UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA AND THE STATE OF CALIFORNIA ex rel. COLLEEN HERREN, Plaintiffs/Relator, v. MARSHALL MEDICAL CENTER; MARSHALL FOUNDATION FOR COMMUNITY HEALTH; EL DORADO HEMATOLOGY & MEDICAL ONCOLOGY II, INC.; LIN H. SOE, M.D.; TSUONG TSAI, M.D., Defendants.	No. 2:12-cv-00098-JAM-KJN **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS**

Colleen Herren brings this action against the hospital where she worked as a registered nurse and two of the hospital's affiliated physicians alleging that these defendants knowingly double billed Medicare and Medi-Cal, billed for services never rendered, and improperly billed for contaminated and expired chemotherapy drugs. Defendants now move to dismiss her Second Amended Complaint ("SAC") on the bases that the allegations lack

specificity and that their billing procedures were proper.[1] Defendants' motions are granted in part and denied in part for the reasons discussed below.

I. FACTUAL ALLEGATIONS AND PROCEDURAL BACKGROUND

Ms. Colleen Herren ("Relator") worked as Clinical Nursing Director for Specialty Clinics at Marshall Medical Center in Placerville, California ("Defendant Marshall" or "the hospital") in 2010 and 2011. SAC ¶ 9. At that time, Defendant Marshall had approximately 200 "affiliated physicians," including Drs. Lin Soe and Tsuong Tsai ("Physician Defendants" or "the physicians"). SAC ¶ 10. Drs. Soe and Tsai ran Defendant Marshall's Hematology/Oncology Center ("the Center"), where they and other staff performed services including chemotherapy infusions. SAC ¶ 13.

Within her first months on the job, Relator alleges that she noticed problems with the Center's practices, including lack of physician oversight, double billing for drugs in single-dose vials ("SDVs"), allowing SDV drugs to expire and become contaminated, and billing for physician visits that never occurred. See SAC ¶¶ 53, 64, 65. The SAC details alleged efforts by Relator and others to bring these concerns to the attention of the physicians and the hospital administration. See SAC ¶¶ 53, 62-63, 65-101. When the physicians insisted that the practices would continue, Relator claims she made further attempts to coerce compliance. See id. Relator contends that

[1] This motion was determined to be suitable for decision without oral argument. E.D. Cal. L.R. 230(g). The hearing was scheduled for March 25, 2015.

the hospital retaliated against her for these actions by terminating her employment. SAC ¶¶ 88-89, 133, 139, 145, 153.

After her termination, Relator sued the hospital, the Marshall Foundation for Community Health ("Defendant Foundation"), the Physician Defendants, and the physicians' medical practice-- El Dorado Hematology and Medical Oncology ("Defendant El Dorado"). SAC ¶¶ 10-13. Her SAC (Doc. #39) asserts causes of action for wrongful termination and for violations of the False Claims Act ("FCA") and the California False Claims Act ("CFCA") for retaliation and improperly billing Medicare and Medi-Cal. Neither the United States nor the state of California has intervened (Docs. ##27, 30).

All Defendants have moved to dismiss in two separate motions based on Federal Rules of Civil Procedure 9(b) and 12(b)(6) (Docs. ##54 ("Marshall Mot."), 48 ("El Dorado Mot.")). Relator opposes both motions (Docs. ##57 ("Opp. to Marshall"), 59 ("Opp. to El Dorado")).

II. OPINION

A. Judicial Notice

Each motion and opposition requests judicial notice of numerous documents. No party contested or objected to any of these documents.

Generally, the Court may not consider material beyond the pleadings in ruling on a motion to dismiss. However, the Court may take judicial notice of matters of public record, provided that they are not subject to reasonable dispute. Fed. R. Evid. 201; see Santa Monica Food Not Bombs v. City of Santa Monica, 450

F.3d 1022, 1025 n.2 (9th Cir. 2006); Lee v. City of Los Angeles, 250 F.3d 662, 689 (9th Cir. 2001).

The Court takes judicial notice of the parties' exhibits containing official publications as well as those exhibits available on government websites (Marshall Defendants' Exhs. 1-15, Physician and El Dorado Defendants' Exhs. 1-7, Relator's Exhs. 1-4 in Doc. #60 and Exhs. 1-7 in Doc. #58). See Cactus Corner, LLC v. U.S. Dept. of Agriculture, 346 F. Supp. 2d 1075, 1097 (E.D. Cal. 2004) (agency publications); Paralyzed Veterans of Am. v. McPherson, 2008 U.S. Dist. LEXIS 69542, at *7 (N.D. Cal. Sept. 9, 2008) (government websites). The Court also takes judicial notice of the remaining documents: two FDA-approved labels for chemotherapy drugs. See Relator's RJN (Doc. #58) Exhs. 8-9; Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977, 984 (D. Ariz. 2013) (noticing an FDA-approved label); In re Epogen & Aranesp Off–Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (same).

B. Analysis

1. Wrongful Termination Claims Against the Physician and El Dorado Defendants

The Physician and El Dorado Defendants assert that the Court should dismiss the wrongful termination claims against them (claims VII-X) because there is no allegation that any of these Defendants employed Relator. El Dorado Mot. at 13. Relator acknowledges that these claims should be dismissed as to these Defendants. Opp. to El Dorado at 15 n.12. Because Relator cannot allege that she was these Defendants' "employee, contractor, or agent," or that they were a "health facility" or

"operate[d] a health facility," the Court dismisses causes of action VII through X against the Physician and El Dorado Defendants with prejudice. See 31 U.S.C. § 3730(h)(1); Cal. Gov't Code § 12653(a); Cal. Labor Code § 1102.5(c); Cal. Health & Safety Code § 1278.5(b)(1)-(2); United States v. Kiewit Pac. Co., 41 F. Supp. 3d 796, 814 (N.D. Cal. 2014).

2. Sufficiency of Allegations Under Federal Rule of Civil Procedure 9(b)

Federal Rule of Civil Procedure 9(b) governs allegations of making or conspiring to make false claims in violation of the FCA and CFCA. Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001); Kiewit Pac. Co., 41 F. Supp. 3d at 801, 810. Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake." For purposes of the pleading a false claim, "it is sufficient to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 999-1000 (9th Cir. 2010) (citation and quotation marks omitted).

Rule 8(a) governs wrongful termination claims under the FCA and CFCA. Mediondo v. Centinela Hosp. Medical Center, 521 F.3d 1097, 1102-03 (9th Cir. 2008). These claims must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 547 (2007).

a. Claims Against Defendant Foundation

The Marshall Defendants argue that the Court should dismiss Defendant Foundation, because the allegations against it do not

comply with Rule 9(b). Marshall Mot. at 2-3. Relator does not contest the insufficiency of the allegations against the Foundation, but instead requests that the Court dismiss the Foundation without prejudice. Opp. to Marshall at 4:21-22.

Relator's allegations meet neither the 9(b) or 8(a) standard. The only mention of acts by Defendant Foundation is in paragraph 11 of the SAC, which alleges that the Foundation "partners with" Defendant Marshall and "contract[s] with" Defendant El Dorado. SAC ¶ 11. These allegations fall far short of the specificity required by Rule 9(b), in that they do not state any circumstances of Defendant Foundation's involvement in any fraud. See Bly-Magee, 236 F.3d at 1018 (holding that allegations did not meet 9(b)'s standard where complaint stated that "'[defendant] concealed the fraudulent submission of false claims . . . to avoid repayment of funds to the United States' and . . . conspired with the CDR and the OAG to 'defraud the United States by obtaining payment of fraudulent claims'"). Even when evaluated under the more lenient Rule 8(a) standard, these allegations are too vague to state a claim, because they do not explain the Foundation's role in any wrongful conduct.

Because Relator has not complied with the pleading requirements with respect to Defendant Foundation, the allegations against the Foundation are dismissed. If discovery reveals grounds for holding the Foundation liable in this case, Realtor may move to amend her complaint at the appropriate time.

b. Blood Transfusion Allegations

The Physician and El Dorado Defendants next attack the allegations that they billed for physician visits (incident to

blood transfusions) that never occurred. Defendants argue that the blood transfusion allegations lack specificity because the SAC "does not . . . allege how [Relator] received the information related regarding [sic] the meeting [described in SAC ¶¶ 99-101]." El Dorado Mot. at 11:19-20. Relator responds that the SAC "amply identifies the false claims submitted by Soe and Tsai and the circumstances under which they submitted such claims." Opp. to El Dorado at 12:19-20.

Relator's allegations are sufficient under Rule 9(b). This Rule does not require a complaint to explain how the relator knew of each and every fact. Defendants cite Ninth Circuit authority, stating that allegations "ma[de] on information and belief must state the factual basis for the belief." El Dorado Mot. at 11:20-21 (quoting Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993)). But "factual basis" does not mean basis of personal knowledge, as Defendants urge. "Factual basis" means that the complaint must contain facts, rather than general circumstances. See Neubronner, 6 F.3d at 672 ("[Plaintiff] has alleged no more than 'suspicious circumstances'; those circumstances – i.e., that [defendant] was an investment banker for Gibralter and that Gibralter eventually sank into financial trouble – do not constitute a sufficient factual basis for allegations of insider trading."). In fact, the Neubronner court noted that in some circumstances "plaintiffs can not [sic] be expected to have personal knowledge of the relevant facts." Id.

Relator here has provided sufficient facts to support the transfusion allegations. In particular, she alleges that Drs. Soe and Tsai billed under CPT codes 99214 and 99215, which

require a physician to visit with the patient for approximately 25 and 40 minutes respectively. SAC ¶ 102. She alleges that the doctors in fact spent no minutes visiting with patients when they billed under these codes, such that the claims billed were false. Id. She also alleges that this was not simply an innocent mistake; rather, the doctors were specifically informed that their billing methods using these codes were illegal and the doctors expressed that they would nonetheless continue billing in that illegal manner and would not refund any money. SAC ¶¶ 99-101. Because these allegations provide a factual basis for a finding of fraud, the Court denies the motion to dismiss them.

c. Physicians' Involvement in SDV Practices

The Physician and El Dorado Defendants further argue that the allegations regarding SDVs are insufficient, because the SAC "makes no allegations that the physician defendants were involved in the billing of SDVs or the decision of how to use SDVs, or that they had knowledge of any alleged regulatory violation." El Dorado Mot. at 12:10-13; see El Dorado Reply at 5. In response, Relator points to multiple paragraphs of the SAC implicating the physicians. Opp. to El Dorado at 14.

Defendants' argument focuses on one portion of the SAC while ignoring other important allegations. Specifically, Defendants' brief states that there is no allegation that the physicians "were involved in submitting [false claims relating to SDVs] to the government." El Dorado Mot. at 12:14-15; see El Dorado Reply at 5:19-20 ("Relator has not pled . . . that the Physician Defendants were involved in decisions regarding administration or billing of [SDVs]."). But in fact the SAC contains allegations

concerning the physicians' involvement at length: "Defendants Tsai and Soe . . . illegally double billed or ordered Defendant Marshall's staff to illegally double bill the Government Healthcare Programs in violation of conditions of payment for SDVs"; "Defendants Tsai and Soe . . . illegally billed or ordered staff to illegally bill the Government Healthcare Programs in violations [sic] of conditions of payment for SDVs of drugs by using them on multiple occasions [and] improperly bill[ing] [contaminated SDVs]"; and "Defendants Tsai and Soe . . . illegally billed or ordered staff to illegally bill the Government Healthcare Programs for [SDV] drugs after they expired[.]" SAC ¶¶ 58-62. The SAC then provides further clarification of why these billing practices were improper and details instances of particular occasions of improper billing. See SAC ¶¶ 58-61, 108-117. These allegations, when read together, adequately identify the physicians' roles in improper SDV billing.

Defendants also contend that the allegations are conclusory because the SAC does not provide "further explanation of the [alleged] agency relationship" between the physicians and the Marshall and El Dorado Defendants. El Dorado Mot. at 13:10-11 (citing Harris v. Harris, 2012 U.S. Dist. LEXIS 58147 (E.D. Cal. Apr. 24, 2012)). As a result, Defendants claim, they do not have "sufficient notice to determine which allegations apply to [which Defendants]." El Dorado Mot. at 13:11-12.

Harris, held that a "[p]rolix, confusing" complaint did not give fair notice to each defendant where it named "a laundry list of defendants" and alleged that "'the defendants' engaged in

certain conduct, making no distinction among the[m][.]" 2012 U.S. Dist. LEXIS 58147, at *25, *29. The court noted that it would have been impossible for each defendant to have actually engaged in the alleged acts. Id. at *27 ("[G]eographic and temporal realities make plain that all defendants could not have participated in every act complained of.") (quoting Magluta v. Samples, 256 F.2d 1282, 1284 (11th Cir. 2001)) (quotation marks omitted).

Unlike the Harris complaint, the SAC here provides adequate notice; it makes clear each defendant's role. Namely, as described above, the SAC explains how the SDV billing happened, who did it and/or directed it, and how the billing practices violated the rules. And unlike the Harris plaintiff, Relator has sued defendants who each could have played – and allegedly did play – a role in the billing practices. The allegations provide adequate notice and so Defendants' argument fails.

3. CMS Non-enforcement Instruction

The Court now turns to the merits of Defendants' 12(b)(6) arguments. Both sets of Defendants contend that they could not have violated Medicare's physician supervision requirements because the hospital was exempt as a matter of law. Specifically, Defendants point to guidance from the Centers for Medicare and Medicaid Services ("CMS") that "small rural hospitals" need not comply with supervision requirements. The parties agree that CMS renewed this directive yearly in the time period relevant to the complaint.

But the parties disagree about whether Marshall qualifies as either "small" or "rural." The parties put forth several

different authorities defining these terms. Defendants first argue that Marshall is rural under 42 U.S.C. section 1395ww(d)(8)(E), because that statute recognizes California's designation of the hospital as "rural." Marshall Mot. at 5; El Dorado Mot. at 5. Relator argues that California's designation does not automatically apply to the Medicare context and directs the Court to regulations that discuss the term "rural." See Opp. to El Dorado at 5-6 (citing 42 C.F.R. §§ 412.64(b), 419.43(g)(1)).

CMS "define[s] 'small rural hospital' for the notice of nonenforcement of direct supervision" as "hospitals with 100 or fewer beds and either geographically located in a rural area or paid under the hospital [Outpatient Prospective Payment System, "OPPS"] with a rural wage index[.]" 76 Fed. Reg. 74122, 74363-64. This is "the same definition of small rural hospital that Congress recognizes for [Transitional Outpatient Payments, "TOPs"] under section 1833(t)(7) of the [Social Security] Act [codified at 42 U.S.C. § 1395*l*]." Id. Section 1395*l* considers a hospital to be "rural" if it is "being treated as being located in a rural area under [42 U.S.C.] section 1395ww(d)(8)(E)[.]" 42 U.S.C. § 1395*l*(t)(16)(A). Section 1395ww(d)(8)(E) in turn designates a hospital "rural" if the state so designates it. 42 U.S.C. § 1395ww(d)(8)(E)(ii)(II). But, as Relator points out, to receive this federal designation, the hospital must submit an "application." 42 U.S.C. § 1395ww(d)(8)(E)(i).

Defendants here provided a judicially noticed document indicating that California considers Marshall to be rural. See

Marshall RJN Exh. 1. Yet they have provided no evidence that they made any application, or that the federal government had otherwise designated Marshall a rural hospital during the relevant period. As a result the Court denies Defendants' request that it find as a matter of law at this early stage of the proceedings that Marshall was "rural" for Medicare purposes and therefore exempt from the supervision requirements as a "small rural hospital."

The Court need not, and does not, reach the parties' further disagreements about how to count the number of beds, whether the Court could invalidate CMS's non-enforcement guidance, and whether lack of supervision was "material" despite this guidance.

4. Applicability of Direct Supervision Requirements

Defendants next argue that even if Marshall was not exempt as a small rural hospital, they need not have complied with the requirements for various other reasons. First, the Marshall Defendants argue that the direct supervision requirements do not apply to them because the Center is "an outpatient department" and therefore "is not subject to [42 C.F.R. § 410.26]." Marshall Mot. at 6:13-14. Defendants cite no authority for this proposition, but indicate that section 410.27 applies instead. Defendants also contend that the direct supervision requirements did not become a condition of payment for Medicare until 2010 and that Medi-Cal never required direct supervision. El Dorado Mot. at 4; Marshall Mot. at 9-10. Each argument is unpersuasive.

Defendants' first argument fails, even assuming that they

are correct that section 410.27, not 410.26, applies. Indeed, section 410.27 also requires "direct supervision" as the default supervision level. See 42 C.F.R. § 410.27(a)(1)(iv) ("Medicare Part B pays for . . . services and supplies . . . if [] [t]hey are furnished . . . [u]nder [] direct supervision . . . ."). This regulation allows only "[c]ertain therapeutic services and supplies" to be rendered under a "lower level" of supervision. 42 C.F.R. § 410.27(a)(1)(iv)(B).

Defendants appear to argue that the procedures referenced in the complaint are among these services permitted under lower level supervision. See Marshall Mot. at 6-7. Defendants rely on Exhibit 8 of their request for judicial notice, entitled "Hospital Outpatient Therapeutic Services That Have Been Evaluated for a Change in Supervision Level." Defendants point to numerous procedures listed as "General" or "NSEDTS" in the column entitled "CMS Decision." See Marshall Mot. at 7.

Two problems arise from Defendants' reliance on this document. First, for the Court to dismiss the SAC pursuant to Defendants' theory, the Court would have to find that each procedure referenced in the SAC appears on this list. It would further have to determine what level of supervision was actually achieved for each procedure alleged in the SAC. But which procedures were performed at Marshall in the relevant period and what level of supervision was achieved are factual questions that cannot be resolved at the motion to dismiss stage.

A second problem is that the "Effective Dates" in the document are between 2012 and 2014. The supervision level during 2012 through 2014 is irrelevant to the SAC's alleged

wrongdoing, which occurred in 2011 and before. The Court therefore declines Defendants' invitation to adjudicate the direct supervision claims on this basis.

Turning to Defendants' next argument, the Physician and El Dorado Defendants state that any alleged failure to supervise prior to 2010 is not actionable because the direct supervision requirement was "only made a condition of payment in the 2010 [OPPS] Final Rule, which applies only to services furnished on or after January 1, 2010." El Dorado Reply at 4:15-17. Defendants cite 75 Fed. Reg. 71800, 71999-2000. However, this Federal Register section in fact states that the 2010 amendments to the regulations only "reiterated" the already existing physician supervision requirements. Id. at 71999. Indeed, these supervision requirements have been a condition of payment since 2000. See id. at 72010 (discussing "payment regulations requiring direct supervision for payment of outpatient services"); 65 Fed. Reg. 18434, 18524 (Apr. 7, 2000) (discussing requirement that outpatient services "must be [rendered] under the direct supervision of a physician" under the heading "Requirements for Payment"). The Court therefore denies Defendants' motion as to any pre-2010 violations of the Medicare supervision requirement alleged in the SAC.

Finally, the Marshall Defendants argue that Medi-Cal did not require direct supervision. Marshall Mot. at 8-9. Relator responds that all Medi-Cal providers agree to comply with the Medi-Cal Provider Manuals, which explicitly state that the procedures are only reimbursable if done by a physician or under direct supervision. Opp. to Marshall at 6. Defendants' reply

does not confront the Provider Manual statements, but instead argues that CMS's non-enforcement directive would preempt any state agency rules. Marshall Reply at 2-3.

Relator is correct that Medi-Cal conditions payment on direct supervision. The SAC alleges that Defendants were Medi-Cal providers. SAC ¶¶ 10, 13. As Medi-Cal providers, Defendants agreed to comply with the Medi-Cal Provider Manuals. Relator's RJN (Doc. #58) Exh. 1 ¶ 23 ("Provider and any billing agent agree that it shall comply with all the requirements set forth in the Welfare and Institutions Code and its implementing regulations, and the Medi-Cal Provider Manuals . . . ."). The Manuals provide in part that chemotherapy infusions, such as those discussed in the complaint, "are reimbursable only when performed by a physician or by a qualified assistant under a physician's direct supervision." Id. Exh. 2 at 2 (emphasis in original). Defendants were therefore required to provide direct supervision in order to bill the services to Medi-Cal.

The Court does not consider Defendants' argument that the non-enforcement directive preempts the Provider Manual, because, as discussed above, the directive does not apply to Defendants.

5. Knowledge of Falsity

Both sets of Defendants argue that the SAC does not plead the requisite scienter for liability under the FCA or CFCA. Marshall Mot. at 11, 14-15; El Dorado Mot. at 8-12. The Physician and El Dorado Defendants take the more extreme position, arguing that they cannot be liable because they "reasonably believed" that they were acting in compliance with the relevant statutes and regulations. El Dorado Mot. at 9.

Relator counters that the SAC's facts plausibly show that Defendants were at least reckless with regard to the truth of the claims submitted. Opp. at El Dorado at 10.

Relator is correct. The FCA establishes liability for a person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of subparagraph (A) [or] (B) . . . .

31 U.S.C. § 3729(a). The Act defines "knowingly" as having "actual knowledge of the information" or "act[ing] in deliberate ignorance of" or "in reckless disregard for the truth or falsity of the information[.]" 31 U.S.C. § 3729(b)(1)(A). This scienter element "require[s] no proof of specific intent to defraud[.]" 31 U.S.C. § 3729(b)(1)(B). Rather, "[t]he requisite intent is the knowing presentation of what is known to be false." Wang v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992). An innocent or negligent mistake is not "knowing" conduct. Id.

Defendants rely on Gonzalez v. Planned Parenthood, 759 F.3d 1112 (9th Cir. 2014), petition for cert. docketed (Mar. 6, 2015), in support of their theory that the existence of their alternative but "reasonable" interpretation of the guidelines precludes any knowing violation. See El Dorado Mot. at 9-10. But, as Relator points out, Gonzalez's facts are distinguishable and the holding does not apply here. In Gonzalez, the defendant

had openly communicated with the state agency about its billing practices and the agency had never made any indication that those billing practices were illegal. 759 F.3d at 1115. The agency had even commented that the billing guidelines were "conflicting, unclear, or ambiguous." Id. at 1116. These facts, the court concluded, could not support a claim of knowing falsity. Id.

Here, in contrast, neither the SAC nor any judicially noticed facts show that Defendants ever discussed their billing practices with a government agency or received any sort of governmental approval of their actions. Nor do the allegations indicate that the regulations were at all ambiguous. To the contrary, the SAC alleges that several people familiar with the Medicare and Medi-Cal guidelines researched the issues and all came to the same, unanimous conclusion: that Defendants' practices violated those guidelines. See, e.g., SAC ¶¶ 64-65 (Relator regarding supervision), 67 (Vice President of Specialty Care Services regarding supervision), 68-69, 75, 77-78, 81 ("compliance officer" regarding supervision), 83 (Chief Operating Officer regarding supervision), 92 (Relator regarding SDV use and billing), 95 ("pharmacy management" regarding SDV use and billing), 97 (Director of Physician Clinical Billing regarding SDV use and billing), 99-101 (Director of Physician Clinical Billing regarding blood transfusion visits). And the SAC does not show that the physicians engaged in a legitimate difference of interpretation. Instead, the SAC portrays them as ignoring their colleagues' concerns and summarily dictating that the status quo would continue. See, e.g., SAC ¶¶ 65 ("Dr. Soe openly and loudly objected to Realtor's comments and the auditor's

findings, arguing that physicians did not need to be present or available and that he and Dr. Tsai had been practicing in that manner for years . . . ."), 72 ("Defendant Dr. Soe stated . . . 'We'll . . . just do what they want until the fire dies down and then return to the way we've always practiced.'"), 79 ("[Drs. Soe and Tsai stated in an email:] 'We will be open for discussing physician coverage when the infusions clinic starts treating larger numbers of patients[.]'"), 101 ("Dr. Soe responded that even though he did not visit the patient, he was on call . . . and that he was not going to remain on call if he was not getting paid for it because 'it was not worth it.' Dr. Soe . . . [gave] no indication that he intended to stop the practice of illegally billing . . . [and] objected to self-reporting and refunding the money."). The SAC thus does not show Defendants' reasoned interpretation, but instead their hasty rejection of unambiguous billing rules.

As to the Marshall Defendants' position on scienter, they argue that they were unaware that billing certain codes for blood transfusions without a physician visit was improper. Marshall Mot. at 14-15. Defendants assert that they only "discover[ed]" that the practice was illegal during a November 2011 meeting, such that any false billing before that time was not "knowing." Id. Relator responds that hospital employees knew of the guidelines before the meeting, and that that knowledge should be imputed to the Marshall Defendants. Opp. to Marshall at 14-15.

Defendants' assertion that they had no way of knowing about the proper billing practices cannot, at this stage of the

proceedings, be taken as true. Moreover, "[p]articipants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment." United States v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001) ("[Defendant's] claim that he did not know of the Medicare requirements does not shield him from liability. By failing to inform himself of those requirements . . . he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question."). Defendants, as participants in Medicare and Medi-Cal, were charged with the knowledge of proper billing practices; the timing of an internal meeting where one of Marshall's employees discussed the billing practices does not change Defendants' responsibilities.

For these reasons, the Court denies Defendants' motions on the scienter issue.

6. SDV Allegations

The Marshall Defendants' final bases for dismissal are that the SDV billing was proper and that any misuse of the vials was not a condition of payment. Marshall Mot. at 9-14. Both these arguments fail.

a. Propriety of Defendants' SDV Billing Practices

Defendants argue that the allegations do not show double billing of "waste," but rather "rounding up" in compliance with Medicare guidelines. Marshall Mot. at 9-10. This billing was proper, according to Defendants, because they "made no representation . . . that any drug was wasted or discarded when

[Defendants] allegedly billed for the [] units administered [and] rounded up" and then used the remaining drug in the vial on another patient. Marshall Mot. at 10:22-23.

Defendants' argument is unpersuasive, because the Court must take as true the allegations that Defendants billed non-discarded drugs "as 'waste.'" See SAC ¶¶ 29, 58, 108-113. The Court must also accept the allegations that instead of discarding expired portions of SDVs as waste (and billing them as such), Defendants pooled these portions and billed them to other patients. See SAC ¶¶ 59-60, 114-116.

Both of these practices are contrary to CMS guidance. CMS specifies that in addition to billing the amount of a drug administered to a patient, "[a] modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. . . . Th[is] JW modifier is only applied to the amount of the drug or biological that is discarded." CMS Transmittal 1962, "Discarded Drugs and Biologicals Update" (Apr. 30, 2010), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1962cp.pdf. Medicare pays for drugs billed with this modifier only if the amount is "actually [] discarded and [] not [] used for another patient . . . ." Marshall RJN Exh. 9 at 4.

Similarly, a provider may only bill an expired or otherwise unusable portion of an SDV as waste; the provider may not bill it to another patient. Id. at 3-4. Whether Defendants in fact used the JW modifier for waste and whether the drugs were in fact expired or unusable cannot be resolved on this motion to dismiss. These arguments for dismissal therefore fail.

Given that Relator's allegations demonstrate improper billing, the Court does not reach her further argument that even if Defendants rounded up instead of billing as waste, their conduct would still violate the regulations. See Opp. to Marshall at 8-9.

b. Safety of Drugs As Condition of Payment

The Court turns next to the issue of whether use of pooled, expired, and contaminated drugs contravened any condition of payment. Defendants argue that Relator has not stated a claim because the statutes and regulatory provisions they allegedly violated by mishandling SDVs were not conditions of payment under Medicare or Medi-Cal. Marshall Mot. at 11-14; Marshall Reply at 3-5 (citing United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996), Ebeid ex rel. United States, 616 F.3d 993, and several out-of-circuit cases). Defendants' briefs point to several paragraphs of the SAC that cite FDA and CDC regulations. See id.

Defendants are correct that an FCA claim can stand only where a defendant made the false statement about a condition of payment. Ebeid ex rel. United States, 616 F.3d at 996-98 (distinguishing conditions of payment from conditions of program participation). But Defendants' argument nonetheless fails because Relator bases her claims on 42 U.S.C. sections 1395n, 1395y(a)(1)(A), and 22 C.C.R section 51305. See SAC ¶¶ 20, 45. Each of these sections describes conditions of payment. See 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under part A or part B of this subchapter for any expenses incurred for items or services . . . [unless conditions listed are met]."); 42

U.S.C. § 1395n(a) ("[P]ayment for services described in section 1395k(a)(2) of this title furnished an individual may be made . . . only if [conditions listed are met]."); 22 C.C.R. § 51305(a) ("Outpatient physician services are covered if [conditions listed are met]."); see Ebeid ex rel. United States, 616 F.3d at 996-98 (explaining that claims for payment that failed to comply with such statutes are actionable under the FCA as an "implied false certification" theory). That the SAC discusses other agency guidance beyond these statutes and regulations does not invalidate Relator's claims.

Defendants further argue that even if Relator bases her claims on statutes setting out conditions of payment, mishandling SDV drugs did not violate any of the enumerated conditions. Marshall Mot. at 12 n.9; Marshall Reply at 3-5. Relator asserts that the contamination and misuse of SDVs violated the condition that a drug be "reasonable and necessary." Opp. to Marshall at 9-12.

Relator is correct. Section 1395y of Title 42 provides that a drug must be "reasonable and necessary" to be covered by Medicare. See 42 U.S.C. § 1395y(a)(1)(A). Medi-Cal uses similar language, requiring any covered drugs to be "medically necessary." 22 C.C.R. § 51305(a). CMS defines the term "reasonable and necessary" to include a requirement that the drug be "safe and effective." Medicare Benefit Policy Manual Ch. 15 § 50.4.1; 54 Fed. Reg. 37239, 37240. A drug is not "reasonable and necessary for the individual patient" if its method of administration falls below the established medical standard. See Medicare Benefit Policy Manual Ch. 15 § 50.4.3 (providing

"examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice[,]" including when a medication is "given by injection . . . [but] administration . . . by mouth [] is effective and is an accepted or preferred method of administration"); accord Friedrich v. Sec'y of Health & Human Servs., 894 F.2d 829, 831 (6th Cir. 1990) (stating the agency's position that the "reasonable and necessary" standard is concerned with "the method of dealing with FDA-approved drugs") (emphasis in original); cf. United States ex rel. Hopper, 91 F.3d at 1266 ("FCA actions have [] been sustained under theories of supplying substandard products or services.") (citing United States v. Aerodex, Inc., 469 F.2d 1003 (5th Cir. 1972)); United States ex rel. Ruhe v. Masimo Corp., 929 F. Supp. 2d 1033, 1036 (C.D. Cal. 2012) ("Requesting payment for defective or goods of lesser quality can constitute a cognizable FCA claim.").

Relator alleges that expired drugs were mixed with viable drugs, such that the resulting "cocktail" was contaminated and thus "improperly billed[.]" SAC ¶¶ 60, 114-116. Contamination and expiration allegedly rendered the drugs unsafe. See SAC ¶¶ 33, 53, 59, 60, 93, 95; Relator's RJN (Doc. #58) Exh. 9 at 4 (describing FDA-approved method for administering avastin, including the direction to "[d]iscard any unused portion left in a vial, as the product contains no preservatives"). An unsafe procedure is not reasonable and necessary. Cf. United States ex rel. Ruhe, 929 F. Supp. 2d at 1037 ("The use of a 'dangerously inaccurate' test would not be a reasonable and necessary procedure . . . ."). The Court therefore concludes that

Defendants' alleged administration of unsafe drugs violated sections 42 U.S.C. section 1395y(a)(1)(A) and 22 C.C.R. section 51305(a).

Defendants cite numerous other cases, none of which controls or directly addresses reasonableness and necessity in these circumstances. Defendants first cite Mikes, 274 F.3d at 698, for the proposition that "medical necessity relates to the level of care indicated and 'does not impart a qualitative element mandating a particular standard of medical care.'" Marshall Mot. at 12 n.9. In Mikes, the Second Circuit held that failure to comply with a regulation mandating frequent calibration of an instrument for measuring force of exhalation did not implicate the medical necessity of that pulmonary test for Medicare purposes. 274 F.3d at 698. The Mikes plaintiff did not argue that the calibration problem rendered the test dangerous in any way and the court noted that its holding may be different if the procedure was unsafe. See id. ("[T]he requisite level of medical necessity may not be met where . . . a particular procedure was deleterious or performed solely for profit, or where a party seeks reimbursement for a procedure that is not traditionally covered[.]") (citations omitted).

Here, unlike Mikes, Relator alleges that Defendants' practices rendered the drugs actively harmful to the patients. Mikes holding is therefore inapplicable to this case, and that court's dicta in fact supports Relator's theory that an unsafe procedure is not medically necessary.

Defendants cite two further cases, both of which are distinguishable. In particular, the relators in both cases

alleged that a defendant (a pharmaceutical producer and a pharmaceutical repackager, respectfully) violated FDA regulatory requirements governing production and packaging of drugs. See United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694, 697 (4th Cir. 2014); United States ex rel. Campie v. Gilead Sciences, Inc., 2015 WL 106255, at *1-*2 (N.D. Cal. Jan. 7, 2015). Both courts dismissed the claims because compliance with FDA regulations is not a condition of payment under Medicare. See United States ex rel. Rostholder, 745 F.3d at 702; United States ex rel. Campie, 2015 WL 106255, at *8. But here, as discussed above, Relator's claims adequately state a condition of payment under 42 U.S.C. section 1395y(a)(1)(A) and 22 C.C.R. section 51305(a). These cases are therefore inapplicable.

Because the SAC sufficiently states a claim for implied false certification, the Court does not consider whether the same allegations state a claim for worthless services.

III. ORDER

For the reasons set forth above, the Court dismisses Defendant Foundation without prejudice and dismisses claims VII through X against the Physician and El Dorado Defendants with prejudice. The Court DENIES both motions on all other grounds. Defendants' answers to the SAC are due within twenty (20) days from the date of this Order.

IT IS SO ORDERED.

Dated: May 11, 2015

JOHN A. MENDEZ,
UNITED STATES DISTRICT JUDGE