UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 15-CV-62617-BLOOM/VALLE

UNITED STATES OF AMERICA
ex rel. MARSIELA CARMEN MEDRANO
and ADA LOPEZ,

Plaintiffs,

DIABETIC CARE RX, LLC, d/b/a
PATIENT CARE AMERICA;
RIORDAN, LEWIS & HAYDEN, INC.;
PATRICK SMITH; and
MATTHEW SMITH

Defendants.

_____/

REPORT AND RECOMMENDATION TO DISTRICT JUDGE

THIS MATTER is before the Court on Defendant Diabetic Care RX, LLC's, d/b/a Patient Care America ("PCA"), Motion to Dismiss the United States' Complaint in Intervention (ECF No. 51), Defendant Riordan, Lewis & Haden, Inc.'s ("RLH") Motion to Dismiss the United States' Complaint in Intervention (ECF No. 52), Defendant Matthew Smith's Motion to Dismiss the United States' Complaint in Intervention (ECF No. 53), and Defendant Patrick Smith's Motion to Dismiss the United States' Complaint in Intervention (ECF No. 54) (collectively, the "Motions"). United States District Judge Beth Bloom referred the Motions to the undersigned for a Report and Recommendation. (ECF No. 82). Accordingly, having reviewed the Motions (ECF Nos. 51, 52, 53 and 54), the Government's Omnibus Response (ECF No. 60), Defendants' Replies (ECF Nos. 61, 62, 63, and 64), the Government's Notice of Supplemental Authority (ECF No. 90), RLH's Response to the Notice of Supplemental Authority (ECF No. 91), and being otherwise duly advised in the matter, the undersigned

recommends that the Motions be **GRANTED IN PART AND DENIED IN PART** for the reasons stated herein.

I. SUMMARY

On December 14, 2015, Relators brought this action against Defendants, alleging violations of the False Claims Act ("FCA"). (ECF No. 1). On March 4, 2016, Relators filed an Amended Complaint, which was dismissed by the District Court for failure to effect service. (ECF Nos. 9, 10, and 11). Thereafter, the Government moved to extend the deadline to file an Intervening Complaint, which the Court granted.[1] (ECF Nos. 12, 13, and 14). The Court granted several additional extensions for the Government to file an Intervening Complaint. (ECF Nos. 17, 20, 23, 26, and 29). On December 20, 2017, the Government filed its Corrected Notice of Election to Intervene in Part and Decline to Intervene in Part. (ECF No. 32). On February 16, 2018, the Government filed the Intervenor Complaint ("Complaint"), which alleges a claim for violation of the FCA (Count I) and common law claims for payment by mistake (Count II) and unjust enrichment (Count III). (ECF No. 36). Each of the Defendants moved to dismiss the Complaint, and the Motions are ripe for adjudication.

II. FACTUAL AND LEGAL BACKGROUND

A. The Parties

Defendant PCA is a compounding pharmacy founded in 2006 to provide intravenous nutritional therapy to end-stage renal disease patients receiving dialysis.[2] (ECF. No. 36 ¶ 37). In

[1] The Court administratively closed the case during the Government's investigation. (ECF No. 14).

[2] Compounding is the practice in which a licensed pharmacist or physician creates a medication with specific ingredients tailored to meet the needs of an individual patient. (ECF No. 36 ¶ 21).

2012, Defendant RLH, a private equity firm, made a controlling investment in PCA.[3] *Id.* ¶¶ 6, 38. RLH planned to increase PCA's value and sell it for a profit in five years. *Id.* ¶ 40. To this end, RLH initiated PCA's entry into the business of non-sterile compounding of topical creams. *Id.* ¶ 41. RLH contemplated from the outset that PCA would bill the federal government for compounded creams and anticipated an insurance reimbursement of between $1,000 to $8,000 per prescription. *Id*. ¶¶ 42-43. RLH estimated a profit margin of nearly 90%. *Id.* ¶ 42. RLH hired Defendant Patrick Smith as the CEO of PCA to launch the new topical compounding business. *Id.* ¶¶ 46-49. Patrick Smith then hired Matthew Smith, a licensed pharmacist, to lead the topical compounding business.[4] *Id.* ¶ 52.

B. The TRICARE Program

TRICARE is a federal health care program that provides health insurance for active duty military personnel, retirees, and their families. *Id.* ¶¶ 1, 19. TRICARE contracts with Express Scripts, Inc. ("ESI") to administer prescription drug coverage for the TRICARE program, including the processing and payment of claims for reimbursement of compounded prescription drugs. *Id.* ¶ 20. From September 1, 2014 to May 1, 2015, TRICARE reimbursed pharmacies for all of the ingredients in a compounded drug, paying the average wholesale price of each ingredient minus a negotiated discount.[5] *Id.* ¶ 22. Beneficiaries enrolled in the TRICARE program were required to pay the cost of the copayment on their compounded prescriptions. *Id.* ¶ 24. Moreover, to receive reimbursement from TRICARE, a pharmacy, such as PCA, had to

[3] RLH made its investment in PCA through a private equity fund, RLH Investors III, LP ("RLH III"). (ECF No. 36 ¶ 38). RLH was the manager of RLH III and controlled and directed the conduct of PCA on behalf of the RLH III's investors. *Id.* ¶¶ 6, 38.

[4] The Complaint does not allege any familial relationship between Patrick Smith and Matthew Smith.

[5] After May 1, 2015, TRICARE paid significantly fewer claims due to a new screening process that more closely evaluated individual ingredients within compounded prescriptions. *Id.* ¶ 23.

enter into a Provider Agreement with ESI. *Id.* ¶ 27.

PCA executed a Provider Agreement with ESI on August 28, 2012. *Id.* ¶ 29. Under the Provider Agreement, PCA agreed to be bound by fraud, waste, and abuse laws; to only submit claims that PCA had determined were based upon valid prescriptions issued in accordance with applicable laws; and to collect copayments from patients and not waive or discount copayments unless authorized by ESI. *Id.* Additionally, PCA agreed to comply with ESI's Provider Manual. *Id.* ¶ 31. The Provider Manual further required PCA to ensure that patients were charged the correct copayment and required PCA to comply with all federal laws, including the Anti-Kickback Statute ("AKS"). *Id.* ¶¶ 32-33.

C. Applicable Statutes

1. The False Claims Act

The FCA was enacted to combat fraud against the federal government. *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996 (2016) (citations omitted). The FCA imposes liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States. 31 U.S.C. § 3729(a)(1)(A). Under Section 3729(a)(1)(A), liability exists either where the defendant directly submits false claims, or where the defendant causes another to submit the false claim. *Id.* The FCA defines "knowingly" as "actual knowledge," "reckless disregard," or "deliberate ignorance" of truth or falsity, and expressly "require[s] no proof of specific intent to defraud." *Id.* § 3729(b)(1). The term "claim" under the FCA means "any request or demand, whether under a contract or otherwise, for money or property" from the United States. *Id.* § 3729(b)(2). A person who violates the FCA is liable to the United States for civil penalties and for three times the amount of the Government's damages. *Id.* § 3729(a)(1).

2. The Anti-Kickback Statute

The AKS makes it illegal for an individual or entity to knowingly and willfully:

> [O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . .

42 U.S.C. § 1320a-7b(b)(2). A claim for reimbursement from a federal health care program for items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA. *See* 42 U.S.C. § 1320a-7b(g).

To prove an underlying violation of the AKS, the Government must show that the defendant acted "knowingly and willfully." *Id.* § 1320a-7b(b)(2). To act knowingly, a defendant must have acted "voluntarily and intentionally and not because of a mistake or by accident." *United States ex rel. Williams v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-130, 2014 WL 2866250, at *12 (M.D. Ga. June 24, 2014). Willfully means that an "act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law." *Id.* (citing *United States v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998)). The Government, however, does not need to show that the defendant acted with specific intent to violate the AKS. 42 U.S.C. § 1320a-7b(h). Rather, the Government need only show that "the defendant acted with the intent to do something the law forbids—even if he is not aware of the specific law his conduct may violate." *Williams*, 2014 WL 2866250, at *13. To plead FCA liability based on an AKS violation, the Government must

allege that defendants "'made kickbacks with the intent of inducing referrals, and [d]efendants knowingly paid remuneration in exchange for referrals' . . . ." *United States ex rel. Schaengold v. Mem'l Health, Inc.*, No. 4:11-CV-58, 2014 WL 7272598, at *13 (S.D. Ga. Dec. 18, 2014).

3. Florida's Prescriber-Patient Laws

Under Florida law, pharmacies may dispense prescription drugs only on the basis of a valid prescription. Fla. Stat. § 465.023(1)(h). In particular, pharmacies are prohibited from dispensing prescription drugs "when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed." *Id*. Pharmacies violating this prohibition may have their licenses revoked or suspended and are subject to fines, probation, or other discipline by the state board of pharmacy. *Id.* § 465.023(1).

D. The Alleged Schemes

The Complaint alleges that between September 1, 2014 and April 29, 2015, Defendants knowingly presented, and/or caused to be presented, false or fraudulent claims for compounded drugs to TRICARE. (ECF No. 36 ¶ 1). According to the Complaint, the claims were fraudulent because: (i) the claims were tainted by kickbacks paid by PCA to marketers, in violation of the AKS; (ii) PCA and a marketing company improperly paid patients' copayments to induce the patients to accept compounded medications, in violation of the AKS; and (iii) the claims did not arise from a valid prescriber-patient relationship, in violation of Florida law. *Id*. ¶¶ 1-2, 35. Each alleged scheme is discussed in greater detail below.

1. Marketer Kickback Scheme

The Complaint alleges that PCA hired several outside marketing companies to generate

patient referrals for topical compounds. *Id.* ¶¶ 53-54, 63. Each marketing company was hired as an independent contractor pursuant to a written agreement. *Id.* ¶¶ 54-57, 63-66. Specifically, PCA executed agreements with MDataRX and TeleMedTech in July 2014, and with MG Ten in September 2014 (collectively, the "Marketers"). *Id.* ¶¶ 55-57. These marketing agreements required the Marketers to refer patients for compounded drug prescriptions to PCA, or arrange for or recommend patients to order compounded drugs from PCA. *Id.* ¶¶ 58-60. Further, the agreements specified that the Marketers' would receive 50% of PCA's profit from their prescription referrals. *Id.* ¶¶ 61-62.

Matthew Smith negotiated the marketing agreements on behalf of PCA. *Id.* ¶ 68. Prior to executing the marketing agreements, an attorney for PCA reviewed the agreements and advised Matthew Smith and Patrick Smith that: (i) PCA should not pay doctors; (ii) independent marketers should not pay third-party referral sources; and (iii) PCA should not bill government health care programs. *Id.* ¶ 69. The attorney also discussed the AKS with Matthew Smith and Patrick Smith. *Id.* Additionally, PCA's compliance training (dated January 2014) advised PCA staff that the AKS prohibits paying remuneration to induce a referral for any item or service reimbursed by a federal health care program. *Id.* ¶ 136.

PCA's revenue from its topical compounding business increased rapidly, largely due to the volume of prescriptions generated by the Marketers and paid by TRICARE. *See id.* ¶¶ 71-75. In fact, at a board meeting attended by Patrick Smith and Matthew Smith on April 28, 2015, PCA's CFO advised RLH that PCA's topical compounding revenue from TRICARE had grown from approximately 75% at the beginning of 2015 to more than 98% by March 2015. *Id.* ¶ 75. Further, at the same board meeting, Matthew Smith reported that PCA earned more than $69 million in total topical compounding revenue in 2015, 90% of which was based on

referrals from the Marketers. *Id.* ¶ 75.

In accordance with the marketing agreements, PCA paid the Marketers a percentage of the profit on each prescription referred to PCA. *Id.* ¶ 76. Accordingly, from November 2014 through April 2015, PCA paid almost $7.5 million to MDataRx, $6.7 million to TeleMedTech, and $19.5 million to MG Ten. *Id.* ¶ 77. Patrick Smith and Matthew Smith tracked PCA's payments to the Marketers and confirmed that PCA paid all commissions owed to the Marketers. *Id.* ¶ 80. Each month, Patrick Smith forwarded to RLH PCA's monthly financial statements, which included the prior month's topical compounding revenue and the commission payments to the Marketers. *Id.* ¶ 81. The notes to the financial statements characterized the commission payments as "an agreed cost based on compounding sales." *Id.* ¶ 82. Moreover, RLH periodically provided cash advances to PCA to cover the commission payments to the Marketers while PCA awaited reimbursements for the compounded prescriptions from TRICARE.[6] *Id.* ¶ 83. The only work the Marketers performed was referring patients to PCA for compounded drug prescriptions. *Id.* ¶ 85.

2. Copayment Waiver Scheme

Next, the Complaint alleges that PCA and TeleMedTech paid patients' prescription copayments (regardless of financial need) to induce the patients to order compounded medications to be filled by PCA. *Id.* ¶ 1, 98-112. According to the Complaint, Matthew Smith and Steve Miller ("Miller") of TeleMedTech directed a scheme in which PCA and TeleMedTech split the cost of prescription copayments and disguised those payments as being made by a sham charitable organization called PFARN. *Id.* ¶ 98-99. PFARN's sole purpose was to serve as a vehicle for TeleMedTech and PCA to pay the copayments. *Id.* ¶ 102. On August 4, 2014, Miller

[6] For example, on December 24, 2014, Patrick Smith asked RLH for cash to fund the marketing commissions, and RLH provided PCA $2 million on January 29, 2015. *Id.* ¶ 84.

advised Matthew Smith that TeleMedTech would fund the copayments for all patients that it referred to PCA because TeleMedTech "will not lose a patient over a copay." *Id.* ¶ 101. Further, in an August 21, 2014 email to Matthew Smith, Miller explained "[PFARN] will be sending 100% of the payment to PCA that is due for each client on behalf of each client so the pharmacy can ACT complaint [sic] – but since they only receive 50% of the profit [on the prescription], they only will pay 50% of the expense – the pharmacy covers the other 50% from their profit (thus equaling 100%) – this keeps things even and fair." *Id.* ¶ 103.

To execute this scheme, Patrick Smith and Matthew Smith signed monthly PCA checks to PFARN to reimburse PFARN for 50% of the cost of the copayments, which were then mailed to TeleMedTech. *Id.* ¶¶ 104, 107. Thereafter, PFARN sent PCA a cashier's check for 100% of the copayment amount. *Id.* ¶ 105. When questioned by PCA staff about PFARN's payment of prescription copayments, Matthew Smith advised that PFARN was a verified non-profit entity and that its payment of copayments was not prohibited. *Id.* ¶ 109. Pursuant to this scheme, PCA did not collect copayments for 3,477 compounded prescriptions, for which TRICARE paid more than $16 million. *Id.* ¶ 111.

3. No Prescriber-Patient Relationship

Lastly, the Complaint alleges that Defendants violated the FCA by submitting claims to TRICARE for prescriptions that did not result from a valid prescriber-patient relationship, but which were specifically formulated by Defendants and the Marketers to use compounds that would maximize PCA's reimbursement from TRICARE on each prescription. *Id.* ¶¶ 1, 113. Specifically, in August 2014, PCA staff was advised that if the difference between the TRICARE reimbursement and the cost of an ingredient was less than 50%, staff must discuss the prescription with Matthew Smith prior to dispensing it and submitting a claim for

reimbursement. *Id.* ¶ 114. Additionally, in response to the Marketers' requests, PCA submitted "test claims" to TRICARE to determine the reimbursement rate for compounded formulas that the Marketers were considering submitting to PCA. *Id.* ¶ 115. In January 2015, for example, Matthew Smith inquired of PCA staff whether they had submitted "test claims" to TRICARE for three formulas requested by MDatatRx. *Id.* ¶ 116. PCA staff advised that one of the ingredients was not profitable and they were evaluating alternatives that would yield a higher reimbursement from TRICARE. *Id.*

Once PCA determined the most profitable prescription formulas, the Marketers arranged to order those compounded medications for hundreds of patients. *Id.* ¶ 118. For example, from September 1, 2014 through April 29, 2015, a compounded scar cream had the highest reimbursement rate from TRICARE. *Id.* During this timeframe, the scar cream was prescribed to 454 patients, and TRICARE reimbursed an average of $16,880 per claim. *Id.* As a result of PCA's efforts to maximize its profits, the average reimbursement per prescription from TRICARE increased over time. *Id.* ¶ 119. In an October 2014 board meeting, Matthew Smith advised RLH and Patrick Smith that the average reimbursement per prescription increased from $803 in September 2014 to $1,672 in October 2014. *Id.* ¶ 120. Similarly, in January 2015, Matthew Smith informed RLH and Patrick Smith that the average reimbursement per prescription had increased from $1,672 in October 2014 to $2,972 in November 2014, and again from $4,371 in December 2014 to $6,695 in January 2015. *Id.* ¶ 121.

Between September 2014 and April 2015, PCA received multiple calls from individuals complaining that they had not ordered the scar cream or spoken to the doctor who purportedly prescribed it. *Id.* ¶ 123. Specifically, on September 26, 2014, December 26, 2014, February 20, 2015, and February 27, 2015, PCA received calls from individuals advising that they had not

authorized the prescriptions ordered on their behalf and/or spoken to the doctor who prescribed them.[7] *Id.* ¶¶ 124-28. In response, Matthew Smith instructed PCA staff to credit all charges to a patient if necessary to prevent the patient from complaining to his or her health insurance provider. *Id.* ¶ 131.

III. LEGAL STANDARD FOR A MOTION TO DISMISS

To withstand a Rule 12(b)(6) motion to dismiss, a plaintiff must plead sufficient facts to state a claim that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A court's review of the sufficiency of the Complaint is limited to the allegations presented in the Complaint. *See GSW, Inc. v. Long Cty., Ga.*, 999 F.2d 1508, 1510 (11th Cir. 1993). Moreover, all factual allegations in the Complaint are accepted as true and all reasonable inferences are drawn in the plaintiff's favor. *Speaker v. U.S. Dep't of Health & Human Servs. Ctrs. for Disease Control & Prevention*, 623 F.3d 1371, 1379 (11th Cir. 2010) (citations omitted); *see also Roberts v. Fla. Power & Light Co.*, 146 F.3d 1305, 1307 (11th Cir. 1998) (citations omitted). Nevertheless, while a plaintiff need not provide "detailed factual allegations," the allegations must consist of more than "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555 (internal citations and quotations omitted). Conclusory allegations will not prevent dismissal. *United States ex rel. Keeler v. Eisai, Inc.*, 568 F. App'x 783, 792-93 (11th Cir. 2014) (internal citation omitted).

Claims brought under the FCA must also satisfy the heightened pleading standard for fraud claims under Federal Rule of Civil Procedure 9(b). *United States ex rel. Clausen v. Lab.*

[7] PCA staff advised Matthew Smith of the complaints received on September 26, 2014 and December 26, 2014. *Id.* ¶¶ 124-25. On February 20, 2015, Matthew Smith advised Patrick Smith that a patient complained that neither the patient nor his doctor had authorized a prescription that was sent to the patient, and the patient's doctor had instructed the patient not to use the prescription. *Id.* ¶ 126.

Corp. of Am., Inc., 290 F.3d 1301, 1308-09 (11th Cir. 2002). Thus, an FCA claim must "state with particularity the circumstances constituting fraud or mistake." *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 703 (11th Cir. 2014) (quoting Fed. R. Civ. P. 9(b)). An FCA complaint "satisfies Rule 9(b) if it sets forth facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Id.* (quoting *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009)). "The purpose of Rule 9(b) is to 'alert[ ] defendants to the precise misconduct with which they are charged and protect[ ] defendants against spurious charges . . . .'" *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012) (quoting *Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001)).

Moreover, the submission of a claim to the United States for payment is "the *sine qua non*" of an FCA violation. *Clausen*, 290 F.3d at 1311. As such, the plaintiff must plead the *submission* of a false claim with particularity. *Mastej*, 591 F. App'x at 703 (emphasis added) (citing *Matheny*, 671 F.3d at 1225). "To do so, a [plaintiff] must identify the particular document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result." *Id.* at 703-04. (citations omitted).

Lastly, Rule 9(b) "does not permit a False Claims Act 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." *Clausen*, 290 F.3d at 1311. Instead, "some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government." *Id.*; *see also Corsello v. Lincare, Inc.*, 428 F.3d 1008,

1014 (11th Cir. 2005) (upholding the dismissal of a Complaint where "[plaintiff] provided the 'who,' 'what,' 'where,' 'when,' and 'how' of improper practices, but [] failed to allege the 'who,' what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government").

IV. LEGAL ANALYSIS

Defendants advance several arguments in support of their Motions. As to the FCA claim, PCA argues that this claim should be dismissed because it fails to: (i) comply with Rule 9(b)'s heightened pleading standard[8] (ECF No. 51 at 5-8); (ii) clearly allege whether the claims submitted were factually or legally false[9] (*Id.* at 8-9); (iii) state a viable claim under the express certification theory because the Complaint fails to allege any express false certification at the time the Provider Agreement was signed (*Id.* at 9-12); and (iv) state a viable claim under the implied certification theory because it does not sufficiently allege materiality (*Id.* at 12-15).

For its part, RLH argues that the FCA claim fails to adequately allege knowledge and causation. (ECF No. 52 at 6-12). In addition, Matthew Smith argues the FCA claim fails to: (i) adequately allege he caused false claims to be presented to TRICARE (ECF No. 53 at 7-12); (ii) properly set forth representative false claims (*Id.*); (iii) allege that his conduct was material to TRICARE's decision to reimburse PCA for claims (*Id.* at 12-16); and (iv) allege that recipients of prescription copayment waivers were not lawfully entitled to those waivers (*Id.* at 16-19). Lastly, Patrick Smith argues the FCA claim fails to adequately allege: (i) that he knew PCA was paying copayments without financial verification (ECF No. 54 at 8-11); (ii) a claim against him based on the lack of a prescriber-patient relationship (*Id.* at 14-17); (iii) that he made any material misrepresentations to TRICARE (*Id.* at 17-18); and (iv) that he caused the presentment of any false claims (*Id.* at 18-20).

[8] RLH joins this argument. (ECF No. 52 at 6)

[9] RLH and Patrick Smith join this argument. (ECF Nos. 52 at 6 and 54 at 17, n.4)

As to the claims for payment by mistake (Count II) and unjust enrichment (Count III), PCA argues for dismissal on the grounds that the Complaint fails to state whether these claims are asserted under federal or state law, and fail to state a cause of action. (ECF No. 51 at 15-16). RLH adopts PCA's arguments. (ECF No. 52 at 12). Matthew Smith and Patrick Smith do not address these counts. *See* (ECF Nos. 53, and 54). Finally, each Defendant argues the Complaint should be dismissed with prejudice. (ECF Nos. 51 at 17; 52 at 12; 53 at 18; and 54 at 20). The undersigned will address these arguments below.

A. The Complaint Makes Clear that the Government is Alleging the Submission of Legally False Claims to TRICARE

The Complaint alleges that the Defendants violated the FCA by submitting false claims to TRICARE. *See generally* (ECF No. 36). "There are two types of false or fraudulent claims that may be alleged by plaintiffs pursuing presentment . . . claims under the False Claims Act: factually false claims and legally false claims." *United States ex rel Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1344 (S.D. Fla. 2015), *aff'd* 857 F.3d 1148 (11th Cir. 2017). "A factually false claim occurs, for example, when a supplier submits a claim that misidentifies the goods supplied or requests reimbursement for goods that it never provided." *Id.* (citation omitted). On the other hand, "[a] legally false claim [exists] when the supplier has falsely certified compliance with the applicable statutes and regulations, but nevertheless has submitted a claim." *Id.* at 1345 (citing *Mastej*, 591 F. App'x at 705-06). "The violation of the regulations and the corresponding submission of claims for which payment is known by the claimant not to be owed make the claims false." *Id.* (quoting *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005)).

PCA argues that the Complaint should be dismissed for failure to clearly allege whether PCA submitted factually false or legally false claims to TRICARE. (ECF No. 51 at 8-9). The

undersigned disagrees. The Complaint alleges that Defendants submitted legally false claims to TRICARE in that the claims did not comply with applicable statutes and regulations, namely the AKS. For example, the Complaint states:

> Defendants[] . . . knowingly present[ed], and caus[ed] to be presented, false or fraudulent claims for compounded drugs to TRICARE, the federal health care program for active duty military personnel, retirees, and their families. . . . Defendants paid kickbacks to "marketers" to target military members and their families for prescriptions for compounded pain creams, scar creams, and vitamins, regardless of need. While these products were supposed to be compounded specifically for individual patients' needs, the formulations were in reality manipulated by the Defendants and marketers to ensure the highest possible reimbursement from TRICARE. The marketers paid telemedicine doctors who prescribed the creams and vitamins but never physically examined the patients. The marketers also colluded with the Defendants to pay many patients' copayments to induce them to accept the compounded drugs. The Defendants and marketers then split the profits, and the scheme generated millions of dollars for them in a matter of months.

(ECF No. 36 ¶ 1).

The Complaint also alleges that between September 1, 2014 and April 29, 2015, "Defendant PCA knowingly submitted claims to TRICARE for reimbursement for compounded drugs that were false or fraudulent because they were tainted by kickbacks to marketers and patients and did not arise from a valid prescriber-patient relationship." *Id.* ¶ 2. The Complaint then further describes these schemes in details. *Id.* at 12-27. This is sufficient. Accordingly, the undersigned finds PCA's argument to be without merit.

B. The Complaint Fails to State a Presentment Claim Under Either the Express Certification or Implied Certification Theory

Having found that the Complaint alleges legally false claims, the undersigned next considers whether the Complaint alleges a viable presentment claim under either the express certification theory or the implied certification theory.

1. Express Certification

Regarding express certification theory, PCA argues that the Complaint fails to allege any express false certification "at the time" PCA signed the Provider Agreement with ESI. (ECF No. 51 at 10). In response, the Government argues that certifications do not need to be made close to or at the time a claim is submitted in order to be actionable. (ECF No. 60 at 15).[10]

As the parties agree, a claim can be legally false under one of two theories: express false certification or implied false certification. *Phalp*, 116 F. Supp. 3d at 1345 (citations omitted). "Express certification means that the supplier has certified compliance with applicable laws and regulations *as part of the claims submission process*." *Id.* (emphasis added) (citing *Keeler*, 568 F. App'x at 798-99 and *Mastej*, 591 F. App'x at 702, 705 n. 19); *see also United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) ("The falsity of a claim is determined at the time of submission."); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006) (holding that a "palpably false statement, known to be a lie when it is made, is required for a party to be found liable under the False Claims Act"); *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 438 (3d Cir. 2004) (holding initial claim cannot be rendered false by subsequent conduct); *cf. United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1105 (7th Cir. 2014) (affirming dismissal of FCA claim under express certification theory based upon defendant's statement in Medicare

[10] The Government also asserts that it is not required to plead its theory of fraud in the Complaint, but only the facts constituting the fraud. (ECF No. 60 at 14) (citing *United States ex rel. McCready v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 114, 118 (D.D.C. 2003)). While the undersigned agrees that the Government's Complaint need not specifically state whether it is alleging claims under an "express certification theory" or "implied certification theory," the allegations in the Complaint must constitute a claim under one of these theories to meet the heightened pleading standard for FCA claims. *See, e.g., Marsteller for use & benefit of United States v. Tilton*, 880 F.3d 1302, 1304 (11th Cir. 2018) (remanding case for determination of whether the relator's complaint alleged a theory of implied certification sufficient to survive a motion to dismiss).

enrollment form where defendant agreed to comply with Medicare laws and regulations, including the AKS, because complaint failed to adequately allege that defendant's statement was false at the time it was made); *but see United States ex rel. Hutchenson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011) (finding that representations in a provider agreement could provide the basis for an FCA claim).

Here, the only allegations pertaining to certification relate to PCA's execution of a Provider Agreement with ESI, TRICARE's pharmacy benefits manager, in August 2012—two years before the Defendants allegedly began submitting false claims to TRICARE. (ECF No. 36 ¶ 29). Specifically, the Complaint alleges that PCA executed a Provider Agreement with ESI on August 28, 2012, in which PCA promised to: (i) be bound by and comply with all applicable "law, rules and regulations including, but not limited to, fraud, waste, and abuse laws;" (ii) "not submit a claim to ESI until it has preliminarily determined . . . that the prescription is valid and issued in accordance with applicable rules and regulations;" and (iii) collect from patients the applicable copayment and not waive or discount copayments unless directed to do so by ESI. *Id.* The Provider Agreement also required PCA to comply with ESI's Provider Manual. *Id.* ¶ 31. ESI's Provider Manual in effect from September 1, 2014 to April 29, 2015, required PCA to ensure that the correct copayment was charged and was not changed or waived. *Id.* ¶ 32. The Provider Manual also stated that if ESI became aware that PCA was offering copayment or cost-sharing discounts, PCA could be terminated from ESI's provider network. *Id.* Lastly, the Provider Manual required PCA to comply with all state and federal laws, including the AKS. *Id.* ¶ 33.

Against this factual backdrop, the undersigned concludes that the Complaint fails to state an FCA claim under an express certification theory because it fails to allege that Defendants

falsely certified compliance with an applicable law or regulation at the time a claim was submitted to TRICARE, or that PCA's agreement to abide by the terms of the Provider Agreement was false at the time it was made. While the Complaint generally alleges the submission of claims, (ECF No. 36 ¶¶ 161-69), it nonetheless fails to allege that the Defendants expressly certified compliance with any law or regulation, including the AKS, as part of the claims submission process. *See United States v. Crumb*, No. CV 15-0655-WS-N, 2016 WL 4480690, at *22 (S.D. Ala. Aug. 24, 2016) (finding that government had stated a claim under an express certification theory where the complaint alleged that the claim submission form contained a certification that "the services on this form were medically indicated and necessary for the health of the patient and were personally furnished by [the provider submitting the form]."). For example, the instant Complaint fails to state whether PCA, in submitting a claim, expressly certified that the prescriptions for which reimbursement was sought were compliant with applicable laws, including the AKS, and regulations regarding copayments, and were based on a valid prescriber-patient relationship. This information is critical to determining whether the Government has asserted a claim under an express certification theory. Additionally, while the Complaint alleges that PCA entered the topical compounding industry to increase its profits and intended to bill TRICARE for the compounded creams, these allegations alone do not show falsity as of August 2012, when the Provider Agreement was signed. Accordingly, the undersigned finds that the Complaint fails to state an FCA claim under the express certification theory as to all Defendants.

2. Implied Certification

PCA next asserts that the Complaint fails to state a claim under the implied certification theory. (ECF No. 51 at 12-15). The Supreme Court recently held that the implied certification

theory can provide a basis for liability under the FCA, resolving disagreements amongst various courts of appeals. *Escobar*, 136 S. Ct. at 1998-99. Under the implied certification theory, a claim must satisfy two conditions. *Id.* ¶ 2001. First, a "claim [must] not merely request payment, but also [must] make[] *specific representations* about the goods or services provided." *Id.* (emphasis added). Second, the defendant must fail to "disclose noncompliance with material statutory, regulatory, or contractual requirements," which make the specific representations "misleading half-truths." *Id.* Moreover, the Court held that a defendant's "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material to the Government's payment decision* in order to be actionable under the [FCA]." *Id.* at 2002 (emphasis added).[11] "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* (quoting *Neder v. U.S.*, 527 U.S. 1, 16 (1999)). The materiality standard is demanding, and whether or not a misrepresentation is labeled a "condition of payment" is relevant to, but not dispositive of, the materiality inquiry. *Id.* at 2001, 2003.

Post-*Escobar*, in *United States v. Crumb*, the court found that the Government had sufficiently stated an FCA claim under an implied certification theory. *Crumb*, No. CV 15-0655-WS-N, 2016 WL 4480690, at *23-24. In *Crumb*, the Government alleged several FCA claims, including a presentment claim, against a physician and his former employer stemming from their fraudulent billing of Medicare and TRICARE for procedures based on false diagnoses. *Id.* at *5-6. The defendants moved to dismiss the presentment claim for, among other grounds, failing to adequately plead a claim under the implied certification theory. *Id.* at *23-24.

[11] The Supreme Court rejected the First Circuit's opinion that every submission of a claim implicitly represents compliance with relevant regulations, and that any undisclosed violation of a precondition of payment (whether or not expressly identified as such) renders a claim "false or fraudulent." *Escobar*, 136 S. Ct. at 2004.

The *Crumb* court found that the complaint adequately pled a claim under the implied certification theory. *Id.* As to the first factor in *Escobar* (specific representations), the *Crumb* court found that the defendants made "specific representations about the services provided and the reasons for those services (i.e. diagnoses)" in the Form CMS-1500[12] used to submit claims. *Id.* at *23. As to the second factor (nondisclosure of a material legal or contractual requirement), the *Crumb* court found that the defendants failed to disclose that: (i) the listed diagnoses had been falsified to create covered claims, (ii) the procedures were not provided for covered diagnoses, and (iii) coding modifiers used in submitting claims did not comport with program requirements. *Id.* As a result of these omissions, the *Crumb* court found the defendants' specific representations were "at best, misleading half-truths," and found that the complaint stated a claim under the implied certification theory.[13] *Id.*

Unlike in *Crumb*, however, the Complaint in this case does not contain any allegations regarding the specific representations Defendants made to TRICARE when submitting a claim. While the Complaint describes several representative claims submitted to TRICARE, these representative claims do not allege what specific representations, if any, Defendants made to TRICARE regarding the claims for which reimbursement was sought.[14] *See* (ECF No.

[12] In *Crumb*, the complaint "describe[d] in substantial detail the so-called 'Form CMS-1500' that a provider must use to submit a claim for reimbursement under Medicare." *Crumb*, 2016 WL 4480690, at *13. Specifically, the complaint alleged that the Form CMS-1500 requires that the provider list a diagnosis code for each service or procedure for which reimbursement is sought, and assign a CPT code to each such service or procedure. *Id.* Further, the complaint alleged that "diagnosis-restricted procedures are not reimbursable unless an approved diagnosis code is used," and "health care benefit programs utilize these codes to determine whether to issue or deny payments as well as the amount of any such payments." *Id.*

[13] The court in *Crumb* also addressed whether the government adequately pled the materiality of defendants' misrepresentations, which will be discussed *infra* Section IV.C.

[14] That said, however, the representative claims otherwise provide the requisite indicia of reliability under Rule 9(b) as they set forth the patient's name, prescription number, date the

36 ¶¶ 161-69). Accordingly, the undersigned finds that the FCA claim fails to state an implied certification claim under *Escobar*, and falls short of Rule 9(b)'s heightened pleading standard. *Cf. Matheny*, 671 F.3d at 1222 (citation omitted) (stating that the objective of Rule 9(b) is to "alert[ ] defendants to the precise misconduct with which they are charged").

C. The Complaint Adequately Alleges Materiality

Although dismissal of the FCA claim is appropriate because it fails to sufficiently allege either an express or implied certification, the undersigned will address Defendants' arguments regarding other deficiencies in the Complaint. As to materiality, PCA and Patrick Smith argue that the Complaint alleges materiality in a conclusory fashion, while Matthew Smith argues that the Complaint fails to allege that his conduct was material to TRICARE's payment decision.[15] (ECF Nos. 51 at 11-14; 53 at 12-16; 54 at 17-18). The undersigned finds that the Complaint adequately alleges materiality.

As the Court stated in *Escobar*, any understanding of materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal citation omitted). Here, the Complaint adequately alleges that compliance with the AKS and Florida's prescriber-patient laws were material to TRICARE's payment decision. For example, the Complaint alleges that to receive reimbursements from TRICARE,

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claim was submitted, date the claim was reimbursed, the amount of the reimbursement, and the marketer that referred the prescription to PCA. (ECF No. 36 ¶¶ 161-69); *see also Clausen*, 290 F. 3d at 1311.

[15] Matthew Smith conflates the FCA's causation element with the Government's materiality obligation under *Escobar*. The Government must prove that the Defendants, including Matthew Smith, presented or caused to be presented a false claim to TRICARE. *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714-15 (10th Cir. 2006). However, under *Escobar*, the Government must prove that Defendant's *misrepresentation*—not conduct—was material to TRICARE's payment decision. *See Escobar*, 136 S. Ct. at 2002 ("As noted, a *misrepresentation* about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act.") (emphasis added).

PCA was required to execute a Provider Agreement that required it abide by applicable laws, collect copayments, and ensure claims were based on valid prescriptions. (ECF No. 36 ¶¶ 27, 29). Also, the ESI Manuals required PCA to comply with the AKS and warned of termination for failing to comply. *Id.* ¶¶ 31-33; *see also id.* ¶¶ 69, 138-40, 142-46, 152. These allegations indicate that compliance with the AKS and prescriber-patient laws was material to the TRICARE's payment decision. Accordingly, at this stage of the proceedings, the undersigned finds the Complaint adequately alleges materiality.

D. The Complaint Sufficiently Alleges RLH's and Patrick Smith's Knowledge of the Marketing Kickback Scheme, but not of the Copayment Waiver Scheme

Next, RLH and Patrick Smith argue that the Complaint fails to adequately allege that they knew of PCA's submission of false claims to TRICARE. Specifically, RLH argues that the Complaint fails to allege that it knew of, directed, or profited from any of the alleged schemes. (ECF No. 52 at 6-10). Similarly, Patrick Smith argues that the Complaint fails to allege that he knew that PCA was paying kickbacks by waiving copayments without verification of financial need and that he willfully violated the AKS by paying kickbacks to Marketers. (ECF No. 54 at 8-13).

The FCA defines "knowingly" as "actual knowledge," "reckless disregard," or "deliberate ignorance" of truth or falsity, and expressly "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). Under Rule 9(b), knowledge may be averred generally. Fed. R. Civ. Pro. 9(b). For FCA claims based on a violation of the AKS—such as the schemes based on kickbacks to marketers and the waiver of copayments—a Complaint must plead with particularity that a defendants "'made kickbacks with the intent of inducing referrals, and [d]efendants knowingly paid remuneration in exchange for referrals' . . . ." *Schaengold*, 2014 WL 7272598, at *13; *see also United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d

654, 665 (S.D. Tex. 2013), *aff'd sub nom.* 587 F. App'x 123 (5th Cir. 2014) (holding that the separate elements of the AKS and FCA are satisfied where complaint pleads that defendants made kickbacks with the intent of inducing referrals, and alleges the particular details of a scheme with reliable indicia that claims were actually submitted).

1. RLH's Knowledge of the Copayment Waiver and Marketing Kickback Schemes

The undersigned finds that the Complaint fails to adequately allege RLH's knowledge of PCA's submission of false claims to TRICARE under the copayment waiver scheme. As to this scheme, the only allegations against RLH are that RLH sent Patrick Smith OIG Guidelines advising that routine copayment waivers could violate the AKS. (ECF No. 36 ¶ 138). But the Complaint is devoid of allegations that RLH was aware that PCA was routinely paying patients' copayments, or doing so without verification of financial need. *See id*. ¶¶ 98-112.

The Complaint does, however, adequately allege RLH's knowledge that PCA submitted false claims to TRICARE under the marketing kickback scheme. Indeed, the Complaint alleges that RLH was advised by counsel that paying commissions to marketers could violate the AKS and that compliance with the AKS was a material requirement for reimbursement from TRICARE. *Id.* ¶¶ 142, 155. The Complaint also alleges that RLH: (i) approved of PCA's decision to use marketers to generate referrals; (ii) knew that TRICARE was the source of the majority of PCA's revenue; (iii) received monthly financial statements, which reported the monthly compounding revenue and the commission paid to the Marketers; and (iv) RLH funded $2 million in commissions to the Marketers in January 2015. *Id.* ¶¶ 53, 67, 71-73, 75, 81-85.

2. Patrick Smith's Knowledge of the Copayment Waiver and Marketing Kickback Schemes

Patrick Smith also argues that the Complaint fails to allege that he knew that PCA was paying patients' copayments without verification of financial need.[16] The undersigned agrees. Although the Complaint alleges that Patrick Smith knew that copayment waivers were illegal under the AKS, it does not contain any allegations that Patrick Smith knew that PCA was routinely waiving copayments without financial verification. *See id.* ¶¶ 134, 136-39. Indeed, the only allegation tying Patrick Smith to the copayment waiver scheme is that Patrick Smith signed checks to PFARN for PCA's share of the waived copayments. *Id.* ¶ 104. As pled, the Complaint does not set forth sufficient allegations to establish Patrick Smith's knowledge of the copayment waiver scheme.

The undersigned finds, however, that the Complaint adequately alleges that Patrick Smith willfully violated the AKS by paying kickbacks to Marketers. For example, the Complaint alleges that: (i) Defendants, including Patrick Smith, paid kickbacks to Marketers for the sole purpose of obtaining referrals; (ii) the attorney who reviewed PCA's contracts with the Marketers advised Patrick Smith that PCA should not bill government health care programs and also discussed with him the AKS; (iii) Patrick Smith was aware that the majority of PCA's revenue came from TRICARE reimbursements; and (iv) Patrick Smith personally tracked commission payments to the Marketers, sent RLH monthly financial statements documenting the commission payments, and asked RLH to fund commission payments when sales were ahead of

[16] Patrick Smith further argues that he relied on the advice of counsel to ensure PCA's compliance with the law. (ECF No. 54 at 11-13). However, as the Government argues, an advice of counsel defense is not a basis to grant a motion to dismiss. *See Kodsi v. Branch Banking & Trust Co.*, No. 15-CV-81053, 2018 WL 830117, at *5 (S.D. Fla. Feb. 12, 2018) ("A Rule 12(b)(6) motion to dismiss is not the proper procedural device to probe the truthfulness of Plaintiff's factual allegations, and assertion of the affirmative defense of advice of counsel is rejected at this stage of the proceedings.")

commissions. *Id.* ¶¶ 16, 67, 69, 71-75, 80-85. Additionally, PCA's compliance training in January 2014 alerted staff of the AKS's prohibition of paying kickbacks for referrals, and Patrick Smith was advised by two additional attorneys that PCA's payments to the Marketers did not comply with the AKS. *Id.* ¶¶ 136, 139, 142-45, 155.

E. The Complaint Fails to Adequately Allege Patrick Smith's and RLH's Knowledge of the Prescriber-Patient Scheme

Patrick Smith and RLH also argue that the FCA claim fails to allege that they had knowledge that PCA submitted claims to TRICARE for prescriptions not based on a valid prescriber-patient relationship. The undersigned agrees. The only allegations regarding Patrick Smith's knowledge of the prescriber-patient scheme involve Patrick Smith being informed of a single patient complaint and Patrick Smith's representation to CBS News that PCA worked closely with physicians to tailor medications to patients' needs. *Id.* ¶¶ 126, 152. These allegations are not enough to support an FCA claim under the prescriber-patient scheme. *See* 31 U.S.C. § 3729(a)(1)(A) (imposing liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States).

Like Patrick Smith, RLH also argues that the Complaint fails to allege RLH's knowledge of the lack of a valid prescriber-patient relationship. *Id.* ¶¶ 113-31. In contrast to the many allegations against Matthew Smith, the Complaint does not allege that RLH was aware of any patient complaints regarding unauthorized prescriptions, or provide any other factual allegations from which the undersigned could infer RLH's knowledge of this scheme. *Id.* Merely alleging that RLH "knew or should have known" that PCA was subject to fraud laws is insufficient to plead RLH's knowledge of the submission of false claims under these schemes.

F. The Complaint Adequately Alleges Causation as to Patrick Smith, Matthew Smith, and RLH Under the Marketing Kickback Scheme and Against Matthew Smith Under the Prescriber-Patient and Copayment Waiver Schemes

Lastly, Patrick Smith, Matthew Smith, and RLH argue that the Complaint fails to adequately allege they caused false claims to be presented to TRICARE under the pleading standard of Rule 12(b)(6) and/or Rule 9(b). As pled, the undersigned finds the Complaint sufficiently alleges Patrick Smith, Matthew Smith, and RLH caused false claims to be submitted to TRICARE pursuant to the marketing kickback scheme. The undersigned also finds the Complaint adequately alleges Matthew Smith caused false claims to be submitted to TRICARE under the prescriber-patient and copayment wavier schemes.

In *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, the Tenth Circuit determined the standard for causation for a presentment claim under the FCA:

> Generally, mere knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish liability under the FCA. *See United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991). Under § 3729(a)(1)'s requirement that a person "cause" a false claim to be presented, the appropriate focus of the inquiry is on "the specific conduct of the person from whom the Government seeks to collect." *United States v. Bornstein*, 423 U.S. 303, 313 (1976). Thus, the appropriate inquiry under § 3729(a)(1) is whether that specific conduct causes the presentment of a false claim.
>
> The Third Circuit has borrowed traditional principles of tort law to analyze causation for damages under the FCA. *See United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977) (holding that, in assessing damages under the FCA, "a causal connection must be shown between loss and fraudulent conduct" and that "a broad 'but for' test is not in compliance with the [FCA]"). Such an approach is useful in analyzing causation under § 3729 as well, and provides a familiar test—that of proximate causation—*to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim to support liability under the FCA*. Such a test separates the wheat from the chaff, allowing FCA claims to proceed against parties who can fairly be said to have caused a claim to be presented to the government, while winnowing out those claims with only attenuated links between the defendants' specific actions and the presentation of the false claim. Attempting to strike this same balance, the district court required "some sort of an affirmative action on the part of the defendants." *We agree that a standard requiring more than mere passive acquiescence is most consistent with the purposes of the FCA.* Furthermore, such a standard strikes the

> appropriate balance between shielding from liability parties who merely fail to prevent the fraudulent acts of others, and ensuring that liability attaches for "affirmative acts" that do cause or assist the presentation of a fraudulent claim.

Sikkenga, 472 F.3d at 714-15 (emphasis added).

1. Causation as to the Marketing Kickback Scheme

Based on the foregoing standard, the undersigned concludes that the Complaint sufficiently pleads that Patrick Smith, Matthew Smith, and RLH caused the presentment of false claims to TRICARE pursuant to marketing kickback scheme. The Complaint alleges that Patrick Smith, Matthew Smith, and RLH took steps to advance the marketing kickback scheme that ultimately led to the presentment of claims to TRICARE. For example, as discussed above, Patrick Smith and Matthew Smith knew the AKS prohibited kickbacks to the Marketers, yet both personally tracked the commission payments to ensure the Marketers were being compensated for the referrals pursuant to their agreements with PCA. (ECF No. 36 ¶¶ 69, 80-82). Further, Patrick Smith arranged for RLH to fund $2 million in commissions when sales were ahead of commissions, while Matthew Smith negotiated the marketing agreements that provided for the commissions to the Marketers. *Id.* ¶¶ 68, 84. Similarly, RLH knew of and approved PCA's agreements with the Marketers, knew of the AKS's prohibition against kickbacks, and nevertheless funded $2 million in commissions to the Marketers. *Id.* ¶¶ 53, 84, 142, 155.

2. Causation as to the Prescriber-Patient and Copayment Waiver Schemes

Additionally, the undersigned finds that the Complaint adequately alleges that Matthew Smith caused the presentation of false claims to TRICARE under the prescriber-patient and

copayment wavier schemes.[17] As to the prescriber-patient scheme, the Complaint alleges that Matthew Smith inquired with PCA staff as to whether they submitted test claims for compounded drugs, and praised a PCA staff member for "reviewing all the TRICARE claims to assure maximum reimbursement, adjusting claims when a "lower reimbursement" ingredient was used, and changing PCA's billing system to only bill the higher-reimbursing ingredient. *Id.* ¶¶ 116-17. Further, Matthew Smith was aware of multiple customer complaints, but instructed staff not to reverse claims despite these complaints, unless necessary to prevent the patient from complaining to the patient's health insurance provider. *Id.* ¶¶ 123-26, 128, 131.

As to the copayment wavier scheme, the Complaint states that Matthew Smith and Steve Miller of TeleMedTech devised the copayment waiver scheme. *Id.* ¶¶ 98-112. Specifically, the Complaint states that: (i) Steve Miller confirmed with Matthew Smith that TeleMedTech would fund the copayments of patients it referred through a sham charity named PFARN; (ii) Steve Miller confirmed in an email to Matthew Smith that PFARN would send the full copayment amount to PCA in order to "act" compliant, but PCA would then reimburse PFARN for 50% of the copayments; (iii) Matthew Smith signed checks to PFARN for half of the copayment amount, which were sent to TeleMedTech's address; (iv) there was no verification of patients' financial need for copayment waivers; (v) and, Matthew Smith knew PFARN was not a legitimate charity, yet advised PCA staff that PFARN was a legitimate charity.[18] *Id.* In total, PCA submitted

[17] Because the undersigned concluded that the Complaint does not adequately allege knowledge as to RLH and Patrick Smith under the prescriber-patient and copayment waiver schemes, the undersigned need not address causation with respect to these two defendants on those schemes. *See supra* Section IV.D.

[18] The undersigned finds that these allegations sufficiently set forth that PCA and/or Matthew Smith did not verify the financial need of the patients receiving the copayments waivers, and, thus, rejects Matthew Smith's argument that this is a basis for dismissal. *See* (ECF No. 53 at 16-18). As recited above, the Complaint alleges that PFARN was a sham charity, there was not verification of financial need, PFARN sent PCA the full amount of the copayment waivers to

3,477 prescriptions to TRICARE, resulting in over $16 million in reimbursements to PCA. *Id.* ¶ 111.

G. The Complaint Sufficiently States a Claim for Payment by Mistake and Unjust Enrichment against PCA

PCA argues that the claims for payment by mistake (Count II) and unjust enrichment (Count III) should be dismissed for: (i) failure to specify whether the claims are asserted under federal or common law; and (ii) improperly incorporating all preceding allegations by reference.[19] (ECF No. 51 at 15-16). The Government responds that these claims are plainly governed by federal law[20] and that incorporation by reference is appropriate because each claim in the Complaint is based on the same set of facts. (ECF No. 60 at 39). The undersigned agrees with the Government.

As to the first point, Rule 8 requires that a pleading contain a statement of the grounds for jurisdiction, a short and plain statement of the claim, and a demand for relief. Fed. R. Civ. P. 8; *see also Iqbal*, 556 U.S. at 677-78 (internal citations omitted). A plaintiff must only make factual allegations sufficient to provide the defendant with adequate notice of the claim "and the grounds upon which it rests." *Matter of Martin*, 532 B.R. 859, 862 (Bankr. N.D. Ga. 2015) (citations omitted). "Nothing requires a plaintiff to invoke the specific statutory construct or case law applicable to the claim itself . . . ." *Id.* Here, PCA does not dispute the Government's contention

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"act" compliant, and PCA then reimbursed PFARN for PCA's share of the copayment under the scheme. (ECF No. 36 ¶¶ 98-112). These allegations support the conclusion that PCA did not verify patients' financial needs when determining whether to waive copayments.

[19] Based on the language in the Complaint, the undersigned finds that Counts II and III to be pled only against PCA. *See* (ECF No. 36 ¶¶ 173-78).

[20] "Because these common-law claims involve rights of the United States under a nationwide federal program, federal common law governs." *United States v. Marder*, 208 F. Supp. 3d 1296, 1318 (S.D. Fla. 2016) (citing *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979) and *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366-67 (1943)).

that its claims for payment by mistake and unjust enrichment are "plainly governed by federal common law," but moves to dismiss them merely because the Complaint does not explicitly state they are governed by federal law. (ECF No. 61 at 8). The undersigned finds this unpersuasive in light of the Federal Rules of Civil Procedure.

On the second point, the undersigned finds that the Government's incorporation of the previous allegations into its claims for payment by mistake and unjust enrichment is proper. "A typical shotgun pleading 'contains several counts, each one incorporating by reference the allegations of its predecessors, leading to a situation where most of the counts (i.e., all but the first) *contain irrelevant factual allegations and legal conclusions*.'" *United States v. Everglades Coll., Inc.*, No. 12-60185-CIV, 2013 WL 11976904, at *2 (S.D. Fla. May 10, 2013) (emphasis added) (quoting *Strategic Income Fund, LLC v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1295 (11th Cir. 2002)). "With a shotgun pleading, it is virtually impossible to know which allegations of fact are intended to support which claims for relief." *Id.* (citing *Anderson v. Dist. Bd. of Trs. of Cent. Fla. Comm. Coll.*, 77 F.3d 364, 366 (11th Cir. 1996)). Here, however, the Government's claims for payment by mistake and unjust enrichment are based on the same nucleus of facts as the FCA claim. As such, the Government's decision to incorporate by reference the preceding allegations into the subsequent claims does not lead to confusion or the inclusion of facts unrelated to these causes of action. Accordingly, the undersigned does not find this is a basis for dismissal. *See Ward v. Ezpawn Fla., Inc.*, No. 6:15-CV-474-ORL-22-DAB, 2015 WL 12915703, at *2 (M.D. Fla. Oct. 28, 2015) (recommending denial of a motion to dismiss arguing that complaint was a shotgun pleading where complaint "present[ed] a factual scenario alleged to be the basis for *all* of the counts"), *report and recommendation adopted*, No. 6-15-CV-474-ORL-22-DAB, 2016 WL 890087 (M.D. Fla. Mar. 9, 2016).

V. RECOMMENDATION

Accordingly, the undersigned respectfully recommends that the Motions be **GRANTED IN PART AND DENIED IN PART** as follows:

(1) Defendants' Motions should be **GRANTED** as to Count I, and Count I should be dismissed without prejudice.[21] The undersigned also recommends that the Government be granted leave to amend its Complaint to cure the deficiencies discussed herein.

(2) Defendants' Motions should be **DENIED** as to Counts II and III (Payment by Mistake and Unjust Enrichment, respectively).

Within fourteen (14) days after being served with a copy of this Report and Recommendation, any party may serve and file written objections to any of the above findings and recommendations as provided by the Local Rules for this district. 28 U.S.C. § 636(b)(1); S.D. Fla. Mag. R. 4(b). The parties are hereby notified that a failure to timely object waives the right to challenge on appeal the District Court's order based on unobjected-to factual and legal conclusions contained in this Report and Recommendation. 11th Cir. R. 3–1 (2018); *see Thomas v. Arn*, 474 U.S. 140 (1985).

DONE AND ORDERED in Chambers at Fort Lauderdale, Florida, on November 30, 2018.

ALICIA O. VALLE
UNITED STATES MAGISTRATE JUDGE

[21] Defendants argue that the Government's Complaint should be dismissed with prejudice because it is the third complaint in this action. *See Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1052 (11th Cir. 2015) (finding three attempts at proper pleadings are enough). While the Complaint constitutes the third complaint in this action, Defendants were never served with or responded to the first and second complaint, and this action was closed for more than a year while the Government investigated and decided whether to intervene. Accordingly, the undersigned finds that Defendants would not be prejudiced by granting the Government leave to amend the Complaint.