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.
_____/

ORDER

This matter comes before the Court pursuant to Defendant Stephen M. Caddick's Motion to Dismiss Relator's Second Amended Complaint (Doc. # 93), filed on December 12, 2017, and Defendants RS Compounding LLC and Renier Gobea's Motion to Dismiss Relator's Second Amended Complaint (Doc. # 97), filed on December 21, 2017. Relator McKenzie Stepe responded on January 4, 2018. (Doc. # 101). For the reasons that follow, the Motions are granted.

I. Background

A. Alleged False Claims Act Violations

Defendants Renier Gobea and Stephen Caddick, Pharm. D., co-founded Defendant RS Compounding LLC in 2004. (Doc. # 91 at ¶ 34). 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 ¶¶ 4, 6). Defendants market many types of creams and gels, some of which contain ketamine. (Id. at ¶ 7). "At least 40% and 50% of Defendants' sales and revenues are earned from Medicare and TRICARE reimbursements." (Id. at ¶ 5).

Caddick is a licensed pharmacist, but Gobea is not. (Id. at ¶¶ 34, 37). Although Gobea at one point sold his ownership interest to Caddick, Gobea returned "to serve in a senior level management position in or around early 2012." (Id. at ¶ 34). Subsequently, Gobea purchased Caddick's ownership interest in February of 2013. (Id. at ¶ 35). Thus, "Gobea is the current owner and director of RS Compounding." (Id. at ¶ 36). Nevertheless, after the sale of his ownership interest, Caddick remained to "serve[] as a senior manager, or sole

manager, of [RS Compounding] until approximately early 2015" and "oversaw all of RS Compounding's operations, including the training of RS Compounding's sales representatives." (Id. at ¶ 37). "Beginning in or around January 2013," Caddick and Gobea "would meet every Monday and Wednesday morning to discuss [RS Compounding's] operations." (Id.).

Plaintiff relator McKenzie Stepe was "personally hired" by Caddick in November 2011 to work for RS Compounding as a sales representative in New York and New Jersey. (Id. at ¶ 29). "During her employment, she also had some communications with [] Gobea." (Id.). Stepe resigned her position in February 2013. (Id.). 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 created by "Gobea and/or [] Caddick," which they called the "1, 2, 3 strategy." (Id. at ¶ 8). 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 ¶¶ 8, 13). According to Stepe, "Defendants [] Gobea 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 ¶ 9). 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 ¶¶ 10, 17).

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 and Medicare reimbursements for those refills despite questionable (and unsupervised by a doctor) medical necessity." (Id. at ¶ 17). Stepe allegedly received "complaints from the physicians she worked with that some of their patients were angered by RS Compounding's automatic shipments of the six compounds and their billing for each compound, even though there was no medical need for the additional five compounds and the patient did not want the extra compounds." (Id. at ¶ 64). According to Stepe, "Defendants' scheme is fraudulent because it causes TRICARE and Medicare to reimburse Defendants . . . for drugs

that uni[n]formed physicians ordered in greater amounts than necessary along with several automatic refills." (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 ¶ 13). 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 mark the most highly-reimbursed drugs with a "1," the second most highly-reimbursed drugs with a "2," and the third most highly-reimbursed drugs with a "3." (Id. at ¶¶ 68-70).

The importance of this numbering was emphasized to sales representatives 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 ¶ 15). "Through this marketing scheme, Defendants also targeted geographical locations with high concentrations of military personnel in order to issue large

quantities of compounding prescriptions . . . knowing that TRICARE would reimburse the highly inflated costs." (Id. at ¶ 71).

According to Stepe, RS Compounding "directed its sales representatives to work with the IT staff or administrators handling their physicians' electronic medical records (EMR) systems to add the Company's compounds into the systems so that the compounds would be prepopulated and 'readily available to share with customers.'" (Id. at ¶ 11). "Although [RS Compounding's] written materials indicated that only non-controlled substance compounds were able to be E-scribed and controlled substance compounds (e.g., ketamine) had to be faxed or mailed, the Company accepted E-scribed controlled substance compounds." (Id.).

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 and Medicare." (Id. at ¶ 76).

Also, Stepe alleges Defendants "do not train their sales representatives regarding proper and improper use, or

potential contra-indications or warnings." (Id. at ¶ 92). "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, and appear on promotional materials rather than in a package insert." (Id. at ¶¶ 93-95). "Patients have complained to RS Compounding about adverse reactions to compounds . . . due to, at least in part, Defendants' failure to inform physicians or their patients about the proper use of the compounds." (Id. at ¶ 93).

Stepe contends that "Defendants' failure to sufficiently inform physicians of the proper uses of RS Compounding's medications in some instances would result in the Company's processing of claims for medications that would initially be rejected due to a High Dose Alert." (Id. at ¶ 98). "However, Defendants would manually override the alert indicating they verified the dosage with the physician, despite not having actually discussed same with the physician. Defendants would rely simply on the physician's signature on the pre-printed script pad." (Id.). "As a result of this scheme, physicians would unknowingly order a greater number or dosage of medications than what should have been ordered, resulting in

unnecessary claims being submitted to TRICARE and Medicare for reimbursement." (Id.).

Stepe alleges "[t]his increase in unnecessary claims being submitted for reimbursement was exacerbated by the automatic refills on the pre-printed script pads that those physicians relied on in prescribing RS Compounding's medications to their patients." (Id. at ¶ 99). "Defendants were aware that physicians were mistaken as to the proper amount of certain medications they could order but failed to make the correction." (Id. at ¶ 101). "Instead, Defendants processed the claims and automatic refills, and disregarded their obligation to return ill-gotten gains to the Government after being reimbursed by Government payors for unnecessary medications." (Id.).

According to Stepe, who identifies six physicians with whom she frequently visited, "the physicians she worked with and sold compounds to often had numerous TRICARE and/or Medicare patients." (Id. at ¶¶ 60, 85). Stepe "knows that RS Compounding's central billing department in Tampa, Florida, submitted claims in connection with compounds that [Stepe] sold to her physicians and which the Government reimbursed [RS Compounding] for because, otherwise, she would not have received commission checks." (Id. at ¶ 86). She alleges that

Gobea and Caddick, "as the two managing officers of RS Compounding with oversight of virtually every activity at the Company, including sales policies, knowingly caused RS Compounding representatives to present the above false claims to Government health care programs," as well to "make false records and statements material to such claims by devising the fraudulent practices and instructing their employees to put them into effect." (Id. at ¶ 103).

Stepe concludes: "Under the FCA, 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 ¶ 104). "If government-funded programs had been aware that Defendants' drugs were prescribed as a result of the conduct alleged in this Complaint, they would not have paid the claims submitted as a result of Defendants' wrongdoing." (Id.).

B. Procedural History

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 Gobea. (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, Gobea, Caddick, and John Doe Corporations 1-10. (Doc. # 39). RS Compounding, Gobea, and Caddick filed motions to dismiss. (Doc. ## 48, 70). The Court granted those motions and dismissed the Amended Complaint with leave to amend on November 8, 2017. (Doc. # 76).

Stepe then filed her Second Amended Complaint on December 7, 2017, alleging FCA violations against RS Compounding, Gobea, Caddick, and John Doe Corporations 1-10. (Doc. # 91). Now, RS Compounding, Gobea, and Caddick have moved to dismiss the Second Amended Complaint, arguing that Stepe's allegations still fail to satisfy Rule 9(b). (Doc. ## 93, 97). Stepe has responded, (Doc. # 101), and 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).

But, the Supreme Court explains that:

> 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

Defendants argue that Stepe has not stated claims under any subsection of the FCA 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. ## 93, 97). The Court will address each count in turn.

And, as a preliminary matter, the Court reminds the parties that Stepe's allegations regarding the disparate pricing of medications are superseded because the Government has intervened as to those allegations. (Doc. # 76 at 12). Thus, "in determining whether Stepe's [Second] Amended Complaint satisfies the Rule 9(b) and 12(b)(6) standards, the Court will not consider the alleged disparate pricing scheme." (Id. at 13).

A. 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. # 91 at ¶ 106). “As a result, the Government has suffered damages in the form of millions of dollars in unearned TRICARE and Medicare payments made to Defendants.” (Id. at ¶ 107).

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).

As the Court explained in its previous Order, “[p]roviding 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 the Second Amended Complaint fails to plead fraud with particularity as to any false claims being submitted to the Government. (Doc. # 93 at 7-8; Doc. # 97 at 4). Again, they are correct that Stepe cannot rely on any disparate pricing allegations to support her claims because those allegations have been superseded. (Doc. # 97 at 8). Thus, Stepe's reference to the Government's analysis of false claims submitted to TRICARE, (Doc. # 91 at ¶ 102), is unavailing – the Government has only intervened as to the disparate pricing allegations and Stepe has not alleged that the Government's calculations of false claims relate to anything besides the alleged disparate pricing.

All of Stepe's allegations of false claims being submitted and her factual support for that contention are overly vague, such as alleging she knows false claims were submitted to the Government because she received commission checks from RS Compounding. (Id. at ¶ 86). Stepe does not allege a single specific false claim, let alone a single false claim unrelated to the superseded disparate pricing allegations. She states that she received complaints from physicians about the extra refills and the high costs of those refills. (Id. at ¶ 64). But she does not identify the physician who informed her of such complaints, nor the complaining patient's initials.

Nor does Stepe identify any specific claims in which the dosage prescribed for a TRICARE or Medicare patient was unnecessarily high or the number of refills medically unnecessary. See Mastej, 591 F. App'x at 708 (noting that, in cases involving reimbursement "for medical services that were unnecessary" or "for improper prescriptions," "representative claims with particularized medical and billing content matter more, because the falsity of the claim depends largely on the details contained within the claim form — such as the type of medical services rendered, the billing code or codes used on the claim form, and what amount was charged on the claim form

for the medical services"); see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997)(affirming dismissal of claim based on medically unnecessary services where the relator "did not identify any specific physicians who referred patients for medically unnecessary services or any specific claims for medically unnecessary services that were submitted by defendants").

Similarly, Stepe identifies six physicians by name to whom she sold compounds and states that each physician "treated a large number of TRICARE and Medicare patients." (Doc. # 91 at ¶ 60). But Stepe never identifies claims submitted based on these physicians' prescriptions for Medicare or TRICARE patients. The Court will not make the assumption that false claims were submitted to TRICARE or Medicare merely because certain physicians had a high number of TRICARE or Medicare patients. See Patel, 2017 WL 4310263, at *6 ("Because Dr. Eligetti and Dr. Elchahal purchased Myoview for patients, and because a substantial number of their patients were Medicare or Medicaid beneficiaries, Patel argues that false claims were necessarily presented for payment to Medicare and Medicaid. These allegations fall well short of alleging 'exact billing data.'"). That the

Government found that Defendants submitted claims for prescriptions written by these physicians is of no import. The Government's analysis relates to claims that are false because the medications were disparately priced. There is no particular allegations that the claims regarding the identified physicians related to any other scheme or theory of falsity pled by Stepe.

And Stepe does not provide other sufficient indicia of reliability that false claims were actually submitted to the Government. "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)." (Doc. # 76 at 17)(citing Hopper, 588 F.3d at 1325; Corsello v. Lincare, Inc., 428 F.3d 1008, 1014 (11th Cir. 2005)). Stepe worked as a sales representative for RS Compounding, rather than as a billing department employee. The Second Amended Complaint still does not allege that Stepe 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."); see also United States ex rel. Walker v. R & F Props. of Lake City, Inc., 433 F.3d 1349, 1360 (11th Cir. 2005)(holding that Relator Walker, a nurse practitioner, had alleged sufficient firsthand knowledge of her employer's billing practices because she was instructed to bill, and had billed, her services under improper billing codes).

For example, Stepe's new allegations include that Defendants manually overrided High Dose Alerts when processing claims, thereby falsely "indicating they verified the dosage with the physician." (Doc. # 91 at ¶ 98). But this allegation still falls short because Stepe, a sales representative, never explains the basis for her knowledge of this practice. Did she learn of it from a billing employee? Nor does Stepe provide a sample false claim in which Defendants falsely stated they had verified dosage with a physician. Without more, this allegation does not provide sufficient indicia of reliability.

As the Court explained in its previous Order, "[c]ourts 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.'" (Doc. # 76 at 18)(quoting Corsello, 428 F.3d at 1013). Because the Second Amended Complaint fails to satisfy Rule 9(b)

regarding the allegation that Defendants submitted false claims to the Government, Count I is dismissed.

B. 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. # 91 at ¶ 109). 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 and Medicare payments made to Defendants." (Id. at ¶ 110).

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 that Stepe fails to identify the false records and statements made or caused to be made by Defendants that relate to the non-superseded allegations. (Doc. # 93 at 8; Doc. # 97 at 10). The Court agrees. The Court previously warned Stepe that it was important to specifically identify the false statements and certifications upon which each claim relies. (Doc. # 76 at 21-22). Stepe has not done so. Thus, the Court and Defendants are left to sift through the copious factual allegations to identify what statements and certifications Stepe alleges were false. The Court must guess which false statements mentioned in the factual allegations form the basis of Count II versus Count III, or if the same statements are relied upon in both.

To the extent the Court can divine what false records or statements Stepe intended to reference in this count, the Court finds those statements insufficiently pled under Rule 9(b). Stepe still has not sufficiently pled how the pre-

printed script pads specifying a high refill number constitute a false statement, given that physicians are free to mark out the default refill number and fill in another. Stepe also has not explained how sales representatives' "coaching" physicians to prescribe more expensive medications is false, given that physicians possess independent medical knowledge and choice of which prescriptions to issue. And, although she has elaborated on the alleged consequences of the sales representatives' poor training and drug warnings, Stepe has not alleged an actual false statement or record made by Defendants.

The closest Stepe comes to alleging a false statement is her allegation that Defendants would manually override High Dose Alerts when processing claims, thereby falsely "indicating they verified the dosage with the physician" without actually doing so. (Doc. # 91 at ¶ 98). But, again, no specific examples of when Defendants falsely overrode a High Dose Alert are pled. Nor does Stepe, a sales representative, allege that she participated in or witnessed the overriding of High Dose Alerts. Thus, this allegation of false statements does not meet the Rule 9(b) particularity standard.

As no false records or statements to support this claim have been pled with particularity, the Court need not also address whether the vaguely identified false statements were material to a false claim. Count II is dismissed.

C. 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. # 91 at ¶ 112). "As a result, the Government has suffered damages in the form of millions of dollars in unearned TRICARE and Medicare payments made to Defendants." (Id. at ¶ 113).

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 this claim should be dismissed because Stepe "failed to remedy any of the[] multiple defects in Count

III identified by the Court" in its previous Order. (Doc. # 97 at 10). In the previous Order, the Court explained the deficiencies with Stepe's reverse false claims count: "No false certifications related to the non-superseded allegations . . . are identified in the Amended Complaint," "the Court is unsure what obligation Defendants had to pay the Government, as Stepe also fails to identify this," and "the Court cannot determine whether the false certification was 'material' to the obligation." (Doc. # 76 at 24-26).

True, the Second Amended Complaint does more clearly identify the alleged obligation: Defendants' "obligation to return ill-gotten gains to the Government after being reimbursed by Government payors for unnecessary medications." (Doc. # 91 at ¶ 101). As the Court explained in its Order denying dismissal of the Government's Amended Complaint in Partial Intervention, the duty to remit known overpayments is a clear obligation under the FCA. (Doc. # 90 at 25-26).

Nevertheless, as Caddick correctly notes, Stepe still "has not identified the false certifications that were made or caused to be made by [D]efendants" or how the certifications "were indeed material to the identified obligation." (Doc. # 93 at 9). The new allegations in the Second Amended Complaint do not clarify the existence of a

false certification. The allegation regarding the overridden High Dose Alerts lacks particularity because Stepe does not provide examples of incidents in which a High Dose Alert was issued and overridden or allege that she participated in or witnessed the overriding of such alerts.

Regarding the refill allegations, it remains unclear how pre-printing a refill number on a script pad, which physicians were free to mark out, qualifies as false. Although Stepe alleges Defendants "were aware" physicians were mistaken about the refill number, she fails to elaborate on how that was known besides referencing occasional vague complaints from patients about excessive refills. Even though she alleges unnamed physicians informed her of these complaints, Stepe never alleges the physicians acknowledged they had mistakenly ordered a high number of refills because of the pre-printed script pads.

Furthermore, as the Court explained in its previous Order, the false certification regarding disparate pricing cannot form the basis of this claim because the disparate pricing allegations have been superseded.

Because no false statements or certifications to support this claim have been pled with particularity, Count III fails to satisfy Rule 9(b) and is dismissed.

D. 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 perform[ing] one or more acts to effect payment of false or fraudulent claims." (Doc. # 91 at ¶ 115). Defendants argue the Second Amended Complaint fails to allege the existence of a conspiracy with the particularity required under Rule 9(b). (Doc. # 93 at 10; Doc. # 97 at 11).

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.

The Court finds that Stepe has not pled with particularity that a conspiracy existed between Defendants RS Compounding, Gobea, and Caddick. Stepe emphasizes her new allegation that Gobea and Caddick met every Monday and Wednesday morning to discuss RS Compounding's operations. (Doc. # 91 at ¶ 37). This falls short of pleading an agreement between Gobea and Caddick to engage in fraud. Similarly, the allegation that Gobea and Caddick "as the two managing officers of RS Compounding" had "oversight of virtually every activity at the Company" is insufficient to allege Caddick and Gobea were aware of and agreed to perpetrate the alleged fraud on the Government. (Id. at ¶ 103).

The allegations regarding Gobea and Caddick's crafting the "1, 2, 3" marketing strategy, directing that script pads be pre-printed with high refill numbers, and their "urging" sales representatives to promote RS Compounding's products despite insufficient training and warnings are conclusory. (Id. at ¶¶ 63, 65, 96). Despite the Court's prior warning (Doc. # 76 at 31), the Second Amended Complaint continues to

lump Caddick and Gobea together — i.e., "Gobea and/or [] Caddick created RS Compounding's marketing scheme." (Doc. # 91 at ¶ 8). Nor does the Second Amended Complaint contain specific allegations of an overt act taken by either Caddick or Gobea. The allegation that comes closest to supporting Stepe's conspiracy claim is that Stepe was informed the disparate prices were set "at the top of the Company," meaning by Caddick and Gobea. (Id. at ¶ 80). But, again, this goes to the superseded allegations regarding disparate pricing, which cannot support Stepe's non-superseded claims.

In short, the Second Amended Complaint's allegations 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).

IV. Conclusion

Stepe's Second Amended Complaint fails to state a claim under the FCA. In her response, Stepe requests leave to file a third amended complaint. (Doc. # 101 at 29).

First, the Court notes that such request is procedurally improper. See Rosenberg v. Gould, 554 F.3d 962, 967 (11th Cir. 2009)("Where a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly. [Plaintiffs] also failed to comply with Federal Rule of Civil Procedure 7(b) when they failed to attach a copy of their proposed amendment or to describe the substance of their proposed amendment." (citations omitted)). Additionally, in its previous Order dismissing Stepe's Amended Complaint with leave to amend, the Court explained: "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." (Doc. # 76 at 32-33)(quoting Patel, 2017 WL 4310263, at *8).

Because Stepe already had the benefit of a detailed Order addressing the substantive issues with her claims and was warned that she would likely receive only one opportunity to

amend, the Court determines that justice does not require a further opportunity to amend. See Cooper v. Blue Cross & Blue Shield of Fla., Inc., 19 F.3d 562, 568–69 (11th Cir. 1994)(stating that relator "is entitled to one chance to amend the complaint and bring it into compliance with [Rule 9(b)]"). Stepe's Second Amended Complaint is dismissed with prejudice and Caddick is terminated as a party to this action.

The case remains pending as to the United States' Amended Complaint in Partial Intervention, which asserts claims against RS Compounding and Gobea.

Accordingly, it is now

ORDERED, **ADJUDGED**, and **DECREED**:

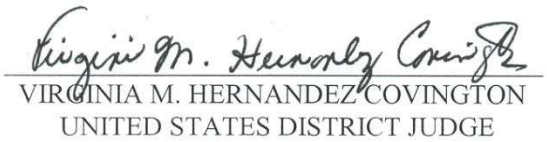
(1) Defendants RS Compounding LLC and Renier Gobea's Motion to Dismiss Relator's Second Amended Complaint (Doc. # 97) is **GRANTED**.

(2) Defendant Stephen Caddick's Motion to Dismiss Relator's Second Amended Complaint (Doc. # 93) is **GRANTED**.

(3) Plaintiff relator McKenzie Stepe's Second Amended Complaint (Doc. # 91) is **DISMISSED WITH PREJUDICE.**

(4) The Clerk is directed to terminate Caddick as a party to this action.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 10th day of January, 2018.



VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE