescription and highlight how you are suggesting they fill it out. . . . Repeating your message on this until it sticks.'" (Id. at ¶ 16).

Another scheme involved disparate pricing of the compounds and gels sold by Defendants, in which different patients were charged different amounts for the same substances. According to Stepe, "the Company charged vastly different prices for individuals who were uninsured, who had private insurance, and who were covered by TRICARE, Medicare, and Medicaid." (Id. at ¶ 76). For example, Stepe alleges "Defendants regularly billed TRICARE \$1,200.00 for the same 120-gram bottle that they charged uninsured patients between \$15.00 and \$45.00 for." (Id. at ¶ 17). After receiving complaints from physicians about the allegedly inflated

prices, Stepe and another sales representative spoke with the Vice President of Sales and Marketing, Mr. Taylor. (Id. at ¶¶ 74-79). Mr. Taylor "instructed them to not question it because prices were set 'at the top of the Company,' thereby directly implicating RS Compounding's owners Mr. Gobeia and/or Dr. Caddick." (Id. at ¶ 80).

Also, Stepe alleges Defendants "do not train their sales representatives regarding proper and improper use, or potential contra-indications or warnings." (Id. at ¶ 89). "Defendants did not offer or provide [Stepe] with any formal training or educate her or any sales representatives about the efficacy or proper use of their products while she was employed." (Id.). "Defendants also do not sufficiently inform patients about the proper use of their compounds for these medical conditions" and the basic instructions provided to physicians "do not provide specific information about Defendants' differing compounds." (Id. at ¶¶ 90-91).

As a result of these various schemes, Stepe alleges Defendants have submitted fraudulent claims to the Government and have made false records and statements material to such claims. (Id. at ¶ 94). According to Stepe, "[u]nder the FCA and its state-level equivalents, claims for Defendants' creams and gels have been and continue to be fraudulent

because the claims submitted for reimbursement are based upon illegal marketing.” (Id. at ¶ 95).

On December 16, 2013, Stepe filed her Complaint against RS Compounding and John Doe Corporations 1-10 under seal, alleging violations of the False Claims Act (FCA), 31 U.S.C. § 3729(a), and Florida’s state equivalent of the FCA. (Doc. # 1). On April 28, 2017, the Government elected to intervene in part as to the fraudulent pricing allegations, but not as to the “remaining allegations (including [Stepe’s] fraudulent marketing and promotional allegations).” (Doc. # 33). The Government filed its Complaint in partial intervention on June 30, 2017, and subsequently filed its Amended Complaint in partial intervention on September 9, 2017, against RS Compounding and Gobeia. (Doc. ## 36, 42).

Stepe filed her Amended Complaint on July 12, 2017, again alleging violations of the FCA and various States’ equivalent statutes against RS Compounding, Gobeia, Caddick, and John Doe Corporations 1-10. (Doc. # 39). Stepe alleges claims under the state equivalents of the FCA for Florida, Virginia, Massachusetts, California, Colorado, Delaware, Georgia, Illinois, Indiana, Louisiana, Maryland, Nevada, New Jersey, New Mexico, Oklahoma, Tennessee, and Texas. (Id.).

RS Compounding and Gobeia filed their Motion to Dismiss Stepe's Amended Complaint on September 20, 2017. (Doc. # 48). Caddick filed his Motion to Dismiss Relator's First Amended Complaint on October 11, 2017.¹ (Doc. # 70). Stepe responded on October 4 and 25, 2017. (Doc. ## 65, 73). The Motions are ripe for review.

II. Legal Standard

On a motion to dismiss, this Court accepts as true all the allegations in the complaint and construes them in the light most favorable to the plaintiff. Jackson v. Bellsouth Telecomms., 372 F.3d 1250, 1262 (11th Cir. 2004). Further, this Court favors the plaintiff with all reasonable inferences from the allegations in the complaint. Stephens v. Dep't of Health & Human Servs., 901 F.2d 1571, 1573 (11th Cir. 1990) ("On a motion to dismiss, the facts stated in [the] complaint and all reasonable inferences therefrom are taken as true.")

However, the Supreme Court explains that:

¹ In her response, Stepe argues Caddick's Motion is untimely and should be denied on that ground. (Doc. # 73 at 8-9). But Stepe never properly applied to the Clerk for entry of default against Caddick, and acknowledged that she had consented to an extension of time for Caddick to file his response to the Amended Complaint. Although Caddick should have filed a motion for extension of time to file his Motion, the Court declines to deny Caddick's Motion as untimely.

While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)(internal citations omitted). Courts are not "bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986).

Rule 9(b) of the Federal Rules of Civil Procedure imposes more stringent pleading requirements on claims alleging fraud. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1305 (11th Cir. 2002). The complaint must allege "facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendant['s] allegedly fraudulent acts, when they occurred, and who engaged in them." Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1324 (11th Cir. 2009).

III. Analysis

Enacted in 1863, the FCA "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)(internal quotation marks omitted). "Since then, Congress has repeatedly amended the Act, but its focus remains on those who present or directly induce the submission of false or fraudulent claims." Id. The FCA's civil penalties are "essentially punitive in nature" and subject defendants to treble damages plus penalties of up to \$10,000 per claim. Id. (internal quotation marks omitted).

The FCA may be enforced by the government or by a relator through a *qui tam* action brought "in the name of the Government." 31 U.S.C. § 3730(b). Thus, the FCA permits private persons to file *qui tam* actions on behalf of the United States against any person who:

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(a)(1)(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); [or]

(a)(1)(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.

31 U.S.C. § 3729(a). Stepe alleges violations of these four subsections.

Defendants argue that Stepe has failed to state claims under any of these subsections because her allegations fail to meet either the Rule 12(b)(6) or Rule 9(b) standards, as well as failing to establish the allegations were material to the Government's decision to pay claims. (Doc. # 48 at 3, 6-7).

Defendants also argue "the companion state FCA claims (Fifth through Twenty-Third Claim) should be dismissed for the same reason since the state FCAs are modeled on the federal False Claims Act." (Id. at 3); see, e.g., United States v. Cypress Health Sys. Fla., Inc., No. 1:09CV137-SPM-GRJ, 2012 WL 467894, at *1 (N.D. Fla. Feb. 14, 2012) ("Because the Florida False Claims Act is modeled after the Federal False Claims Act, the claims will be analyzed using the same general standards."); United States ex rel. Nudelman v. Int'l Rehab. Assocs., Inc., No. CIV.A. 00-1837, 2006 WL 925035, at *12 (E.D. Pa. Apr. 4, 2006) ("The False Claims Acts of California, Delaware, Florida, Illinois, Nevada and the Tennessee Medicaid False Claims Act read similarly and are substantively the same as the FCA under the United States Code.").

A. Disparate Pricing Allegations are Superseded

Defendants argue that Stepe cannot base her claims on the alleged disparate pricing scheme because the Government has intervened as to those allegations. (Doc. # 48 at 7-8). Indeed, as another court has explained, “[w]hen the government has intervened, that portion of the relator’s complaint effectively ceases to exist because it has been superseded.” United States v. Pub. Warehousing Co. K.S.C., 242 F. Supp. 3d 1351, 1357 (N.D. Ga. 2017); see also United States ex rel. Sansbury v. LB & B Assocs., Inc., 58 F. Supp. 3d 37, 47 (D.D.C. 2014)(“[B]y automatic operation of the statute, the Government’s complaint in intervention becomes the operative complaint as to all claims in which the government has intervened.”). Stepe “does not dispute her disparate pricing claim against Defendants is superseded by the Government’s Usual and Customary Price claim in the Government’s Complaint.” (Doc. # 65 at 19).

The Court need not dismiss Stepe’s disparate pricing allegations. “[T]he appropriate action for the Court to take when a defendant moves to dismiss those portions of a relator’s complaint that have been superseded by government intervention is to deny the motion as moot as it relates to the intervened claims.” Pub. Warehousing Co. K.S.C., 242 F.

Supp. 3d at 1357. Still, because these claims have been superseded by the Government's claims and have "effectively cease[d] to exist," the disparate pricing allegations cannot serve as a basis for Stepe's non-superseded claims in her Amended Complaint. Id. Therefore, in determining whether Stepe's Amended Complaint satisfies the Rule 9(b) and 12(b)(6) standards, the Court will not consider the alleged disparate pricing scheme.

B. The Amended Complaint Does Not Satisfy Rule 9(b)

1. Count I for Presentment of False Claims

In Count I, Stepe alleges "Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A)." (Doc. # 39 at 28). Section 3729(a)(1)(A) imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

The key issue under § 3729(a)(1)(A) is whether the defendant "presented or caused to be presented" a false claim. Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1052 (11th Cir. 2015)(quoting Hopper, 588 F.3d at 1325-26). Stepe "must allege the actual presentment of a claim . . . with particularity, meaning particular facts about the 'who,'

'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government." Id. at 1052 (internal quotation marks omitted).

"Providing exact billing data – name, date, amount, and services rendered – or attaching a representative sample claim is one way a complaint can establish" presentment of a false claim. United States ex rel. Mastej v. Health Mgmt. Assocs., Inc., 591 F. App'x 693, 704 (11th Cir. 2014). "However, there is no per se rule that an FCA complaint must provide exact billing data or attach a representative sample claim." Id. (citing Clausen, 290 F.3d at 1312 & n.21). Rather, a complaint must contain "some indicia of reliability" that a false claim was actually submitted. Clausen, 290 F.3d at 1311. "For instance, a relator with first-hand knowledge of the defendant's billing practices may possess a sufficient basis for alleging that the defendant submitted false claims." United States ex rel Patel v. GE Healthcare, Inc., No. 8:14-cv-120-T-33TGW, 2017 WL 4310263, at *6 (M.D. Fla. Sept. 28, 2017)(citing Mastej, 591 F. App'x at 704).

Defendants argue that the Amended Complaint fails to plead fraud with particularity as to any false claims being submitted to the Government. (Doc. # 48 at 3; Doc. # 70 at 6-7, 10). Defendants highlight that Stepe worked for RS

Compounding in the New York area, "far from RS Compounding's office in Tampa" and that Stepe "lacked any direct, first-hand knowledge of RS [Compounding]'s submission of claims to federal health care programs." (Doc. # 48 at 3). As to the presentation of false claims, Defendants note that "[n]o actual or example false claims or reverse false claims are pled" and Stepe "fails to explain the basis for her assertion that fraudulent claims were actually submitted to federal health care programs." (Id.).

Stepe insists the Amended Complaint presents sufficient indicia of reliability. According to Stepe, her role as a sales representative for RS Compounding in New York and New Jersey gave her "first-hand knowledge" supporting her belief that false claims were submitted to the Government. (Doc. # 65 at 12-13; Doc. # 73 at 12). She argues that her detailed allegations about the various schemes, which she alleges were targeted to TRICARE and Medicare patients, "support[] a reasonable inference that Defendants' claims were submitted to Government healthcare programs, since the *sine qua non* of the scheme was to get paid exorbitant amounts for their compounds." (Doc. # 65 at 12).

True, Stepe has provided detailed allegations regarding marketing schemes and allegedly inadequate training by

Defendants. The statement by her superior, Mr. Taylor, encouraging sales representatives to "coach" physicians on how to rank their prescription preferences supports that the "1, 2, 3" marketing scheme exists. And the comments by physicians about upset patients receiving superfluous refills implies that doctors may have mistakenly prescribed a higher number of refills because of the pre-printed script pads. Nevertheless, it is not plainly alleged that the physicians were confused about how many refills they had prescribed, or whether they would have prescribed a lower number of refills if they had not been confused by the pre-printed script pad. And it is unclear whether the patients who complained about receiving unwanted refills were covered by Medicare or TRICARE. Nor is the Court certain on how Defendants' inadequate training of its sales representatives about drug warnings makes the prescriptions submitted by physicians for Defendants' drugs false or fraudulent.

In short, the Court agrees with Defendants. The *sine qua non* of an FCA case is the submission of a false claim for payment to the Government. Clausen, 290 F.3d at 1311. The Eleventh Circuit has held that the FCA does not allow a plaintiff "merely to describe a private scheme in detail but then to allege simply and without any stated reason for his

belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." Atkins v. McInteer, 470 F.3d 1350, 1357 (11th Cir. 2006)(citing Clausen, 290 F.3d at 1311).

Although Stepe focuses on her status as an insider of RS Compounding, that status, without more, does not provide sufficient indicia of reliability to satisfy Rule 9(b). See, e.g., Hopper, 588 F.3d at 1325 (requiring employee sales representatives to link the fraudulent scheme to the submission of false claims); Corsello v. Lincare, Inc., 428 F.3d 1008, 1014 (11th Cir. 2005)(stating that sales representative's allegation that he was "aware" of billing practices was neither particular to any specific fraudulent claim, nor factually supported). Stepe worked as a sales representative for RS Compounding, rather than as a billing department employee. Indeed, Stepe does not allege that she had firsthand knowledge of RS Compounding's billing practices – she does not state that she personally billed any false claims or that she witnessed other employees bill false claims. See Mastej, 591 F. App'x at 704 ("[A] plaintiff-relator without firsthand knowledge of the defendants' billing practices is unlikely to have a sufficient basis for such an allegation.").

Courts cannot draw inferences in favor of relators concerning the submission of fraudulent claims because doing so would strip "all meaning from Rule 9(b)'s requirements of specificity." Corsello, 428 F.3d at 1013 (citing Clausen, 290 F.3d at 1312 n.21). Therefore, the Court declines to make the inferential leap that false claims were actually submitted to the Government because Defendants maintained schemes (1) to encourage doctors to prescribe their products with the highest reimbursement rates, (2) to provide doctors pre-printed script pads specifying automatic refills, and (3) to encourage sales of compounds with insufficient warnings and poor training of sales representatives.

Defendants also argue that the Amended Complaint fails to show that allegations regarding the "1, 2, 3 strategy," the automatic refills, and the failure to warn patients are material to the Government's decision to pay claims. (Doc. # 48 at 5-6). Defendants cite Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). There, in the context of an implied-false certification claim under § 3729(a)(1)(A), the Supreme Court held that the "materiality standard is demanding" and materiality "look[s] to the effect on the likely or actual behavior of the

recipient of the alleged misrepresentation." Id. at 2002-03 (citation omitted).

Because the Court has already determined that Stepe's § 3729(a)(1)(A) claim fails to meet the Rule 9(b) standard, the Court need not address the materiality argument at this juncture. But Stepe is advised that, in amending this claim, she should consider the importance of alleging facts supporting materiality – i.e. why the "1, 2, 3 strategy," pre-printed script pads with high refill numbers, and inadequate training regarding drug warnings would influence the Government's decision to pay such claims. And she should remember that her disparate pricing allegations, because they have been superseded, cannot be used to meet the materiality requirement.

2. Count II for False Statements

In Count II, Stepe alleges Defendants made or used, or caused to be made or used, false records and statements that were material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B). (Doc. # 39 at 28). These false records or statements were "false certifications and representations made or caused to be made by RS Compounding." (Id.). "As a result, the Government has suffered damages in

the form of millions of dollars in unearned TRICARE, Medicare, and Medicaid payments made to Defendants.” (Id.).

Section 3729(a)(1)(B) creates liability for any person who “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)(B). Thus, “[t]o prove a claim 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.” United States ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1154 (11th Cir. 2017).

For this provision, the FCA defines “material” as “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). “Under this version of the statute, a relator is not required to allege presentment because the statutory language includes no express presentment requirement.” Patel, 2017 WL 4310263, at *8 (citing Hopper, 588 F.3d at 1328).

Defendants argue this claim should be dismissed because the Amended Complaint “fails to specify what precisely the ‘false certifications and representations’ made by RS Compounding are, as required by Rule 9(b).” (Doc. # 48 at 6;

Doc. # 70 at 7-9). Additionally, they contend the Amended Complaint "fails to provide a plausible factual basis to support the allegation that these unidentified certifications and representations were in fact 'material' to payment" and "does not contain sufficient facts regarding this claim to meet the Iqbal standard." (Doc. # 48 at 6).

In response, Stepe argues Defendants made a "demonstrably false" certification when they "falsely certified under their provider agreement with TRICARE that they were charging the Government the same prices they charged cash buyers." (Doc. # 65 at 18). But, as the disparate pricing allegations are superseded, the allegation that Defendants falsely certified their pricing was flat cannot support Stepe's claims, which may be based only on the fraudulent marketing and inadequate training allegations. (Doc. # 65 at 18).

The Amended Complaint does not explicitly identify false statements or certifications made, or caused to be made, by Defendants relating to the non-superseded allegations. While the Amended Complaint identifies sales representatives' encouragement of physicians to prescribe more expensive medications, Stepe does not explain how those statements are false. And, although she alleges Defendants placed a number

"6" on the refill line of the pre-printed script pads, physicians were free to mark that number out and write the refill number they believe is appropriate. Essentially, Stepe has alleged that Defendants pre-filled the refill section of the script pads to set a default position of numerous automatic refills. But, again, Stepe fails to allege with particularity what part of this action constitutes a false statement under the FCA. The same is true for the inadequate training and drug warning allegations - no false statements or certifications related to these allegations are identified with particularity. Therefore, this claim is dismissed for failure to satisfy Rule 9(b).

Because the § 3729(a)(1)(B) claim does not satisfy Rule 9(b) for the false statement requirement, it is unnecessary to deal with the materiality requirement. Nevertheless, the Court notes that Defendants argue the Escobar materiality requirement applies to this § 3729(a)(1)(B) claim, as well as the § 3729(a)(1)(G) claim. (Doc. # 48 at 6-7). This is not necessarily so. Escobar deals with the judicially-imposed materiality requirement for § 3729(a)(1)(A) implied-false certification claims. See Patel, 2017 WL 4310263, at *9 ("In an implied-false certification case under § 3729(a)(1)(A), the materiality requirement is a judicially-imposed doctrine,

which is designed to ensure that only significant omissions trigger the FCA's considerable penalties."). In contrast, the materiality requirement for §§ 3729(a)(1)(B) and (G) claims is created by the statute's language, and thus the definition of "material" used is that found in the statute. The parties have not presented case law indicating that Escobar's rigorous materiality standard applies to these claims. See Id. ("GE cites no case holding that Escobar's heightened definition of materiality applies to a claim under § 3729(a)(1)(B). Indeed, the Fourth Circuit has declined to alter its analysis under § 3729(a)(1)(B) following Escobar." (citing United States v. Triple Canopy, Inc., 857 F.3d 174, 179 (4th Cir. 2017))). If Defendants choose to reassert the same materiality argument, they should address why Escobar's heightened materiality definition should apply to the §§ 3729(a)(1)(B) and (G) claims.

3. Count III for Reverse False Claims

Regarding Count III for violation of 31 U.S.C. § 3729(a)(1)(G), Stepe alleges

Defendants have knowingly made, used, or caused to be made or used, false records or false statements (i.e., the false certification made or caused to be made by Defendants) material to an obligation to pay or transmit money to the Government or knowingly concealed or knowingly and improperly

avoided or decreased an obligation to pay or transmit money or property to the [G]overnment.

(Doc. # 39 at 29). "As a result, the Government has suffered damages in the form of millions of dollars in unearned TRICARE, Medicare, and Medicaid payments made to Defendants." (Id.).

Section 3729(a)(1)(G) creates liability for a person who "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 who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). "This is known as the 'reverse false claim' provision of the FCA because liability results from avoiding the payment of money due to the government, as opposed to submitting to the government a false claim." United States ex rel. Matheny v. Medco Health Sols., Inc., 671 F.3d 1217, 1222 (11th Cir. 2012).

"Importantly, to establish a reverse false claim cause of action, a relator must show that the defendant owed a definite and clear 'obligation to pay money to the United States at the time of the allegedly false statements.'" United States v. Space Coast Med. Assocs., L.L.P., 94 F. Supp. 3d

1250, 1263 (M.D. Fla. 2015)(quoting Matheny, 671 F.3d at 1223)). "Congress has defined a False Claims Act 'obligation' as 'an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.'" Id. (quoting 31 U.S.C. § 3729(b)(3)). Again, "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).

Defendants argue Stepe "fails to specify precisely what [] both the 'false certification made or caused to be made by Defendants' and the 'obligation' was, as required by Rule 9(b)." (Doc. # 48 at 7; Doc. # 70 at 7, 9). They also argue the Amended Complaint "fails to provide a plausible factual basis to support the allegation that these unspecified certifications were in fact 'material' to the unidentified obligations." (Doc. # 48 at 7). In her response, Stepe insists she has identified the false certification made and obligation owed to the Government: "Defendants were obligated but failed to return their 'ill-gotten gains' to the Government," specifically the money they received from

charging higher prices to the Government and by "ship[ping] unsuspecting patients six automatic refills of its creams and gels that were medically unnecessary." (Doc. # 65 at 18).

The Court finds that Stepe has not identified with particularity the false certification that was allegedly made or caused to be made by Defendants. As already discussed, the disparate pricing allegations are superseded. So, the allegation that Defendants falsely certified to TRICARE that "they were charging the Government the same prices they charged cash buyers" cannot support Stepe's claims, which may be based only on the fraudulent marketing, automatic refills, and inadequate training/warning allegations. (Doc. # 65 at 18). No false certifications related to the non-superseded allegations, such as the automatic refills, are identified in the Amended Complaint. Similarly, the Court is unsure what obligation Defendants had to pay the Government, as Stepe also fails to identify this beyond stating Defendants "failed to return their 'ill-gotten gains'." (Id.).

Furthermore, because neither the false certification nor the obligation have been alleged with particularity, the Court cannot determine whether the false certification was "material" to the obligation. This claim is dismissed for

failure to comply with the particularity requirement of Rule 9(b).

4. Count IV for Conspiracy

In Count IV, Stepe alleges Defendants violated 31 U.S.C. § 3729(a)(1)(C), which creates liability for any person who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." According to Stepe, Defendants violated this section by "conspir[ing] to make or present false or fraudulent claims and performed one or more acts to effect payment of false or fraudulent claims." (Doc. # 39 at 29). Defendants argue the Amended Complaint fails to allege the existence of a conspiracy plausibly, as required under Rule 12(b)(6), or with the particularity required under Rule 9(b). (Doc. # 48 at 7).

Complaints alleging a conspiracy to violate the FCA are also subject to Rule 9(b)'s heightened pleading standard. See Corsello, 428 F.3d at 1014 ("The district court correctly dismissed [the relator's] [conspiracy count] for failure to comply with Rule 9(b)."). A relator must establish "(1) that the defendant conspired with at least one person to get a false or fraudulent claim paid by the Government; and (2) that at least one of the conspirators performed an overt act to get a false or fraudulent claim paid." United States ex

rel. Chase v. LifePath Hospice, Inc., No. 8:10-cv-1061-T-30TGW, 2016 WL 5239863, at *8 (M.D. Fla. Sept. 22, 2016)(citing United States ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc., 597 F. Supp. 2d 1280, 1289 (M.D. Fla. 2009)). “‘Conspire’ in this context requires a meeting of the minds ‘to defraud the Government.’” Chase, 2016 WL 5239863, at *8 (citing Bane, 597 F. Supp. 2d at 1289; Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662, 672 (2008)).

District courts in the Eleventh Circuit – and at least one other circuit court – have held that a failure to adequately allege the existence of a false claim is fatal to a conspiracy claim. See, e.g., Chase, 2016 WL 5239863, at *8-9; United States ex rel. Marsteller v. Tilton, No. 5:13-cv-830-AKK, 2016 WL 1270586, at *7 (N.D. Ala. Mar. 21, 2016); accord United States ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 801 (8th Cir. 2011)(“Because the Complaint fails to state claims under sections 3729(a)(1) and (2), it likewise fails to state an actionable conspiracy claim under § 3729(a)(3).”). As one district court reasoned:

Because the existence of a false claim – whether ultimately paid by the Government or not – is an element of a cause of action for conspiracy to violate the FCA, the failure of a relator to sufficiently plead that claim’s existence

necessarily means that, as a matter of law, the relator cannot prevail.

Chase, 2016 WL 5239863, at *8-9.

Regardless, the Court finds that Stepe has not pled with particularity that a conspiracy existed between Defendants RS Compounding, Gobeia, and Caddick. Stepe emphasizes her allegations that "Gobeia and [] Caddick worked together, through and with RS Compounding, to set the disparate prices at issue, devise and implement the '1, 2, 3' marketing scheme and automatic refills, and to provide insufficient warnings to patients and inadequate training to RS Compounding's sales representatives." (Doc. # 65 at 18).

But the allegations she points out are conclusory and insufficient to support that Defendants entered a specific agreement to submit fraudulent claims to the Government or that they took any overt act to fulfill that agreement. See Corsello, 428 F.3d at 1014 (affirming dismissal where relator "alleged that 'Lincare and Varraux conspired to defraud the Government,' but this bare legal conclusion was unsupported by specific allegations of any agreement or overt act"). Count IV is dismissed for failure to comply with Rule 9(b).

5. Individual Allegations against Caddick and Gobe

Both Caddick and Gobe argue that the allegations about their personal involvement in any scheme or submission of false statements or claims are conclusory and must be dismissed. (Doc. # 48 at 4-5; Doc. # 70 at 7-8). Indeed, the Amended Complaint includes numerous conclusory allegations, such as: "pursuant to [] Gobe's and [] Caddick's directives, [] Defendants instructed their sales representatives to write in the physician's name and address, and the number '6' on each refill line." (Doc. # 39 at ¶ 63). As Gobe points out, the Amended Complaint "neither quotes nor cites any statements by [] Gobe to [Stepe] or any others to direct or encourage FCA violations." (Doc. # 48 at 4). Similarly, the Amended Complaint fails to allege details about Caddick's supposed directives.

Stepe retorts that she has made specific allegations about Gobe and Caddick's personal involvement in the alleged fraud. (Doc. # 65 at 13-14; Doc. # 73 at 13-14). Stepe emphasizes that Mr. Taylor, the Vice President of Sales and Marketing, told her that the disparate pricing decision came from "the top" of RS Compounding. (Doc. # 65 at 14). Stepe interprets this statement to mean that Caddick and Gobe

themselves crafted the scheme. (Id.). But, again, the disparate pricing allegations are superseded. Regardless, a single vague statement that higher-up officials – who are unnamed – were involved in an allegedly fraudulent scheme is insufficient to satisfy Rule 9(b). Additionally, as Gobeia notes, it is unclear which actions were allegedly taken by Gobeia or Caddick. (Doc. # 48 at 5). Stepe frequently alleges that Gobeia “and/or” Caddick were involved in the allegedly fraudulent practices together. For example, the Amended Complaint states “Gobeia and/or [] Caddick created RS Compounding’s marketing scheme.” (Doc. # 39 at ¶ 9).

Lumping two Defendants together without any supporting factual allegations to suggest the actions were taken jointly is insufficient. See Brooks v. Blue Cross & Blue Shield of Florida, Inc., 116 F.3d 1364, 1381 (11th Cir. 1997) (concluding that RICO claim did not satisfy Rule 9(b) where the allegations of fraud “lumped together” all Defendants and noting that a complaint “should inform each defendant of the nature of his alleged participation in the fraud” (citation and internal quotation marks omitted)); United States v. Corinthian Colleges, 655 F.3d 984, 997–98 (9th Cir. 2011)(“Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to

differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." (quotation omitted)).

The lumping together of Caddick and Gobeia is especially problematic because it is unclear if Gobeia was even associated with RS Compounding during Stepe's employment. The Amended Complaint states Gobeia and Caddick co-founded RS Compounding in 2004, but Gobeia left "[a]t some point after founding the company," without a date specified. (Doc. # 39 at ¶ 35). Stepe alleges Gobeia returned to buy out Caddick's ownership interest in February of 2014 – after Stepe's employment (and, thus, her insider knowledge about RS Compounding's practices) ended. Greater particularity about the conduct of the individual Defendants, Gobeia and Caddick, is required under Rule 9(b).

IV. Conclusion

Counts I, II, III, and IV under the FCA, as well as the parallel claims under the States' false claims laws, are dismissed. Stepe requests leave to amend her claims. (Doc. # 65 at 20). Pursuant to Fed. R. Civ. P. 15(a)(2), "[t]he court should freely give leave [to amend] when justice so requires." "In light of the liberal policy favoring amendment, and

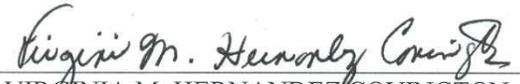
because this Court has not previously issued any substantive ruling in this action, the Court will grant [Stepe] one – and very likely only one – opportunity to amend.” Patel, 2017 WL 4310263, at *8. Stepe’s Second Amended Complaint is due December 7, 2017.

Accordingly, it is now

ORDERED, ADJUDGED, and DECREED:

- (1) Defendants RS Compounding LLC and Renier Gobeas’s Motion to Dismiss Relator’s First Amended Complaint (Doc. # 48) is **GRANTED**.
- (2) Defendant Stephen Caddick’s Motion to Dismiss Relator’s First Amended Complaint (Doc. # 70) is **GRANTED**.
- (3) Plaintiff relator McKenzie Stepe’s Amended Complaint (Doc. # 39) is **DISMISSED**. Stepe may file a Second Amended Complaint by **December 7, 2017**.

DONE and ORDERED in Chambers in Tampa, Florida, this 8th day of November, 2017.


VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE