IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *ex. rel*. Pamela Lynn Scalamogna,	)	
Plaintiff,	)	Civil Action No. 14-524
v.	)	Judge Cathy Bissoon
STEEL VALLEY AMBULENCE., *et al*.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

Pending before the Court is a Motion to Dismiss Plaintiff's Second Amended Complaint filed by Defendants Steel Valley Ambulance, John T. Jumba, Sr., Patricia Jumba, John J. Jumba and Lori Jumba (collectively, "Defendants") (Doc. 46), pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. For the reasons that follow, Defendants' Motion to Dismiss will be granted in part and denied in part. Specifically, the Court will deny Defendants' Motion to Dismiss as to Plaintiff's claims based on medical necessity requirements, and grant their Motion to Dismiss to the extent Plaintiff's theories of liability are based on other requirements.

BACKGROUND

Defendant Steel Valley Ambulance, Inc. ("Steel Valley") is an ambulance service based in Homestead, Pennsylvania that provides services for patients who are insured by Medicare and Medicaid. (2d Am. Compl. ¶¶ 10-14, Doc. 45.) Its former emergency medical technician ("EMT"), Pamela Scalamogna ("Plaintiff"), filed claims against Steel Valley and four individuals, John T. Jumba, Sr., Patricia Jumba, John J. Jumba and Lori Jumba, under the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA") (Counts 1-7). (See generally 2d Am. Compl.)

As the United States has declined to intervene in this action (see Doc. 13), Plaintiff is pursuing these claims individually.

According to the Second Amended Complaint, Plaintiff began working for Steel Valley in September 2010. (2d Am. Compl. ¶ 30.) Plaintiff alleges that, during her employment with Steel Valley, she observed Defendants violate the FCA by deviating from five Medicare and Medicaid standards, and that she believes that false claims for payment were submitted to the government by virtue of these deviations. (Id. at ¶¶ 58-179.) For each of the claimed deviations, Plaintiff contends that these are the types of issues that would affect government payment decisions, and therefore she avers on belief that they influenced the government's payments to Steel Valley. (Id. at ¶¶ 76-77, 129-30, 142-45, 164-65, 178-79.)

First, Plaintiff claims that Defendants deviated from vehicle and staff requirements. (Id. at ¶¶ 58-77.) She alleges that Medicare-reimbursable ambulance service providers are required to meet state motor vehicle standards, as well as "Star of Life" standards. (Id. at ¶¶ 58, 61.) She contends that Steel Valley's ambulances did not meet these standards. Specifically, she alleges that on or about October 13, 2010, two ambulances failed to pass inspection for proper heating, cooling and ventilation; that one ambulance failed to pass inspection for oxygen equipment; and that one ambulance was not available for inspection. She also alleges that an ambulance's vehicle registration was expired on November 4, 2006. (Id. at ¶¶ 64-66.) Plaintiff alleges that vehicles and their crews registered to provide Basic Life Support ("BLS") services were used for Advance Life Support ("ALS") calls in November 2010 and February 2011, in violation of Medicare's requirements. (Id. at ¶¶ 68-72.)

Second, Plaintiff claims that Defendants billed for services that were medically unnecessary, such as transporting patients by ambulance when Defendants could have used a

wheelchair van. (Id. at ¶¶ 78-130.) Plaintiff claims that Defendant John J. Jumba, Jr. "repeatedly instructed Plaintiff-Relator to remove statements about a patient's ability to walk or ride in a wheel chair [sic] from trip documentation" and "explained to [Plaintiff] that Medicare would not reimburse for ambulance transport that could have been performed in [a] wheelchair van." (Id. at ¶¶ 91-92.) She claims that Defendant John Jumba, Jr. "would either approve of the submission of the trip to Medicare, or return the documentation to employees to have the trip documentation amended or changed for submission to Medicare." (Id. at ¶ 90.) Consistent with her claim above, Plaintiff describes eleven specific patients, who, at specified times, were picked up by Plaintiff in non-emergency situations for medically unnecessary services, such as transportation in an ambulance. (Id. at ¶ 95.) She further states, for several of these patients, that Defendant John Jumba, Jr. instructed her to alter trip documentation sheets ("trip sheets") to reflect the necessity of the services provided in order to justify Medicare reimbursement.[1]

Third, Plaintiff claims that Defendants deviated from "origin and destination requirements" by transporting patients farther than the nearest facility. (Id. at ¶¶ 137-141.) She alleges that Steel Valley has trip sheets that contradict its submissions to Medicare concerning the nearest facilities. (Id.)

Fourth, Plaintiff claims that Defendants violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). (Id. at ¶¶ 146-65.) She alleges that Steel Valley has "illegal provider agreements with several providers," including a list of anonymized entities. (Id. at ¶ 152.) She alleges that

[1] Under the heading "Medical Necessity Requirements," Plaintiff also claims that on one specified occasion Steel Valley took 55 minutes to respond to an emergency call, rather than responding immediately as required by regulation, and then billed for an emergency response. (Id. at ¶¶ 112-121.)

these agreements violate the Anti-Kickback Statute, and the FCA, because they are used to facilitate several kickback schemes that result in billing the government. (Id. at ¶¶ 153-162.)

Fifth, and last, Plaintiff claims that Defendants deviated from periodic billing certification and reporting requirements. (Id. at ¶¶ 166-79.) In support of this theory, she alleges that Steel Valley did not maintain the required records, including certificates of medical necessity. (Id. at ¶¶ 171-74.) She also alleges that Steel Valley completed paperwork that falsely certified two patients as bedridden. (Id. at ¶¶ 175.)

ANALYSIS[2]

Defendants move to dismiss Plaintiff's Second Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)") for failure to state a claim on two grounds: (1) Plaintiff has failed to allege fraud with sufficient particularity under Federal Rule of Civil Procedure 9(b) ("Rule 9(b)"); and (2) Plaintiff has not alleged facts that establish the materiality of the fraud to the government's payment decisions, as required for FCA liability. (See generally, Defs.' Br. Supporting MTD, Doc. 47.)

I. Sufficiency of Plaintiff's Claims under Rule 9(b)

A. Legal Standard

"[T]he FCA makes it unlawful to knowingly submit a fraudulent claim to the government." U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P., 769 F.3d 837, 840 (3d Cir.

[2] In deciding whether to grant a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must take as true all of the well-pleaded facts in the complaint, Fowler v. UPMC Shadyside, 578 F.3d 201, 211 (3d Cir. 2009), and determine whether these facts raise a reasonable expectation that discovery will reveal the evidence necessary to prove each element of plaintiff's claims, Thompson v. Real Estate Mortgage Network, 748 F.3d 142, 147 (3d Cir. 2014).

2014).[3] As relevant here, FCA liability attaches when a claimant knowingly and falsely certifies compliance with a material statute, regulation, or contract provision, or "makes specific representations about the goods or services provided" but fails "to disclose noncompliance with material statutory, regulatory, or contractual requirements." U.S. ex rel. Whatley v. Eastwick Coll., 657 F. App'x 89, 94 (3d Cir. 2016) ("Eastwick") (quoting U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011) ("Wilkins")).

"Plaintiffs must plead [FCA] claims with particularity in accordance with Rule 9(b)." Wilkins, 659 F.3d at 301 n.9 (citing U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs, 149 F.3d 227, 234 (3d Cir. 1998)).[4] For a plaintiff to satisfy Rule 9(b)'s heightened pleading standard in the context of an FCA claim, she must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 157-58 (3d Cir. 2014) (citations omitted). "Describing a mere opportunity for fraud will not suffice." Id. at 158. The particular details of such a scheme must include information "as to *who* provided the payments, to *whom* the payments were made, [and] under *what* criteria the payments were awarded." Eastwick, 657 F. App'x at 95; U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC, 812 F.3d 294, 307 (3d Cir. 2016) (a plaintiff must support her "allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story'" (quoting In re Rockefeller Ctr. Props., Inc. Securities Litig., 311 F.3d 198, 217 (3d Cir. 2002)).

[3] Specifically, the FCA creates liability when a person "knowingly presents, or causes to be presented, a false claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or when a person "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).

[4] Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

Under this pleading standard, a plaintiff need not identify a specific claim for payment. Foglia, 754 F.3d at 156 (citing Wilkins, 659 F.3d at 308); see also United States ex rel. Brown v. Pfizer, Inc., No. 05-6795, 2016 WL 807363, at *11 (E.D. Pa. Mar. 1, 2016) ("The fact that Relators did not identify a single reimbursement is not fatal to their claims at this stage of the proceedings."); United States v. Medco Health Sys., Inc., No. 12-522, 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014) (a plaintiff need not identify specific claims as "such specific proofs are usually inaccessible to a qui tam plaintiff"). Indeed, a plaintiff may allege that claims were submitted to the government for payment based on information and belief if she alleges that the submissions were peculiarly within a defendant's knowledge and control, as long as other reliable indicia lead to a strong inference that claims were actually submitted. United States ex rel. Chorches for Bankruptcy Estate of Fabula v. American Medical Response, Inc., 865 F.3d 71, 85-86 (2d Cir. 2017) ("Chorches").

B. Pleading on Information and Belief

In this Court's Order granting Defendants' prior Motion to Dismiss (Doc. 44), the Court noted that the facts of this case resemble those alleged in Chorches, in which the FCA relator pleaded key elements of his complaint on information and belief. The Chorches court found that the plaintiff, an EMT for an ambulance company, had satisfied the pleading requirements of Rule 9(b). Id. at 86.

The relator in Chorches alleged that his employer engaged in a scheme: the ambulance company asked EMTs to alter patient reports to falsely demonstrate the medical necessity of ambulance runs, which would then be billed to Medicare. Id. at 76-77, 85. Although the relator did not identify particular claims that were submitted to the government based on his personal knowledge, he "set[] forth facts establishing specific reasons why such information . . . is

'peculiarly within [the ambulance company's] knowledge.'" Id. at 82 (quoting Wexner v. First Manhattan Co., 902 F.2d 169, 172 (2d Cir. 1990)). In addition, the relator alleged on personal knowledge that his "supervisors specifically referenced Medicare as the provider to whose requirements the allegedly falsified revisions were intended to conform." Id. at 85. The Chorches court found that this pleading was sufficient—even though the EMT's allegation that his employer submitted bills to the government was based on information and belief rather than personal knowledge—because it contained "plausible allegations creating a strong inference that specific false claims were submitted to the government." Id. at 86.

Recognizing the similarities between Plaintiff's allegations and the facts alleged in Chorches, Defendants argue that Plaintiff's Second Amended Complaint is nonetheless distinguishable because Plaintiff has not shown that her access to Steel Valley's billing records was restricted to the same extent as in Chorches. (Defs.' Br. Supporting MTD 6, 10-12.) Plaintiff responds, to the contrary, that she "alleged that Defendants exclusively controlled the submission of medical billing information for Steel Valley . . . and Steel Valley's owners and family members were responsible for the submission of the claims for payment to [M]edicare." (Pl.'s Br. Against MTD 7, Doc. 50.) Defendants reply that the Second Amended Complaint contains no such allegations. (Defs.' Reply Supporting MTD 1-2, Doc. 51.)

The first question for the Court to resolve is whether the allegations in the Second Amended Complaint sufficiently demonstrate that medical billing was peculiarly within Defendants' knowledge and control, thus permitting Plaintiff to make her claim submission allegations on information and belief. The Court finds that Plaintiff's allegations are sufficient to show that medical billing was peculiarly within Defendants' knowledge and control. Specifically, Plaintiff alleges that:

- "The Defendant, John T. Jumba, (a.k.a. John Jumba[,] Sr.), is the 100% owner and Chief Executive Officer of Defendant, Steel Valley Ambulance. . . . John Jumba, Sr., personally makes the business decisions related to billing," (2d Am. Compl. ¶ 17),
- "Defendant, Patricia Jumba (Wife of John Jumba, Sr.) is the Billing Manager of Steel Valley Ambulance. Defendant, Patricia Jumba, personally performs and supervises the billing practices," (Id. at ¶ 20),
- "The Defendant, John J. Jumba, (a.k.a. John Jumba, Jr.) is the Chief Operations Officer of Defendant, Steel Valley Ambulance. . . . John Jumba, Jr. personally makes the business decisions related to billing," (Id. at ¶ 23),
- "Defendant, Lori Jumba (Wife of John Jumba, Jr.) is the Office Manager of Steel Valley Ambulance. Defendant, Lori Jumba personally performs and supervises billing practices and office practices, in order to ensure that the office practices conform to their billing practices," (Id. at ¶ 26), and that
- "The Plaintiff-Relator, is Pamela Lynn Scalamogna. . . . At all times material, she was employed by Defendants as an EMT and driver," (Id. at ¶ 29).

Collectively, taking these allegations as true and drawing reasonable inferences, they show that Plaintiff had no role in the billing process, which was under the control of the listed Defendants. Although Defendants are correct that Plaintiff's Brief overstates the contents of her Second Amended Complaint, Plaintiff's allegations are sufficient to show that the billing process and the submission of claims to the government were not her job responsibilities, thus leading to the reasonable inference that she had no access to particular billing statements. See Foglia, 754 F.3d at 158 (where "[the defendant], and only [the defendant], has access to the documents that could easily prove the claim one way or another—the full billing records from the time under

consideration," a plaintiff satisfies Rule 9(b) by presenting sufficient circumstantial details of the alleged fraud).

The Court disagrees with Defendants' argument that Plaintiff must allege that Defendants intentionally or improperly prevented her from gaining access to billing records. (See Defs.' Reply Supporting MTD 2.) Rather, it is sufficient that the employer, "advertently or inadvertently[,] made it virtually impossible for most employees to have access to all of the information necessary to certify on personal knowledge both that a particular invoice was submitted for payment and that the facts stated to justify the invoice were false." Chorches, 865 F.3d at 82. Or simply, it is sufficient for Plaintiff to show that only Defendants "ha[ve] access to the documents that could easily prove the claim[s] one way or another." Foglia, 754 F.3d at 158. Given the parties' alleged job responsibilities, it is a natural inference that Plaintiff had no access to the billing records, which were peculiarly within Defendants' control.

The Court may thus consider whether Plaintiff's allegations based on information and belief, coupled with her allegations based on personal knowledge, lead to a strong inference that claims were actually submitted. Defendants argue that "it would be speculative (at best) to assume that a false claim resulted from the allegations in the [S]econd [A]mended [C]omplaint." (Defs.' Br. Supporting MTD 9.) To the contrary, the Court finds that Plaintiff's allegations lead to a nearly undeniable inference that such claims were submitted to the government, but that only one of the alleged bases for a false claim—lack of medical necessity—survives under Rule 9(b).

C. Medical Necessity Requirements

As Defendants argue, Rule 9(b) requires the Court to examine, for each of the claimed deviations from Medicare or Medicaid payment requirements, whether Plaintiff has alleged sufficient details about the allegedly fraudulent conduct giving rise to claim submissions.

Eastwick, 657 F. App'x 89, 95; U.S. ex rel. Judd v. Quest Diagnostics Inc., 638 F. App'x 162, 168-69 (3d Cir. 2015) (to satisfy Rule 9(b)'s requirement to allege "the who, what, when, where and how of the events" giving rise to an FCA claim, a plaintiff must allege the *particular details* of a scheme). Concerning medical necessity requirements, Plaintiff alleges that "Defendant, John Jumba[,] Jr.[,] repeatedly instructed Plaintiff-Relator to remove statements about a patient's ability to walk or ride in a wheel chair [sic] from trip documentation" and that he "explained to Relator-Plaintiff that Medicare would not reimburse for ambulance transport that could have been performed in a wheelchair van." (2d Am Compl. ¶¶ 91-92.) In addition to alleging this general practice, Plaintiff also claims that there were numerous specific ambulance trips for which Defendant John Jumba, Jr. instructed her to manufacture false trip documentation for government billing purposes. For instance, to take one of eleven examples, she states:

> Patient, GH, was picked-up by Plaintiff-Relator on December 24, 2010, at FN and taken to DVEE Dialysis by an ambulance. The trip was without medical necessity for use of an ambulance. The trip was a non-emergency trip, it was a BLS trip. Plaintiff-Relator observed the patient walk to the stretcher. Defendant, John Jumba, Jr. instructed Plaintiff-Relator to write that GH was moved from the bed to the stretcher with a two-man sheet lift, and if the trip sheet was not worded correctly, no payment from Medicare would be issued.

(Id. at ¶ 95(c).) As the Chorches court found when analyzing similar allegations, "in alleging that supervisors specifically referenced Medicare as the provider to whose requirements the allegedly falsified revisions were intended to conform, the [operative complaint] supports a strong inference that false claims were submitted *to the government*." Chorches, 865 F.3d at 85. Accordingly, Plaintiff's allegations concerning medical necessity requirements are sufficient to survive a motion to dismiss based on Plaintiff's supposed failure to show that any claims were submitted.

Having addressed medical necessity requirements, the Court will address each remaining category of claimed deviation in turn.

D. Vehicle and Staff Requirements

Concerning the alleged deviations from vehicle and staff requirements, Defendants argue that Plaintiff "fails to allege that Steel Valley transported Medicare or Medicaid patients while the alleged defects were supposedly present, and while the allegedly untrained crews were on duty." (Defs.' Br. Supporting MTD 14.) As a result, they argue, the Second Amended Complaint cannot give rise to a strong inference that specific false claims were submitted to the government based on Steel Valley's failure to meet vehicle and staff requirements. (Id.) For example, the patients transported in the allegedly defective ambulances may have had private insurance, in which case no claims for payment would have been submitted to the government. (Id.) Plaintiff does not respond directly to this argument in her brief, but does point to the Second Amended Complaint, which alleges that "[i]t is believed and therefore averred that Defendants knowingly and repeatedly billed for the use of vehicles, equipment, and staff which failed to meet the standards for Medicare and Medicaid reimbursement." (2d Am. Compl. ¶ 74.)

A careful reading of the Second Amended Complaint shows that Defendants are correct, although this is a close case. To survive under Rule 9(b), Plaintiff's allegations must include information "as to *who* provided the payments, to *whom* the payments were made, [and] under *what* criteria the payments were awarded," Eastwick, 657 F. App'x at 95, and provide "reliable indicia that lead to a strong inference that claims were actually submitted," Foglia,754 F.3d at 156. Yet, Plaintiff's allegations fail to indicate the details of an alleged scheme that would strongly imply that false claims were submitted to the government *based on vehicle and staff defects*.

Plaintiff's allegations concerning ambulance defects, which indicate specific defects that were present at specific points in time, would be consistent with either Steel Valley's prompt correction of those defects upon their discovery, or with Steel Valley's eventual billing that falsely certifies compliance. (See Defs.' Br. Supporting MTD 15 ("Taken to its logical extreme, Ms. Scalamogna's argument would force ambulance companies to remove vehicles from service immediately, even if they have a minor defect (such as air conditioning refrigerant needing to be recharged), or risk liability under the False Claims Act."); Exhibit 6 to 2d Am. Compl. (noting next to each comment on defects "Replaced SLC").) Plaintiff's allegations fail to show that the prompt correction scenario is less likely than the false billing scenario. Cf. Foglia,754 F.3d at 158 (court must be able to conclude that false billing scenario is more likely).

Further, unlike in Plaintiff's detailed allegations concerning Defendants' failure to comply with medical necessity requirements, Plaintiff does not provide a single example of a patient's billable trip that could have given rise to a false claim for payment based on either staff or vehicle requirements. While "representative samples" are not required, see Foglia,754 F.3d at 155-57, Plaintiff's allegations must permit the Court to strongly infer that such claims were submitted. Taking all of Plaintiff's allegations concerning vehicle and staff defects as true, there is insufficient reason to conclude that Defendants submitted a false claim arising from these defects. Cf. id. at 157-58 (acknowledging "a close case as to meeting the requirements of Rule 9(b)" where a nurse employed by a dialysis clinic alleged the details of a fraudulent scheme *and* provided inventory logs showing a pattern of drug use best explained by fraudulent billing). For this reason, Plaintiff's claims based on vehicle and staff requirements will be dismissed.[5]

[5] In addition, as Defendants also argue, it is clear that Plaintiff's claims based on vehicle and staff requirements fail to show that the alleged deviations were material to the government's payment decisions. Under the "demanding" standard for materiality under the FCA, the statute

E. Origin and Destination Requirements

Turning to origin and destination requirements, the same reasoning applies to a greater degree. The Court finds that Plaintiff's allegations fail to satisfy the requirements of Rule 9(b). Defendants argue that Plaintiff "fails to identify any statements that were allegedly made by the defendants to the government about origin and destination requirements." (Defs.' Br. Supporting MTD 19.) The Second Amended Complaint alleges, entirely on Plaintiff's belief and with no specific examples or other information on personal knowledge, that "Defendants submit claims made for services that fail to meet [Medicare's] origin and destination requirements," including "deliver[ing] dialysis patients to facilities that are not the nearest facility that is capable of providing the required level of service" and "deliver[ing] 'emergency service' patients to facilities that are not the nearest facility that is capable of providing the required level of service." (2d Am. Compl. ¶ 137.) Although Plaintiff does allege that "[t]he proof of the nearest facility is to be found in the documents retained by the service provider," (id. at ¶ 138), which would place the specific proof beyond her control, she provides no reliable indicia that would suggest that claims based on improperly long ambulance trips were submitted. As a result, this speculative claim must be dismissed. See Eastwick, 657 F. App'x at 95 ("when pleading on

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"is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations. . . . [m]ateriality, in addition, cannot be found where noncompliance is minor or insubstantial." Universal Health Servs. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 2003 (2016). Plaintiff's only examples of cases in which noncompliance with vehicle and staff requirements led to nonpayment or recoupment concern instances in which an ambulance provider's alleged misconduct was far more egregious than the conduct alleged here. See U.S. v. Comerio Ambulance Servs., 2005 BL 18757 (D.P.R. May 31, 2005) (provider's vehicles were unlicensed and, in many cases, were vehicles such as SUVs and sedans rather than ambulances—the provider pleaded guilty to criminal fraud); R.F. (Beneficiary) First Coast Serv. Options Inc. (Contractor), 2012 WL 3582978 (Medicare Appeals Council June 18, 2012) (Medicare refused payment where vehicle was a luxury car rather than an ambulance; the Appeals Council upheld this denial on the ground that the vehicle was not an ambulance *and* the services were medically unnecessary).

information and belief, boilerplate and conclusory allegations will not suffice and the [FCA] plaintiffs must make factual allegations that make their theoretically viable claim plausible" (internal citation and quotation marks omitted)).

F. Anti-Kickback Statute

Plaintiff's claims concerning the Anti-Kickback Statute require a separate, but related, analysis. The Anti-Kickback Statute makes it illegal to:

> [K]nowingly and willfully offer[] 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 . . . to refer an individual to a person for the furnishing or arranging of any item or service 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).[6] Under the Anti-Kickback Statute, "a claim that includes items and services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g); U.S. ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018) ("Greenfield"). An FCA violation based on the above-cited provisions of the Anti-Kickback Statute requires that a patient be exposed to an illegal referral; that a provider submits a claim for government reimbursement pertaining to that patient; and that a party to the transaction solicits, receives or offers a kickback to the referrer in exchange for the referral. See Greenfield, 880 F.3d at 100. Accordingly, under Rule 9(b), Plaintiff's factual allegations must enable the Court to discern the relationships among the parties to the transaction and infer that compensation has been paid in exchange for a referral, rather than for typical on-call services pursuant to an arms-length contract. Cooper v. Pottstown Hosp. Co. LLC, 651 F. App'x 114, 116 (3d Cir. 2016). It follows that the Court must, at a

[6] A parallel provision makes it illegal to "solicit[] or receive[] any remuneration" in the same transaction. 42 U.S.C. § 1320a-7b(b)(1)(A).

minimum, be able to discern that Defendants offered or received compensation in exchange for an illegal referral.

Plaintiff alleges that Steel Valley has several illegal provider agreements, and she incorporates one of the allegedly illegal agreements by reference in her Second Amended Complaint.[7] (See 2d Am. Compl. ¶¶ 152-53; Exhibit 9 to 2d Am. Cmpl.) She also alleges, on belief, several kickback schemes that are incomprehensible. For example, she alleges that "Steel Valley Ambulance has an agreement that does not disclose the storage of supplies," which constitutes "a commercially unreasonable" deviation from the agreement itself because "supplies are retained and distributed by the contracting parties without provision for storage, distribution, or payment." (2d Am. Compl. ¶¶ 153, 155.) And, she alleges that Steel Valley has agreements that identify it as a preferred emergency care transportation provider, even though Steel Valley is not a 911 provider, which is allegedly required for such designation. (Id. at ¶ 154.) These asserted schemes do not come close to alleging a kickback. To name the most obvious deficiency, they do not state or imply that any form of compensation has been exchanged among the parties.

[7] This contract designates Steel Valley as the "primary provider" for a nursing facility, which the contract defines to mean "that, unless prohibited by law, [Steel Valley] shall be the first ambulance provider contacted by [the nursing facility] for services for [the facility's] residents who require such services," subject to certain exceptions. (Exhibit 9 to 2d Am. Cmpl. ¶ 2.) As for payment, the contract states:

> a. When permitted by law, [Steel Valley] will bill the patient . . . or any available insurance . . . for services provided under this agreement.
>
> b. Where required by law, including but not limited to trips arising under the Medicare Prospective Payment System . . . , [Steel Valley] will bill [the facility] for services rendered to its residents . . . according to the fee schedule set forth in Appendix A, which . . . [is] reflective of the fair market value for the services rendered and not substantially below the Medicare-approved charges for such services.

(Id. at ¶¶ 5.a., 5.b.) On its face, there is nothing in this contract that would indicate an illegal kickback scheme.

Plaintiff asserts two additional schemes that come slightly closer, but ultimately fail. First, she alleges that Steel Valley has provider agreements with nursing care facilities. (2d Am. Compl. ¶ 156.) In the alleged scheme, the nursing care facilities bill Medicare (under Part A) for Steel Valley's ambulance services, and the nursing facilities ought to forward the Medicare payments to Steel Valley. (Id.) However, Steel Valley does not bill the nursing facilities for transporting their patients and the facilities do not forward Medicare's payments to Steel Valley. (Id.) Instead, Steel Valley bills Medicare (under Part B) such that Medicare pays twice for the same ambulance services. (Id.) From this arrangement, Steel Valley garners customer loyalty. (Id.) This scheme contains an alleged kickback, unlike those above, because it alleges that Steel Valley gets contracts for services and loyalty in exchange for illicitly billed patient referrals to its ambulance services. However, it lacks any reliable indicia—such as statements on personal knowledge, specific examples, dates, or provider identities—that would permit the Court to strongly infer that actual claims for payment were submitted based on the alleged scheme. As a result, this claim fails under Rule 9(b).

Second, Plaintiff asserts a scheme in which Steel Valley had an exclusive agreement for service with a nursing care facility. Here, she alleges that she personally "observed that Defendant, Steel Valley Ambulance[,] had an exclusive agreement for service with MM" and that she "was provided with copies of the contracts . . . when picking up patients." (2d Am. Compl. ¶¶ 159-60.) Pursuant to this scheme, she claims that Steel Valley responded to an emergency call on May 5, 2012 instead of 911 services, due to the existence of the exclusive agreement. (Id. at ¶ 161.) While this scheme does contain more specificity than any of the alleged kickback schemes described above—and contains information on personal knowledge—it does not allege a kickback. There is no basis on which the Court could conclude that Steel

Valley offered anything of value to the referrer in exchange for a referral.[8] Thus, for one reason or another, none of Plaintiff's allegations concerning Anti-Kickback Statute schemes suffices under Rule 9(b).

G. Billing Certification and Reporting Requirements

Plaintiff's final category of alleged deviations from Medicare payment requirements concern periodic certifications of compliance. Specifically, Plaintiff alleges that, to maintain Medicare billing privileges, ambulance suppliers must certify on a 5-year cycle that they comply with relevant laws and regulations, pursuant to 42 C.F.R. §§ 424.516(a)(2) and 424.515. (2d Am. Compl. ¶¶ 166-67.) Plaintiff's overall theory is that Steel Valley has failed to comply with various Medicare requirements, such as keeping trip records and retaining certificates of medical necessity, and thus that Steel Valley's certifications of compliance have been false. (Id. at ¶¶ 172-75.) In support of this theory, Plaintiff also asserts two exemplary scenarios:

> [(1)] A wheelchair patient refused to get on a stretcher and the paramedic, R.V., called Defendant, Steel Valley[,] to report the uncooperative patient. It is believed and therefore averred that Defendant certified the patient as bedridden. Certifying the patient as bedridden is a knowingly false certification.
> [(2)] A patient is taken to a dialysis clinic and placed in a dialysis chair. He is not bedridden because he can sit in the dialysis chair. It is believed and therefore averred that Defendant certified the patient as bedridden. Certifying the patient as bedridden is a knowingly false certification.

(2d Am. Compl. ¶¶ 175(c)-(d).)

Defendants' primary argument for dismissing claims based on its allegedly false certifications is that none of the requirements cited by Plaintiff apply to Defendants. (Defs.' Br. Supporting MTD 21.) Defendants argue that Steel Valley is a "supplier" rather than a "provider"

[8] Notably, despite alleging that she was provided with a copy of this exclusive contract, she does not aver any of its specific contents.

under the relevant regulations. (Id.) Defendants also argue for dismissal based on lack of materiality and lack of specificity. (Id. at 22.)

The plain language of the regulations contradicts Defendants' primary argument that the regulations do not apply to suppliers. First, 42 C.F.R. § 424.516(a)(2) states that "CMS enrolls and maintains an active enrollment status for a *provider or supplier* when that *provider or supplier* certifies that it meets . . . all of the following requirements: . . . [including] [c]ompliance with Federal and State licensure, certification, and regulatory requirements, as required, based on the type of services or supplies the *provider or supplier* type will furnish and bill Medicare." 42 C.F.R. § 424.516(a)(2) (emphases added). And 42 C.F.R. § 424.515 similarly applies to "a provider or supplier" throughout. Thus, Defendants' primary argument is inapposite.

Defendants' remaining argument, however, has merit.[9] None of Plaintiff's allegations concerning certification and reporting requirements go beyond conclusory assertions. For example, Plaintiff's most specific assertions are the two exemplary scenarios quoted above, which merely allege a belief that Defendant at some point in time falsely certified a patient as bedridden. Without any supporting information or indicia of reliability, this claim cannot survive under Rule 9(b).

Plaintiff's only allegations that survive under Rule 9(b) concern Steel Valley's false claims based on medically unnecessary billing. To survive Defendants' Motion to Dismiss,

[9] While Defendants describe their argument as concerning "materiality," the content of the argument concerns whether Plaintiff has properly alleged sufficient details to give rise to an inference that a false claim was submitted. Thus, the Court takes this argument to be addressing the pleading standard under Rule 9(b). (See Defs.' Br. Supporting MTD 22 ("[Plaintiff] does not identify whether any of these patients were insured, let alone covered by Medicare or Medicaid.").)

Plaintiff's allegations must also show that the defects are material to government payment decisions. Accordingly, the Court will now analyze materiality.

II. Sufficiency under Materiality Standard

A. Legal Standard

To state a valid FCA claim, a plaintiff must allege a "misrepresentation about compliance with a statutory, regulatory, or contractual requirement [that is] material to the Government's payment decision." United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 489 (3d Cir. 2017) (quoting Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S.Ct. 1989, 1996 (2016) ("Escobar")). As the United States Supreme Court has held, "[t]he materiality standard is demanding." Escobar, 136 S. Ct. at 2003. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." Id. Rather, materiality may be found where "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." Id. Applying Escobar's holistic approach to materiality, the relevant factors to consider are: "whether compliance with a statute is a condition of payment; whether the violation goes to 'the essence of the bargain' or is 'minor or insubstantial'; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations." U.S. ex rel. Emanuele v. Medicor Assocs., 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017) (quoting Escobar, 136 S. Ct. at 2003-04).

B. Materiality of Medical Necessity Requirements

Defendants argue that their alleged failure to comply with medical necessity requirements, if true, would not be material to the government's payment decisions. (Defs.' Br.

Supporting MTD 13 n.5, 18-19.) They focus their analysis on Plaintiff's inability to show "whether the government consistently refuses to pay claims where a trip sheet misstates that a patient is able to walk or ride in wheelchair van." (See id. at 19.) They also discount the cases that Plaintiff cites by arguing that these cases merely show the government's desire to claw back spent funds as opposed to the government's refusal to pay claims in the first place. (Id. at 13 n.5.).

Defendants' arguments are unpersuasive. Defendants concede that medical necessity is a condition of payment under 42 C.F.R. 410.40, (see Defs.' Br. Supporting MTD 18), but contend that their patients' health conditions were such that ambulance transportation was medically necessary as defined by 42 C.F.R. 410.40(d), (see id.). Such arguments are inappropriate at this stage, as the Court must take Plaintiff's factual allegations as true. Further, billing for unnecessary services goes to the heart of the bargain between Medicare and ambulance service providers—other than billing for services that were not provided at all, it is difficult to conceive of a more fundamental breach of the bargain than deliberately inflating billing to charge for unnecessary services. Concerning the government's general behavior in the mine run of cases, Plaintiff's Second Amended Complaint cites eight instances in which the government has initiated actions for noncompliance with medical necessity requirements against ambulance service providers. (2d Am. Compl. ¶ 129.) For example, Plaintiff cites U.S. v. Advantage Med. Transp. Inc., 698 F. App'x 680 (3d Cir. 2017), a criminal case that arose from the investigation of ambulance transportation claims based on trip sheets that were fraudulently altered to show that patients could not walk. Id. at 682-83. The Court of Appeals noted in that case that "ambulance transport claims have long been a vector for fraud and abuse of the Medicare system" and that "[a]n investigation by the Department of Health and Human Services Inspector

General revealed, for example, that Medicare paid more than $50 million to ambulance companies for improper rides for beneficiaries in the first six months of 2012 alone." Id. at 682 (internal citations omitted). That the government frequently takes action to recoup money paid on fraudulent claims in this area bolsters Plaintiff's argument that these claims are important to the government. See, e.g., U.S. v. Louthian, 756 F.3d 295, 297-98 (4th Cir. 2014) ("Because of the large volume of such claims for Medicare payments, little or no inquiry is made into the validity of claims as they are received. If a paid claim is ultimately suspected of having been fraudulently submitted, the authorities will investigate and pursue an appropriate reimbursement . . . ."). As a result, the Court finds that Plaintiff's claims based on billing for medically unnecessary ambulance services are sufficiently material to the government's payment decisions to survive a Motion to Dismiss.

* * *

Accordingly, in consideration of the discussion above, Defendants' Motion to Dismiss (Doc. 46) is **GRANTED** as to all of Plaintiff's claims to the extent they are based on theories of liability other than Defendants' medically unnecessary billing, and **DENIED** as to Plaintiff's claims to the extent they are based on Defendants' medically unnecessary billing.

It is further ordered that, as the Court previously provided Plaintiff with an opportunity to correct the pleading deficiencies discussed above (see Doc. 44) and as she has failed to do so, additional amendment opportunities would be futile and this dismissal will operate with prejudice against Plaintiff's reassertion of her dismissed theories of liability.[10] See Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 165-66 (3d Cir. 2004).

[10] As the Court noted in its prior order, the government may elect to intervene and reassert claims that have been dismissed. (Doc. 44.)

IT IS SO ORDERED.

June 26, 2018

s/Cathy Bissoon
Cathy Bissoon
United States District Judge

CC (via ECF email notification):

All Counsel of Record