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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

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UNITED STATES OF AMERICA, et al.,  
Plaintiffs,  
v.  
MCKESSON CORPORATION,  
Defendant.

Case No. 19-cv-02233-DMR

**ORDER ON DEFENDANT'S MOTION  
TO DISMISS**

Re: Dkt. No. 40

Qui tam plaintiffs and relators Carl Kelley and Michael McElligott filed this action on behalf of the United States against Defendant McKesson Corporation (“McKesson”), alleging a claim for violation of the False Claims Act (“FCA”), 31 U.S.C. § 3729 et seq. Relators amended the complaint once as of right before McKesson appeared. [Docket No. 11 (“FAC”).] McKesson now moves to dismiss the FAC under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. [Docket Nos. 40 (“Mot.”), 50 (“Reply”).] Relators timely opposed.<sup>1</sup> [Docket No. 45 (“Opp.”).] The court held a hearing on June 23, 2020.

For the reasons stated below, the motion is granted.

**I. BACKGROUND**

The following facts are alleged in the FAC or are subject to judicial notice. McKesson is “one of the largest distributors of drugs throughout the United States.” FAC ¶ 2. Kelly was employed by McKesson from 2001 to 2017. Id. ¶ 5. From 2006 until 2017, he served as a senior IT Distribution manager for McKesson’s national pharmaceutical distribution centers. Id. He also provided technology assistance to McKesson’s former CEO John Hammergren and other senior

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<sup>1</sup> Relators also filed an administrative motion to file a sur-reply. [Docket No. 54.] They offer three reasons in support of their request. The first two reasons relate to the public disclosure bar argument. As explained below, the public disclosure bar does not apply to Relators’ FCA claim and so further argument from Relators on that point is unnecessary. The third reason relates to McKesson’s argument on materiality. The court does not reach the issue of materiality in this order because Relators have not adequately pleaded the other elements of their claim. Accordingly, the administrative motion to file a sur-reply is denied as moot.

1 members of McKesson. *Id.* McElligott worked for McKesson from 1999 until 2009, providing  
2 personal security for Hammergren. *Id.* ¶ 6.

3 McKesson operates 35 distribution centers (“DC”) located throughout the United States.  
4 FAC ¶ 10. Among other drugs, McKesson distributes narcotic opioids, including morphine,  
5 hydrocodone, oxycodone, and fentanyl. *Id.* ¶ 2. The United States Drug Enforcement  
6 Administration (“DEA”) classifies these drugs under Schedule II, which indicates a “high potential  
7 for abuse, with use potentially leading to severe psychological or physical dependence.” *Id.* (citation  
8 omitted). Relators allege that, in their time working for McKesson, they “personally witnessed  
9 evidence of lack of security at DCs, and other corporate facilities,” which “allow for the easy theft  
10 of products in the supply chain, including Schedule II opiates.” *Id.* ¶¶ 7, 10. According to Relators,  
11 other McKesson employees have confirmed that McKesson lacks adequate security to prevent theft  
12 in the supply chain. *Id.* ¶ 7.

13 In 2006, McKesson hired a security expert named John Tippit to review McKesson’s  
14 security procedures. FAC ¶ 11. Relators allege that Hammergren “expressly told Tippit not to  
15 investigate inventory of Schedule II drugs,” apparently because such investigation would have  
16 “created evidence that McKesson knew that Schedule II drugs were being stolen from McKesson’s  
17 DCs.” *Id.* According to Relators, Tippit was able to access secured areas within McKesson’s DCs,  
18 including areas where Schedule II opioids were stored. *Id.* Relators claim that Tippit found  
19 “numerous security lapses at McKesson’s DCs, many of which remain today . . . .” *Id.* Tippit made  
20 several recommendations to improve security at the DCs, but McKesson failed to implement most  
21 of them due to the cost. *Id.*

22 In 2008 and 2017, McKesson entered into settlement agreements with the United States  
23 Department of Justice (“DOJ”) and the DEA regarding McKesson’s alleged failure to identify and  
24 report suspicious orders of opioids (“the Agreements”). FAC ¶ 12; see also Docket Nos. 42-1  
25 (“2008 Agreement”), 42-2 (“2017 Agreement”).<sup>2</sup> The 2008 Agreement required McKesson to

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26 <sup>2</sup> The court takes judicial notice of the Agreements and related documents (Exhibits 1-4 to  
27 McKesson’s Request for Judicial Notice (“RJN”)) because they are matters of public record and  
28 relevant to the issues in this order. See Fed. R. Evid. 201; *Lee v. City of Los Angeles*, 250 F.3d 668,  
689 (9th Cir. 2001). McKesson’s RJN is otherwise denied as moot because the documents listed  
therein are not relevant to the court’s decision.

1 develop a Controlled Substance Monitoring Program (“CSMP”). See 2017 Agreement at 3.  
2 Relators attached to the complaint a printout from McKesson’s website that describes the CSMP.  
3 FAC, Ex. A. Some features of the CSMP include an “experienced compliance team,” analysis of  
4 prospective pharmacy customers, monitoring of orders for potential diversion, regular reporting of  
5 suspicious orders, a “tightly controlled physical supply chain,” training employees and customers  
6 on compliance with DEA and state agency regulations, and participation in state and federal  
7 legislative efforts around controlled substances. Id.

8 Despite the Agreements and the development of the CSMP, McKesson allegedly continues  
9 to allow opportunities for unlawful diversion of controlled substances through failing to implement  
10 adequate security protocols. For example, in one DC, “the entire on-duty security staff . . . consisted  
11 of one absentee manager who traveled extensively, borrowed assistance from the facilities team who  
12 are not trained or qualified to perform security work, a small contingency of contracted security  
13 workers instructed only to check badges, and a single security guard at the entrance to the DC.”  
14 FAC ¶ 12. Relators highlight several points in the supply chain where opportunities for diversion  
15 arose, including at the truck loading dock and during storage. Id. Allegedly, Hammergren once  
16 told McElligott that “[the product] comes in and goes out so fast, we don’t know where it is.” Id. ¶  
17 10. McKesson’s failure to correct known security flaws allegedly “contribut[es] to the pandemic  
18 of opioid abuse in the United States,” which is a recognized public health crisis. Id. ¶ 2.

19 Relators allege that McKesson has violated the Comprehensive Drug Abuse Prevention and  
20 Control Act of 1970, 21 U.S.C. §§ 801 et seq. (“CSA”) and its implementing regulations by failing  
21 to adopt security measures that adequately prevent diversion of Schedule II opioids. FAC ¶ 16.  
22 Relators’ FCA claim is premised on McKesson’s alleged failure to disclose its CSA violations to  
23 the federal government when submitting claims for payment under various federal programs.

24 **II. LEGAL STANDARDS**

25 **A. Rule 12(b)(6)**

26 A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the claims alleged in  
27 the complaint. See *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). When  
28 reviewing a motion to dismiss for failure to state a claim, the court must “accept as true all of the

1 factual allegations contained in the complaint,” *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (per  
2 curiam) (citation omitted), and may dismiss a claim “only where there is no cognizable legal theory”  
3 or there is an absence of “sufficient factual matter to state a facially plausible claim to relief.”  
4 *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1041 (9th Cir. 2010) (citing *Ashcroft*  
5 *v. Iqbal*, 556 U.S. 662, 677-78 (2009); *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001))  
6 (quotation marks omitted). A claim has facial plausibility when a plaintiff “pleads factual content  
7 that allows the court to draw the reasonable inference that the defendant is liable for the misconduct  
8 alleged.” *Iqbal*, 556 U.S. at 678 (citation omitted). In other words, the facts alleged must  
9 demonstrate “more than labels and conclusions, and a formulaic recitation of the elements of a cause  
10 of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 555 (2007) (citing *Papasan v.*  
11 *Allain*, 478 U.S. 265, 286 (1986)); see *Lee v. City of L.A.*, 250 F.3d 668, 679 (9th Cir. 2001),  
12 overruled on other grounds by *Galbraith v. Cty. of Santa Clara*, 307 F.3d 1119 (9th Cir. 2002).

13 As a general rule, a court may not consider “any material beyond the pleadings” when ruling  
14 on a Rule 12(b)(6) motion. *Lee*, 250 F.3d at 688 (citation and quotation marks omitted). However,  
15 “a court may take judicial notice of ‘matters of public record,’” *id.* at 689 (citing *Mack v. S. Bay*  
16 *Beer Distrib.*, 798 F.2d 1279, 1282 (9th Cir. 1986)), and may also consider “documents whose  
17 contents are alleged in a complaint and whose authenticity no party questions, but which are not  
18 physically attached to the pleading,” without converting a motion to dismiss under Rule 12(b)(6)  
19 into a motion for summary judgment. *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994), overruled  
20 on other grounds by *Galbraith*, 307 F.3d at 1125-26. The court need not accept as true allegations  
21 that contradict facts which may be judicially noticed. See *Mullis v. U.S. Bankr. Court*, 828 F.2d  
22 1385, 1388 (9th Cir. 1987).

23 **B. Rule 9(b)**

24 Rule 9(b) requires that “[i]n alleging fraud or mistake, a party must state with particularity  
25 the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). In addition to meeting the  
26 plausibility standard of Rule 8(a), an FCA claim must be pled with particularity under Rule 9(b)’s  
27 heightened pleading standard. *United States v. Corinthian Colleges*, 655 F.3d 984, 991 (9th Cir.  
28 2011) (explaining that FCA claims implicate Rule 9(b) because they involve allegations of fraud).

1 To satisfy the Rule 9(b) standard, “a pleading must identify the who, what, when, where, and how  
2 of the misconduct charged, as well as what is false or misleading about the purportedly fraudulent  
3 statement, and why it is false.” *United States ex rel. Anita Silingo v. WellPoint, Inc.*, 904 F.3d 667,  
4 677 (9th Cir. 2018) (citation and alterations omitted). “[A]llegations of fraud must be specific  
5 enough to give defendants notice of the particular misconduct which is alleged to constitute the  
6 fraud charged so that they can defend against the charge and not just deny that they have done  
7 anything wrong.” *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (internal quotation  
8 marks and citation omitted).

9 **III. DISCUSSION**

10 The FCA imposes liability on anyone who “knowingly presents, or causes to be presented,  
11 a false or fraudulent claim for payment or approval” or “knowingly makes, uses, or causes to be  
12 made or used, a false record or statement material to a false or fraudulent claim.”<sup>3</sup> 31 U.S.C. §  
13 3729(a)(1)(A), (B). To prevail on a FCA claim, a plaintiff must show “(1) a false statement or  
14 fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the  
15 government to pay out money or forfeit moneys due.” *United States ex rel. Campie v. Gilead Scis.,*  
16 *Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (quoting *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d  
17 1166, 1174 (9th Cir. 2006)).

18 An FCA claim can proceed under either an express or implied false certification theory.  
19 Express false certification occurs when “the entity seeking payment certifies compliance with a law,  
20 rule or regulation as part of the process through which the claim for payment is submitted.” *Ebeid*  
21 *ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). By contrast, an implied false certification  
22 theory is appropriate “when an entity has previously undertaken to expressly comply with a law,  
23 rule, or regulation, and that obligation is implicated by submitting a claim for payment even though  
24 a certification of compliance is not required in the process of submitting the claim.” *Id.* “The key  
25 difference between the two is whether the entity seeking payment must certify that it has complied

26 \_\_\_\_\_  
27 <sup>3</sup> The FAC also appears to contain a conspiracy claim under 31 U.S.C. § 3729(a)(1)(C) but does not  
28 allege any facts supporting the existence of a conspiracy. See FAC ¶ 14. Relators failed to respond  
to McKesson’s argument on this point. See Mot. at 13 n. 4. Accordingly, to the extent that the FAC  
alleges a claim for conspiracy, that claim is dismissed.

1 with the applicable law, rule, or regulation each time a claim is made, or if that certification is made  
2 initially and later implied with each subsequent claim.” United States ex rel. Armstrong-Young v.  
3 Carelink Hospice Servs., Inc., Case No. 15-cv-04095-WHO, 2018 WL 4773111, at \*2 (N.D. Cal.  
4 Oct. 1, 2018).

5 In order to state a claim for relief under an implied certification theory, a plaintiff must plead  
6 two essential elements: (1) that “the claim does not merely request payment, but also makes specific  
7 representations about the goods or services provided”; and (2) “the defendant’s failure to disclose  
8 noncompliance with material statutory, regulatory, or contractual requirements makes those  
9 representations misleading half-truths.” Universal Health Servs., Inc. v. United States ex rel  
10 Escobar, 136 S. Ct. 1989, 2001 (2016). On their own, “[m]ere regulatory violations do not give rise  
11 to a viable FCA action.” U.S. ex rel. Hopper v. Anton, 91 F.3d 1261, 1267 (9th Cir. 1996). Instead,  
12 “[i]t is the false certification of compliance which creates liability when certification is a  
13 prerequisite to obtaining a government benefit.” Id. at 1266 (emphasis in original).

14 In this case, Relators are relying on an implied certification theory. See FAC ¶ 14. They  
15 assert that McKesson submitted claims for payment to the federal government while failing to  
16 disclose that they were not in compliance with the CSA. Id. ¶ 16. Defendants argue that Relators  
17 have failed to adequately allege that (1) McKesson made false statements about its compliance with  
18 the CSA; (2) that McKesson submitted any claims for payment to the U.S. government; or (3) that  
19 the alleged false statements were material to the government’s payment of any claim. They also  
20 assert that Relators’ claims are prohibited by the public disclosure bar.

21 **A. Falsity**

22 The complaint alleges that McKesson submitted claims for payment under various federal  
23 programs but failed to disclose that it was not in compliance with the CSA. CSA regulations apply  
24 to “[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled  
25 substance,” or proposes to do so, “unless exempted by law” or other regulations. 21 U.S.C. §  
26 1301.11(a). McKesson does not dispute that it is required to comply with CSA regulations. In order  
27 to plead that McKesson made any misrepresentations or misleading omissions about its CSA  
28 compliance, Relators first must adequately plead that McKesson was in fact not compliant with CSA

1 regulations.<sup>4</sup>

2 According to Relators, McKesson violated various CSA regulations, including 21 C.F.R. §  
3 1307.71(a) (requiring entities registered under the CSA to “provide effective controls and  
4 procedures to guard against theft and diversion of controlled substances”); 21 C.F.R. § 1301.72(d)  
5 (requiring that controlled substances storage areas to be accessible “only to an absolute minimum  
6 number of specifically authorized employees”); 21 C.F.R. § 1301.74(c) (requiring registrants to  
7 notify the DEA, “in writing, of any theft or significant loss of any controlled substances within one  
8 business day of discovery of the theft or loss”); and 21 C.F.R. § 1304.11(a), (e) (requiring registrants  
9 to keep a “complete and accurate record of all controlled substances on hand the date the inventory  
10 is taken”). McKesson argues that Relators’ claim boil down to a subjective opinion that McKesson’s  
11 security “could have been better” without identifying specific violations. Mot. at 1, Reply at 5.

12 Relators have not adequately alleged that McKesson violated any regulations or made false  
13 representations about its compliance with the CSA. The CSA safety regulations do not always  
14 require strict compliance, and “[s]ubstantial compliance . . . may be deemed sufficient by the [DEA]  
15 after evaluation of the overall security system and needs of the applicant or registrant.” 21 C.F.R.  
16 § 1301.71(b). Section 1301.71(a) does not require any specific security measures and instead grants  
17 the Administrator discretion to decide whether a facility is substantially compliant with the CSA,  
18 considering any of fifteen different factors in evaluating a particular registrant.<sup>5</sup> Moreover, similar

19 \_\_\_\_\_  
20 <sup>4</sup> Relators also claim that McKesson has breached certain terms of the 2017 Agreement. They  
21 confirmed at the hearing that their FCA claim is not premised on conduct covered by the  
22 Agreements, including McKesson’s alleged failure to vet potential customers and report suspicious  
23 orders. See also Opp. at 14 n. 7.

24 <sup>5</sup> The factors include:

- 25 (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing  
26 dosage forms, packaging, labeling, cooperative buying, etc.);
- 27 (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage  
28 units, usable powders or nonusable powders);
- (3) The quantity of controlled substances handled;
- (4) The location of the premises and the relationship such location bears on security  
needs;
- (5) The type of building construction comprising the facility and the general  
characteristics of the building or buildings;
- (6) The type of vault, safe, and secure enclosures or other storage system (e.g.,  
automatic storage and retrieval system) used;

1 security measures may be deemed sufficient at some facilities and inadequate at others. See 21  
2 C.F.R. § 1301.71(e) (“Any new facilities or work or storage areas constructed or utilized for  
3 controlled substances. . . shall not necessarily be deemed to comply substantially . . . notwithstanding  
4 that such facilities or work or storage areas have physical security controls similar to those  
5 previously approved by the Administration.”).

6 The Ninth Circuit has held that when the statutory or contractual requirement underlying an  
7 FCA claim contains “imprecise and discretionary language,” there is only a “disputed legal issue”  
8 rather than an objective statement of fact that can be deemed “false” under the FCA. Hagood v.  
9 Sonoma Cty. Water Agency, 81 F.3d 1465, 1477 (9th Cir. 1996) (finding that a statute that granted  
10 the government “fairly wide discretion” could not support a claim that a FCA defendant made a  
11 false statement), abrogated on other grounds by United States ex rel. Hartpence v. Kinetic Concepts,  
12 Inc., 792 F.3d 1121 (9th Cir. 2015); see also U.S. ex rel. Lamers v. City of Green Bay, 168 F.3d  
13 1013, 1018 (7th Cir. 1999) (“[I]mprecise statements or differences in interpretation growing out of  
14 a disputed legal question are . . . not false under the FCA.”); U.S. ex rel. Wilson v. Kellogg Brown  
15 & Root, Inc., 525 F.3d 370, 378 (4th Cir. 2008) (“An FCA relator cannot base a fraud claim on  
16 nothing more than his own interpretation of an imprecise contractual provision.”). The Ninth Circuit  
17 later affirmed that statutes and regulations subject to discretionary interpretation by the government

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- 19 (7) The type of closures on vaults, safes, and secure enclosures;
  - 20 (8) The adequacy of key control systems and/or combination lock control systems;
  - 21 (9) The adequacy of electric detection and alarm systems, if any including use of
  - 22 supervised transmittal lines and standby power sources;
  - 23 (10) The extent of unsupervised public access to the facility, including the presence
  - 24 and characteristics of perimeter fencing, if any;
  - 25 (11) The adequacy of supervision over employees having access to manufacturing
  - 26 and storage areas;
  - 27 (12) The procedures for handling business guests, visitors, maintenance personnel,
  - 28 and nonemployee service personnel;
  - (13) The availability of local police protection or of the registrant’s or applicant’s
  - security personnel;
  - (14) The adequacy of the registrant’s or applicant’s system for monitoring the
  - receipt, manufacture, distribution, and disposition of controlled substances in its
  - operations; and
  - (15) The applicability of the security requirements contained in all Federal, State,
  - and local laws and regulations governing the management of waste.

21 C.F.R. § 1301.71(b).



1 do not support a finding of falsity under the FCA. See *United States ex rel. Oliver v. Parsons Co.*,  
2 195 F.3d 457, 463 (9th Cir. 1999) (distinguishing *Hagood* on the grounds that “this case involves  
3 regulations that, while unquestionably technical and complex, are not discretionary”). In this case,  
4 Relators do not identify specific conduct by McKesson that constitutes a violation of the CSA  
5 regulations. For example, Relators allege that McKesson’s DC in Olive Branch has only one  
6 security worker at the entrance, but they do not point to a provision specifying the number of security  
7 personnel required.<sup>6</sup> Nor have Relators explained how the court could find that such a violation or  
8 others alleged in the FAC must be construed to mean that McKesson is not in substantial compliance  
9 with the CSA under the discretionary standard of 21 C.F.R. § 1301.71. Moreover, the Supreme  
10 Court has warned that the CSA is not a “vehicle for punishing garden-variety breaches of contract  
11 or regulatory violations.” *Escobar*, 136 S. Ct. at 2003. “Mere regulatory violations” can be  
12 addressed through the administrative process or other avenues. *Hopper*, 91 F.3d at 1267. In this  
13 case, as currently pleaded, the determination of whether violations occurred and thus whether  
14 McKesson made false certifications to obtain payment on claims turns on a regulation that the  
15 government has broad discretion to interpret. This is a significant indicator that Relators’ claim is  
16 not of the kind the FCA is meant to address.

17 In their opposition, Relators assert that McKesson made other false certifications that are not  
18 alleged in the complaint.<sup>7</sup> See *Opp.* at 3, 10. McKesson’s contract with the Department of Veterans  
19 Affairs (“VA”), for example, requires McKesson “to comply with all applicable Federal, State, and  
20 local laws, executive orders, rules and regulations applicable to its performance” under the contract.  
21 [Docket No. 46, Ex. B, Pharmaceutical Prime Vendor Contract with the Department of Veterans  
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23 <sup>6</sup> At the hearing, Relators also pointed to the representations McKesson makes on its website  
24 regarding its CSMP. However, even if Relators are correct that these statements can be proven to  
25 be false, they must still allege how McKesson’s conduct violates the CSA.

26 <sup>7</sup> The court may not rely on allegations that do not appear in the complaint to decide a Rule 12(b)(6)  
27 motion. See *Schneider v. California Dep’t of Corr.*, 151 F.3d 1194, 1197 n. 1 (9th Cir. 1998) (“In  
28 determining the propriety of a Rule 12(b)(6) dismissal, a court may not look beyond the complaint  
to a plaintiff’s moving papers, such as a memorandum in opposition to a defendant’s motion to  
dismiss.”). However, even if the statements in Relators’ opposition were alleged in the FAC, they  
would be insufficient for the reasons stated herein, at least as currently pleaded.

1 Affairs (“VA Contract”) 52.212-4(q).] The VA Contract also requires McKesson to comply with  
2 certain clauses of the Federal Acquisition Regulation (“FAR”), including the Contractor Code of  
3 Business Ethics and Conduct (“Ethics Code”). VA Contract, 52.212-5(b). In turn, the Ethics Code  
4 requires that contractors “[e]xercise due diligence to prevent and detect criminal conduct” and  
5 “promote an organizational culture that encourages ethical conduct and a commitment to  
6 compliance with the law,” among other requirements. See 52.203-13(b)(2)(i)-(ii). These allegations  
7 fail for the same reasons offered above—namely, that any representations McKesson made about  
8 its compliance with imprecise regulations and standards cannot be “adjudged true or false in a way  
9 that admit[s] of empirical verification.” *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d  
10 776, 792 (4th Cir. 1999).

11 For the reasons stated above, the court finds that Relators have not adequately pleaded that  
12 McKesson made representations or omissions that can be deemed “false” within the meaning of the  
13 FCA.

14 **B. Claim for Payment**

15 McKesson also argues that Relators failed to allege that McKesson submitted any false  
16 claims for payment to the federal government. To meet the heightened pleading requirements of Rule  
17 9(b), a relator “must plead with particularity allegations that provide a reasonable basis to infer  
18 that (1) the defendant explicitly undertook to comply with a law, rule or regulation that is implicated  
19 in submitting a claim for payment and that (2) claims were submitted (3) even though the defendant  
20 was not in compliance with that law, rule or regulation.” *Ebeid*, 616 F.3d at 998. Although a relator  
21 is not required to “identify representative examples of false claims to support every allegation,” they  
22 must still allege “particular details of a scheme to submit false claims paired with reliable indicia  
23 that lead to a strong inference that claims were actually submitted.” *Id.* As explained above,  
24 Relators have not adequately alleged that McKesson made any false statements. However, even  
25 assuming they did, Relators have not sufficiently pleaded that such statements were made in  
26 connection with a claim submitted for payment.

27 The FAC alleges that McKesson submitted various claims for payment under several federal  
28 programs, including Medicare, Tricare, the Civilian Health and Medical Program of the Department

1 of Veterans Affairs (“CHAMPVA”), and the Federal Employee Health Benefit Program  
2 (“FEHBP”). FAC ¶ 15. However, the details of McKesson’s involvement with these federal  
3 programs is vague and Relators cite no facts supporting that McKesson submitted claims under these  
4 federal programs. In *United States ex rel. Modglin v. DJO Global Inc.*, 48 F. Supp. 3d 1362 (C.D.  
5 Cal. 2014), for example, the court found that the relator adequately pleaded that the defendant  
6 submitted claims to Medicare and Medicaid when the defendant’s regional sales director explicitly  
7 told him that such claims were submitted. *Id.* at 1408. However, the court found that there was no  
8 inference that the defendant submitted claims to any other federal program when the relator’s only  
9 allegation was a statement by the defendant that it “routinely billed federally-sponsored health care  
10 programs.” *Id.* The allegations here are even more general because they do not explain the basis or  
11 source of Relators’ knowledge with respect to the listed federal programs. Further, the allegation  
12 that McKesson was in some way involved with various federal programs do not give rise to an  
13 inference that it actually submitted claims under those programs. For example, it is unclear whether  
14 McKesson directly submits claims to the federal government or merely sells pharmaceuticals to  
15 third parties who submit claims. Although Relators submit McKesson’s contract with the VA as  
16 part of their opposition, they do not explain the basis for their assertion that McKesson submitted  
17 any claims for payment pursuant to that contract.<sup>8</sup> In sum, Relators’ cursory reference to various  
18 federal programs does not satisfy Rule 9(b)’s requirement to identify “the who, what, when, where,  
19 and how of the misconduct charged.” *Silingo*, 904 F.3d at 677.

20 Therefore, Relators fail to allege with particularity that McKesson submitted claims for  
21 payment to the federal government, much less that it made false statements in connection with those  
22 claims.

23 **C. Materiality**

24 Under the FCA, a misrepresentation is material when it “[has] a natural tendency to  
25 influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. §

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26  
27 <sup>8</sup> At the hearing, Relators explained that McKesson is a direct provider to the VA and submits claims  
28 directly to that agency. These allegations are not in the FAC and so the court cannot consider them  
for the purposes of this motion.

1 3729(b)(4). “The materiality standard is demanding” and “[a] misrepresentation cannot be deemed  
2 material merely because the Government designates compliance with a particular statutory,  
3 regulatory, or contractual requirement as a condition of payment.” Escobar, 136 S. Ct. at 2003. It  
4 is not sufficient to allege that the government could decline payment if it knew of the defendant’s  
5 noncompliance. *Id.* Rather, “materiality is satisfied . . . only where compliance is a sine qua non of  
6 receipt of state funding.” Ebeid, 616 F.3d at 998 (internal quotation marks and citation omitted).

7 Relators argue that McKesson’s CSA violations were material to the government’s payment  
8 of claims because the security requirements of 20 C.F.R. § 1301.71 must be met for a facility to  
9 register as a distributor of controlled substances. Thus, they assert, the government would not pay  
10 claims to a facility that is not eligible to register as a distributor. In order to pursue this theory,  
11 Relators must first adequately allege that McKesson has not met the eligibility requirements of 20  
12 C.F.R. § 1301. As explained above, Relators’ current allegations, taken as true, do not establish that  
13 McKesson fails to meet the registration requirements because that determination rests within the  
14 discretion of the DEA. See 20 C.F.R. § 1301.36 (detailing the Administrator’s power to suspend or  
15 revoke registration).

16 Accordingly, on this foundational basis alone, Relators have not sufficiently alleged that  
17 McKesson made false claims that were material to the government’s decision to pay any claims  
18 submitted by McKesson. The court therefore need not reach the additional arguments regarding  
19 materiality.

20 **D. Public Disclosure Bar**

21 McKesson argues that Relators’ FCA claim is precluded under the public disclosure bar,  
22 which “deprives federal courts of subject matter jurisdiction when a relator alleges fraud that has  
23 already been publicly disclosed, unless the relator qualifies as an ‘original source.’”<sup>9</sup> *U.S. ex rel.*  
24 *Mateski v. Raytheon Co.*, 816 F.3d 565, 569 (9th Cir. 2016). In relevant part, the FCA requires  
25 courts to “dismiss an action . . . if substantially the same allegations or transactions as alleged in the  
26 action or claim were publicly disclosed . . . in a Federal criminal, civil, or administrative hearing in

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27 <sup>9</sup> Because the court holds that the public disclosure bar does not apply in this case, it need not  
28 determine whether Relators are original sources.

1 which the Government or its agent is a party.” 31 U.S.C. § 3730(e)(4)(A)(i). The public disclosure  
2 bar applies “when the prior public disclosures are ‘sufficient to place the government on notice of  
3 the alleged fraud or practice prior to the filing of the qui tam action.’” *United States v. Kiewit Pac.*  
4 *Co.*, 41 F. Supp. 3d 796, 803 (N.D. Cal. 2014). Here, McKesson argues that the alleged violations  
5 underlying Relators’ FCA claims was already prosecuted by the United States, as evidenced by the  
6 Agreements. Relators respond that the prior actions addressed only McKesson’s failure to take  
7 appropriate action in response to suspicious orders and did not cover allegations of inadequate  
8 security.

9 For the most part, the Agreements cover different ground than Relators’ FCA claim. The  
10 2008 Agreement focuses on McKesson’s obligation to detect and report suspicious orders. See 2008  
11 Agreement at 3-4. Similarly, the 2017 Agreement reflects that McKesson “failed to conduct  
12 adequate due diligence of its customers,” “bypassed suspicious order reporting procedure,” “failed  
13 to inform the DEA . . . of suspicious orders of controlled substances,” and “distributed controlled  
14 substances to pharmacies” that it knew were out of compliance with the CSA. 2017 Agreement at  
15 3-4. McKesson points to no portion of either Agreement that discusses the adequacy of McKesson’s  
16 security protocols within its DCs. While the Agreements specifically address McKesson’s  
17 obligations to report suspicious orders, Relators confirmed at the hearing that their FCA claim is not  
18 based on failure to meet those obligations. See, e.g., 2008 Agreement at 2 (“McKesson has failed  
19 to report suspicious orders of controlled substances and to report thefts or significant losses of  
20 controlled substances.”); 2017 Agreement at 4 (“McKesson failed to inform the DEA . . . of  
21 suspicious orders of controlled substances made by its customers . . .”).

22 Therefore, the public disclosure bar does not operate to prevent Relators’ FCA claim.  
23 However, as stated above, Relators’ FCA claim fails because Relators have not adequately alleged  
24 that McKesson made false certifications in connection with claims for payment submitted to the  
25 U.S. government.

26 **IV. LEAVE TO AMEND**

27 Under Federal Rule of Civil Procedure 15(a), leave to amend should be granted as a matter  
28 of course, at least until the defendant files a responsive pleading. Fed. R. Civ. P. 15(a)(1). After

1 that point, Rule 15(a) provides generally that leave to amend the pleadings before trial should be  
2 given “freely . . . when justice so requires.” Fed. R. Civ. P. 15(a)(2). “This policy is to be applied  
3 with extreme liberality.” *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir.  
4 2003) (quotation omitted). In the absence of an “apparent” reason, such as undue delay, bad faith  
5 or dilatory motive, prejudice to the opposing party, futility of the amendments, or repeated failure  
6 to cure deficiencies in the complaint by prior amendment, it is an abuse of discretion for a district  
7 court to refuse to grant leave to amend a complaint. *Foman v. Davis*, 371 U.S. 178, 182 (1962);  
8 *Lockheed Martin Corp. v. Network Sols., Inc.*, 194 F.3d 980, 986 (9th Cir. 1999).

9 None of the Rule 15 factors weigh against denying leave to amend. Although McKesson  
10 points out that Relators have already amended their complaint once, the amendment was as of right  
11 and before McKesson appeared in the action. There is no prejudice to McKesson in allowing  
12 amendment at this stage. Accordingly, Relators are granted leave to file an amended complaint that  
13 addresses the deficiencies identified in this order.

14 **V. CONCLUSION**

15 For the foregoing reasons, McKesson’s motion to dismiss is granted. Relators shall file a  
16 second amended complaint by no later than September 8, 2020.

17 **IT IS SO ORDERED.**

18 Dated: August 18, 2020

