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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. RONDA OSINEK,

Plaintiff,

v.

KAISER PERMANENTE, et al.,

Defendants.

Case No. 3:13-cv-03891-EMC

REPLY IN SUPPORT OF MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION

Hearing Date: October 13, 2022
Time: 1:30 PM
Judge: Hon. Edward M. Chen
Courtroom: 5, 17th Floor

(CAPTION CONTINUED)

UNITED STATES OF AMERICA ex rel. NASER AREFI, AJITH KUMAR and PRIME HEALTHCARE SERVICES, INC., Plaintiff, v. KAISER FOUNDATION HEALTH PLAN, INC., et al., Defendants.	Case No. 3:16-cv-01558-EMC **REPLY IN SUPPORT OF MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: October 13, 2022 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

UNITED STATES OF AMERICA ex rel. MARCIA STEIN and RODOLFO BONE, Plaintiff, v. KAISER FOUNDATION HEALTH PLAN, INC., et al., Defendants.	Case No. 3:16-cv-05337-EMC **REPLY IN SUPPORT OF MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: October 13, 2022 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

UNITED STATES OF AMERICA ex rel. GLORYANNE BRYANT and VICTORIA HERNANDEZ, Plaintiff, v. KAISER PERMANENTE, et al., Defendants.	Case No. 3:18-cv-01347-EMC **REPLY IN SUPPORT OF MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: October 13, 2022 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

(CAPTION CONTINUED)

UNITED STATES OF AMERICA and STATE OF CALIFORNIA ex rel. MICHAEL BICOCCA, Plaintiffs, v. PERMANENTE MEDICAL GROUP, INC., et al., Defendants.	Case No. 3:21-cv-03124-EMC **REPLY IN SUPPORT OF MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: October 13, 2022 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

UNITED STATES OF AMERICA ex rel. JAMES M. TAYLOR, Plaintiff, v. KAISER PERMANENTE, et al., Defendants.	Case No. 3:21-cv-03894-EMC **REPLY IN SUPPORT OF MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: October 13, 2022 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

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I. INTRODUCTION[1]

The Motion explained that the United States alleges two distinct theories of fraud concerning Defendants' diagnosis coding from medical-record addenda.[2] First, the Complaint alleges that Defendants knowingly submitted diagnosis codes to CMS for Medicare Advantage members that reflected ***clinically inaccurate diagnoses***; in other words, medical conditions that members did not actually have. Second, the Complaint asserts that Defendants knowingly submitted diagnosis codes for ***clinically accurate diagnoses***, but the coding of the conditions violated the ICD Guidelines.[3] The Opposition now deliberately conflates these two theories and contends that the United States alleges a "single scheme" to violate a single clause of the ICD Guidelines. The United States employs this framing to argue that it need not allege clinical falsity with particularity, yet the United States refuses to disclaim a theory of clinical falsity as a basis of FCA liability.

The Court should not allow the United States to avoid its pleading obligations by conflating the two alleged fraud schemes that appear on the face of the Complaint. If the United States insists on relying on allegations of clinical falsity, it must plead them as required under Federal Rules of Civil Procedure 8 and 9(b). It is imperative for the Court to decide now whether the United States can prosecute allegations of clinical falsity because discovery regarding such allegations will be broad and voluminous. To support such a fraud theory, the United States will need to prove that each Medicare Advantage member at issue did not have the diagnosed condition and Defendants will be entitled to documentary and testimonial discovery to rebut that

[1] The parties stipulated to and requested a five-page extension for the United States' Opposition and Defendants' Reply. Dkt. No. 192. The Court has not ruled on the request. Defendants will refile this Reply if the Court denies the request.

[2] Defined terms and acronyms have the same meaning as in Defendants' Motion to Dismiss ("Motion"), unless otherwise specified.

[3] To help differentiate the alleged schemes, Defendants labeled the allegations of clinical falsity the "factually false" scheme and the allegations based on diagnosis coding guidelines the "legally false" scheme in keeping with the distinction between legal and factual falsity in the FCA caselaw. *See* Mot. at 1–2. Defendants maintain that this distinction is accurate. In fact, the United States endorses the distinction elsewhere in the Opposition, explaining that payments for "invalid diagnosis submissions" would be based on "mistake of fact" while payments made with the mistaken belief that the ICD Guidelines apply to Defendants' risk adjustment submissions would be based on "mistake of law." Opp'n at 28. But the technical label does not matter here—in the end, the United States alleges two types of fraud schemes and must sufficiently plead both.

proof. As the Motion explained, the Court should dismiss any FCA claims based on clinical falsity—the Complaint's scattered allegations of clinical falsity do not plead a scheme by Defendants to submit diagnosis codes to CMS for members who do not have the diagnosed medical conditions, much less with the particularity required by Rule 9(b). Nor do the allegations support any plausible inference that Defendants ***knowingly*** submitted clinically false diagnosis codes to CMS.

The United States does not contest that its remaining fraud allegations depend on whether Defendants must comply with a single clause of the ICD Guidelines. For a violation of the ICD Guidelines to sustain an FCA action, the United States must show that the ICD Guidelines are legally binding on Defendants and determine their right to payment. The United States has failed to make that critical showing. The Opposition offers a tortured reading of MAOs' contracts with CMS to suggest that Defendants must comply with the ICD Guidelines when submitting risk-adjustment data to CMS. Those contracts do not even mention the ICD Guidelines, let alone the part of the contract on which the United States relies to address data submissions to CMS or payment requirements. The Opposition also fails to show that any regulation promulgated through notice-and-comment rulemaking requires MAOs to comply with the ICD Guidelines. The Opposition instead cites regulations that either do not apply to risk-adjustment data submissions at all or vaguely reference compliance with "national standards" without specifying what those standards are. In any event, the United States cannot overcome its failure to plead the straightforward materiality allegation that the FCA requires here—that CMS would have denied the risk-adjustment payments at issue had it known that Defendants submitted clinically accurate diagnosis codes but those medical conditions were coded in a manner that violated the ICD Guidelines.

The Court should not allow the United States to use the specter of FCA liability—with its threat of treble damages—to transform compliance with the ICD Guidelines into a precondition for MAOs' right to payment. If CMS wants to make the ICD Guidelines binding on MAOs, then it must write its contracts and promulgate its regulations to require MAOs to comply with the ICD Guidelines when submitting risk-adjustment data. Until then, however, the United States

cannot premise an FCA claim against Defendants on the purported violation of nonbinding guidance.[4]

For these reasons, and the other reasons discussed in the Motion, the Court should dismiss the Complaint in full.

II. ARGUMENT

A. The United States Fails to Allege FCA Claims Based on Clinically Inaccurate Diagnoses

In opposing the Motion, the United States asserts that the Complaint alleges a single scheme to defraud CMS. Opp'n at 16. This argument cannot be squared with the Complaint, which brings claims based on both clinically inaccurate diagnoses and clinically accurate diagnoses that allegedly violate the ICD Guidelines. *See, e.g.*, Compl. ¶ 126 ("Some of the diagnoses that Kaiser added via addenda did not even exist, and many more did not require or affect patient care, treatment, or management at the patient visit as required by the ICD Guidelines."). Even the Opposition continues to advance both theories, doubling down on allegations that Defendants fabricated medical conditions. *See* Opp'n at 16 n.11 (citing Complaint).[5]

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[4] As Defendants noted in their Motion, they also disagree with the textual interpretation of the ICD Guidelines proffered by the United States, but the Motion does not put that interpretation at issue in this pleading challenge. Mot. at 13 n.5. Rather, in this Motion, Defendants contest whether an alleged violation of the ICD Guidelines can ***ever*** sustain an FCA action. In the event the Court denies the Motion, Defendants intend to contest the United States' interpretation of the ICD Guidelines.

[5] *Montcrieff*, on which the United States relies to argue that the Complaint alleges a single scheme, actually illustrates the difference between the types of fraud schemes alleged here. *See United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F. Supp. 3d 734, 761 (W.D. Tex. 2020). The *Montcrieff* relator alleged that the defendant submitted Current Procedural Terminology ("CPT") codes for a service that it had not fully performed. *Id.* The court determined that such allegations, analogous to the allegations of clinical inaccuracy here, turned on whether the codes themselves were false on their face. *Id.* The court distinguished this type of falsity theory from allegations that a defendant violated "a legal condition of payment." *Id.* Though the *Montcrieff* court found only the former theory was implicated there, it recognized the important distinction between claims for payment that are false because they state untrue facts on their face and claims for payment that are false because they violate an alleged legal requirement for payment. Here, because the United States alleges that Defendants submitted claims for both clinically inaccurate diagnoses and for clinically accurate diagnoses that otherwise violated purported payment conditions, it must adequately allege both types of claims in compliance with Rules 8 and 9(b).

The United States recognizes the distinction but contends that both types of false claims are the result of the same scheme to violate the ICD Guidelines—in particular, the ICD Guidelines' statement to code medical conditions that "require or affect patient care, treatment or management." *Id.* at 16. According to the United States, it need not sufficiently allege that Defendants submitted diagnosis codes to CMS for nonexistent medical conditions because ***every*** submission violated at least this clause in the ICD Guidelines. *See id.*

The problem with this framing is that the submission of a clinically inaccurate diagnosis code could lead to FCA liability regardless of whether Defendants were required to comply with the ICD Guidelines. In other words, the ICD Guidelines are irrelevant to the allegations of clinical falsity. A diagnosis code communicates that a member suffers from a given medical condition. And a statement that a member has a given medical condition when the member does not have that condition is a false statement on its face. *See United States ex rel. Rasmussen v. Essence Grp. Holdings Corp.*, 2020 WL 4381771, at *4 (W.D. Mo. Apr. 29, 2020) (explaining that the relator did not bring any "factually false" claims as he "concede[d] that he is not alleging that any diagnostic code entered . . . was wrong, or that [d]efendants otherwise submitted or otherwise encouraged false diagnoses"). There is no need to consult the ICD Guidelines to understand or prove why the statement is false. That is not true, however, for the remaining fraud allegations that do ***not*** depend on clinical falsity—the ***only reason*** the clinically accurate diagnosis codes would be false is because they reflect medical conditions that members have but that were allegedly coded in violation of the ICD Guidelines.

The distinction between the two theories of fraud is not just academic; it has profound consequences for ultimate proof and discovery. If the United States' FCA claims premised on clinical falsity remain, the parties will need discovery into the diagnostic judgment and medical condition relating to every single diagnosis that the United States contends is clinically inaccurate to determine whether the member actually had the underlying medical condition. This discovery will implicate documentation for tens of thousands of individual patients and healthcare providers and require expert analyses of every single medical record in dispute. The Complaint puts millions of diagnosis codes at issue, so the breadth of this discovery could be enormous and

consume a tremendous amount of resources for the parties and the Court. It is thus essential at this early stage of the case to determine whether the Complaint adequately pleads a fraud scheme based on clinical falsity.

As explained in the Motion, the Complaint's allegations of clinical falsity do not establish a scheme to submit diagnosis codes for nonexistent medical conditions. Mot. at 20–21. Nor does the Complaint adequately allege that Defendants knowingly submitted diagnosis codes for medical conditions that the members did not have.

1. Falsity

The United States' falsity allegations fail to show with the required particularity either (1) that Defendants engaged in a concerted scheme to submit clinically inaccurate diagnosis codes to CMS or (2) that any diagnosis code that Defendants submitted to CMS in fact reflected a clinically inaccurate diagnosis.

First, the Complaint does not support a strong inference of a ***scheme*** to submit clinically false diagnosis codes to CMS. *See Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010) (FCA plaintiff must 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" (citations omitted)). At most, the United States points to only a handful of purported clinical inaccuracies in members' medical records. But the Complaint lacks any allegation of coordinated efforts by employees or management at any Defendant to submit clinically inaccurate diagnosis codes to CMS: no executive decisions to diagnose patients with fabricated medical conditions, no meetings among healthcare providers or coding groups to record nonexistent medical conditions, and no memoranda or presentations directing healthcare providers and coders to falsify medical conditions. To the contrary, the Complaint describes Defendants' efforts to identify and diagnose ***medical conditions that members actually had***. *See, e.g.*, Compl. ¶¶ 201–02, 214.

The Opposition argues that Defendant TPMG's "cachexia data-mining initiative" was a scheme to submit "diagnosis codes for patients that Kaiser knew did not have cachexia." Opp'n at 17. But the allegations cited, even when accepted as true, do not support a plausible inference that TPMG engaged in any concerted effort to misdiagnose members with cachexia. The

Complaint alleges merely that TPMG identified cachexia as a medical condition that could increase revenue if diagnosed; that TPMG created a data-mining algorithm to identify "potential cachexia diagnoses"; that healthcare providers were sent those results to see if they should add potentially missed cachexia diagnoses to medical records; and that some providers expressed concern that the algorithm incorrectly identified cachexia diagnoses. *See* Compl. ¶¶ 294–300.

This is not indicia of fraud and certainly does not support the inference that TPMG, much less the other Defendants, set about to submit cachexia diagnoses for members who did not have that condition. Rather, the allegations suggest that TPMG acted with rational business interests in mind when establishing the data-mining initiative, which is not improper. *See Integra Med Analytics LLC v. Providence Health & Servs.*, 854 F. App'x 840, 844 n.4 (9th Cir. 2021) ("CMS has acknowledged that there is nothing 'inappropriate, unethical or otherwise wrong with [healthcare providers] taking full advantage of coding opportunities to maximize [the] Medicare payment that is supported by documentation in the medical record.'" (citations omitted)). While the Complaint cites allegations that the data-mining algorithm had flaws, the allegations do not suggest that TPMG required that healthcare providers blindly accept the results of the algorithm—they still had to use their clinical judgment to determine whether to add a cachexia diagnosis to a member's medical record.

Second, even where the Complaint attempts to identify alleged examples of clinically false diagnoses, it does not sufficiently allege that these diagnoses were actually incorrect. The United States relies heavily on purported inconsistencies in medical records to support alleged clinical falsity, *see* Opp'n at 17–18, but speculation about these inconsistencies does not establish that Defendants submitted diagnosis codes to CMS for clinically inaccurate medical conditions. For example, the Complaint highlights allegations about a healthcare provider who diagnosed a member with prostate cancer despite a note in the medical record that the member had a "history of" prostate cancer. *Id.* at 17; Compl. ¶ 338. But there are no allegations in the Complaint about the member's actual cancer status. Compl. ¶ 338. Nor are there any allegations about what information the diagnosing provider did or did not consider when adding the cancer diagnosis to the medical record. *Id*.

Without such allegations, the inconsistency asserted does not establish a strong inference of falsity. The United States asks the Court to leap to the conclusion "that doctors lied about underlying medical conditions." *See Integra*, 854 F. App'x at 844 (an inference of fraud based on a statistical trend did not meet Rule 8 where the trend was "consistent with a plausible alternative (and legal) explanation"). But there are more probable, nonfraudulent inferences to draw from these allegations—for example, that the "history of" note in the medical record was either a mistake corrected by the healthcare provider with the addenda, or an indication, based on the provider's clinical judgment and other facts in the medical record, that the cancer had returned. *See Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014) (in evaluating plausibility, "courts must also consider an 'obvious alternative explanation' for [the] defendant's behavior" (citations omitted)). In the face of these plausible alternatives, the Court need not accept the improbable explanation of fraud as true. *See Integra*, 854 F. App'x at 845.

The United States' reliance on allegations about a member diagnosed with severe obesity and another member diagnosed with obesity hypoventilation syndrome fails for the same reasons. *See* Opp'n at 17–18. As with the prostate cancer example, there are no allegations that would allow the Court to infer that these members did not have the reported medical conditions. *See* Compl. ¶¶ 210–11, 339. To the contrary, the Complaint alleges that the query that resulted in the obesity hypoventilation syndrome diagnosis specifically requested that the healthcare provider make the diagnosis ***only*** "if clinically appropriate" and that the healthcare provider responded to that request by adding the diagnosis. *Id.* ¶¶ 210–11. Absent any affirmative allegation that the members did not have the diagnosed medical conditions, the Complaint fails to allege that these healthcare providers falsified diagnoses.

Finally, allegations about cachexia audits do not establish clinical falsity. The Complaint alleges that a TPMG audit showed that, when healthcare providers added a cachexia diagnosis to medical records based on a query sent to the provider, the medical-record documentation often lacked or contradicted the definition of cachexia. *Id.* ¶ 321. These allegations still do not suggest that Defendants submitted cachexia diagnosis codes for members who did not have cachexia. Allegations that the medical-record documentation was "lacking" or inconsistent say nothing

about the member's actual health status. *See id.* ¶¶ 300, 321–22. This is particularly true in light of the Complaint's allegation that cachexia is "based on clinical judgment rather than clinical indicators." *Id.* ¶ 295. Similarly, allegations that a single healthcare provider speculated that certain practices would result in "inappropriate" diagnoses is not evidence that those practices ***actually*** resulted in Defendants submitting to CMS any ***clinically false*** diagnoses. *See id.* ¶ 297.

After eight years of investigation, the United States has had the opportunity to review millions of pages of documents, yet it still points to only a handful of examples of allegedly clinically false diagnosis codes. Even then, the Complaint cannot muster factual allegations—with particularity—that any of those examples reflected conditions that members did not actually have. The Opposition now makes clear that this case is not about clinical falsity, but the United States refuses to disclaim FCA liability based on that theory of fraud. The Court should not allow the United States to proceed on that fraud theory without factual allegations that satisfy Rule 9(b).

2. Knowledge

The scattered allegations of clinical falsity highlighted in the Opposition also do not plausibly allege that Defendants ***knew*** they submitted clinically inaccurate diagnosis codes to CMS. Nothing in the Complaint plausibly alleges that Defendants had the requisite state of mind—whether actual knowledge, deliberate indifference, or reckless disregard—when they submitted allegedly clinically inaccurate diagnosis codes to CMS.[6] While the United States argues that "Kaiser's own internal audit showed over 90% of the addenda adding cachexia were not accurate," the three paragraphs that the Opposition cites say nothing about audits revealing that members diagnosed with cachexia did not have cachexia. *See* Opp'n at 17. The one audit referenced in these paragraphs showed alleged "***documentation***" errors, where the documentation was "lacking" or "contradict[ed]" the technical definition of cachexia. Compl. ¶ 321 (emphasis added). The Complaint does not explain anything about the scope of this audit (e.g., time period, sample size, patient population reviewed); and in any event, these allegations could not give rise

[6] The Opposition argues that Defendants rely on a definition of "knowledge" under the FCA that excludes deliberate indifference and reckless disregard. Opp'n at 19. Defendants do not dispute that the FCA knowledge standard includes: (1) actual knowledge, (2) deliberate indifference, and (3) reckless disregard. *United States ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991). Nothing in the Motion is to the contrary.

to the inference that Defendants were on notice that healthcare professionals diagnosed cachexia for members who did not have cachexia. As noted, the Complaint acknowledges that a cachexia diagnosis is "based on clinical judgment rather than clinical indicators," *id.* ¶ 295, so audits of the documentation could not have plausibly given Defendants relevant knowledge of clinical falsity.

The Opposition argues that Defendants knew the diagnosed conditions were clinically false because the diagnosis codes were added to the medical record through addenda months after the patient encounter, but this timing argument fails to support an inference of knowledge. *See* Opp'n at 20. The timing of a diagnosis does not make it per se false, and no facts alleged in the Complaint support such an inference. The Opposition's reliance on resistance from healthcare providers to code certain queried conditions similarly fails. *See id*. If anything, that healthcare providers alerted Defendants to flawed queries indicates that healthcare providers responded thoughtfully to the queries and did not mindlessly and reflexively add a diagnosis if it was not clinically indicated.

B. The United States Fails to Allege FCA Claims Based on Clinically Accurate Diagnoses That Violate the ICD Guidelines

The Opposition makes abundantly clear that the United States' case boils down to a strained attempt to impose FCA liability for the submission of clinically accurate diagnosis codes that Defendants allegedly recorded in violation of the directive in the ICD Guidelines to code medical conditions that "require or affect patient care, treatment or management." *See* Opp'n at 16. Although the Opposition focuses on the meaning of this clause, *see id.* at 4–5, 16, that is not the pertinent issue before the Court. The relevant legal question is whether Defendants' right to payment under the Medicare Advantage program was premised on compliance with the ICD Guidelines. The United States contends that Defendants falsely represented that they would comply with the ICD Guidelines when they submitted risk-adjustment data to CMS. *Id.* at 9. But Defendants made no such representation to CMS and there is no legally binding requirement for MAOs to comply with the ICD Guidelines when submitting risk-adjustment data to CMS. The Complaint fails to allege falsity for this theory because the cited clause of the Guidelines is not legally binding on Defendants, does not define Defendants' right to payment for risk-adjustment

submissions, and cannot form the basis for an FCA action.[7] In addition, the United States has not adequately alleged that the purported violation of the ICD Guidelines would have been "material" to CMS's payment decision.

1. Falsity

The United States does not dispute that nonbinding subregulatory guidance cannot supply the basis for an FCA action against an MAO. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1817 (2019). Yet the United States continues to argue that the ICD Guidelines—which were not promulgated through notice-and-comment rulemaking—define Defendants' right to payment for risk-adjustment submissions (1) given the Health Plan Defendants' contracts with CMS and (2) certain regulations about data formatting. Opp'n at 9–14. Both arguments miss the mark.

CMS contracts do not require MAOs to comply with the ICD Guidelines when submitting risk-adjustment data. The Opposition reads as though compliance with the ICD Guidelines is the heart of the bargain between CMS and Defendants. *See id.* at 9–12. But such a view is belied by the contracts themselves, which do not mention the ICD Guidelines at all.

The Health Plan Defendants' contracts with CMS do not require compliance with the ICD Guidelines' directive to code medical conditions that "require or affect patient care, treatment or management" when submitting risk-adjustment data.[8] Mot. at 17–18. The Opposition incorrectly argues that Article II of the contract requires compliance, *see* Opp'n at 9–10, but Article II does not refer to the ICD Guidelines, diagnosis coding, or CMS payments at all. Dkt. No. 179, Request for Judicial Notice ("RJN"), Ex. I at 2. Instead, it concerns plan design. It explains that contracting MAOs agree to establish a coordinated care plan under 42 C.F.R. § 422.4(a)(1)(iii), which establishes the types of organizations that can offer coordinated care plans. *See id.*

[7] The Motion explained that the United States has failed to show that the ICD Guidelines apply to diagnosis coding from medical-record addenda—the type of documentation at the center of this case. *See* Mot. at 13. The Opposition argues that there is no "addenda exception" to the ICD Guidelines. Opp'n at 15. Defendants agree, but because the United States' case rests entirely on coding from addenda, the Motion focuses on the standards that apply to such coding. And the Court's decision can be similarly narrow.

[8] The three Medical Group Defendants are not parties to CMS's contracts with the Health Plans. And the United States makes no allegation of any contracts between CMS and the Medical Group Defendants. The United States cannot therefore rely on CMS's contracts with the Health Plans to support its FCA claims against the Medical Group Defendants.

It is true that Article II of the contract states that MAOs must structure a coordinated care plan "in compliance with the requirements of this contract and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.)."[9] *Id.* But again, this provision appears in the part of the contract about plan structure—not payment—and says nothing about the ICD Guidelines. The Opposition argues that the ICD Guidelines are incorporated into the contract by reference because they are cited in a single sentence of the Medicare Managed Care Manual, which is in turn referenced in the parenthetical quoted above. Opp'n at 9–11. To even locate this single sentence requires flipping through seven chapters of the Manual. RJN, Ex. C at 4.

That lone sentence does not support the United States' proffered interpretation of the CMS contract. Read in the context of Article II, the reference to the Manual at most requires MAOs to follow any policies within the Manual that relate to the structure of the coordinated care plan. Such policies could include those in Chapter 1 of the Manual, which defines a coordinated care plan as "a plan that includes a network of providers that are under contract or arrangement with the MA organization to deliver the benefit package approved by CMS" and explains the relevant structural requirements.[10] But Article II does not state that an MAO's right to payment hinges on strict compliance with every syllable of the Medicare Managed Care Manual—a voluminous document that spans nearly 800 pages across twenty-one chapters and that is updated periodically. And it certainly does not require compliance with every word of every secondary document that happens to be mentioned in the Manual without any indication that each party expressed a mutual intent to be bound by such a double incorporation by reference. Not even the most sophisticated parties would agree to be bound by such a sprawling contract that could commit them to innumerable unknown obligations, obligations that continually change and often at the whim of CMS. In fact, the United States acknowledges that there may be limits on its

[9] While the Opposition cites *Silingo* as recognizing that "MAOs must comply" with the Medicare Managed Care Manual, Opp'n at 10, *Silingo* includes no such holding, and the parties in that case did not litigate whether the Manual binds MAOs. *See United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 672–73 (9th Cir. 2018).

[10] CMS, Medicare Managed Care Manual, Chapter 1, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c01.pdf.

ability to require compliance with "surprise" policies in contracts. Opp'n at 11.

The section of the contract that governs CMS payments—Article IV—reinforces Defendants' reading because it says nothing about the Medicare Managed Care Manual. Nor does it reference the ICD Guidelines. That section requires compliance with only regulations and statutes. RJN, Ex. I at 6–7. The absence of nonbinding subregulatory guidance from this section makes sense, given that *Allina* requires Medicare payment rules to be promulgated through notice-and-comment rulemaking. *See* 139 S. Ct. at 1816. The Court can therefore harmonize the contract as written with *Allina* and the Medicare statute. Had CMS wanted to condition MAOs' right to payment on strict compliance with the ICD Guidelines, it could have stated so clearly in a regulation promulgated through notice-and-comment rulemaking or, at the very least, in the relevant payment section of its MAO contracts. But the United States cannot lawfully litigate into existence a contractual obligation that it never included in contracts with MAOs.

It is not plausible that Defendants' contractual right to payment depends on a stray sentence in subregulatory guidance that is referenced nowhere in the Health Plan Defendants' contracts with CMS, but is instead described in a nearly 800-page document that is in turn referenced once, within parentheses, in a section of the contracts unrelated to payment or risk-adjustment data submissions. A far more reasonable reading of the contract is that the right to payment requires compliance with applicable statutes and regulations, while the Medicare Managed Care Manual applies insofar as it describes polices related to plan structure.

No regulation requires MAOs to comply with the ICD Guidelines when submitting risk-adjustment data to CMS. In its Opposition, just like the Complaint, the United States fails to point to any statute or regulation that requires MAOs to comply with the ICD Guidelines when submitting diagnosis codes to CMS for risk-adjustment purposes. Without such regulations, the ICD Guidelines cannot form the basis for an FCA action. *See Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019).

The United States relies on Part 162 of the Code of Federal Regulations to argue that MAOs must follow ICD Guidelines when submitting risk-adjustment data to CMS, *see* Opp'n at 13, but Part 162 does not apply to risk-adjustment data submitted to CMS. Part 162 was intended

to standardize the code sets used in nine categories of specific medical transactions to solve data incompatibility problems in the healthcare industry. *See* Mot. at 15. By its own terms, Part 162 applies only when covered entities are "conducting a ***transaction covered by this part***." 45 C.F.R. § 162.1000 (emphasis added). Because the code sets listed in 45 C.F.R. § 162.1002(a)(1) are required only when a covered entity is conducting one of those nine transactions described in Part 162, that section does not apply broadly to all healthcare transactions.[11] Mot. at 15. The Opposition conspicuously ignores this argument, and does not attempt to demonstrate that the submission of risk-adjustment data to CMS falls within one of the nine specific categories.

The rulemaking history confirms the plain-text reading of Part 162. *Id.* at 15–16. Contrary to the United States' assertions, Opp'n at 14 n.9, Defendants do not rely on the rulemaking history to exempt them from Part 162. The rulemaking history merely corroborates the plain-text reading of Part 162, which shows that the transmission of risk-adjustment data to CMS is not a covered transaction. Indeed, that history confirms that any healthcare transaction that does not fall within one of the specifically enumerated categories does not need to be a standardized transaction. *See, e.g.*, 65 Fed. Reg. 50,312, 50,317 ("Data submissions or exchanges for purposes other than those designated in this regulation . . . do not require use of the standards."). And the example CMS provides of a nonstandard transaction is instructive: the remittance of a bill from a managed care organization to a state, which is a transaction analogous to the remittance of risk-adjustment data to CMS. *Id.* at 50,318.

Part 162 also does not apply because it does not purport to define any right to payment. It merely standardizes the data format used in covered transactions to ease sharing healthcare information and data between covered entities to create cost savings and efficiencies. 65 Fed. Reg. 50,312; *see also* 42 U.S.C. § 1320d-2; 63 Fed. Reg. 25,272–73. It does not limit those conditions for which MAOs are entitled to reimbursement. Nor does it dictate when healthcare

[11] If Part 162 applied broadly to all healthcare transactions as the Opposition argues, then the limiting language describing the nine types of covered transactions subject to the regulation would be a nullity. A reading of a regulation that creates extreme surplusage is contrary to canons of interpretation and Supreme Court precedent. *United States v. Grandberry*, 730 F.3d 968, 981 (9th Cir. 2013) ("[A] statute or regulation should be construed so that effect is given to all its provisions, ***so that no part will be inoperative or superfluous, void or insignificant***[.]" (emphasis added) (quotations omitted)).

providers can diagnose medical conditions or submit risk-adjustment data to CMS.

The United States' reliance on 42 C.F.R. § 422.310(d)(1) fails for similar reasons. Mot. at 16. As explained in the Motion, that regulation addresses data format. *Id.* Like Part 162, it does not purport to define rights to payment or create limits on the ability of healthcare providers to diagnose medical conditions.[12] And the regulation does not even reference the ICD Guidelines; instead, it requires MAOs to "submit data that conform to . . . all relevant national standards," and then does nothing to define those standards. 42 C.F.R. § 422.310(d)(1). The Opposition baselessly asserts that there is "only one ICD standard" that is "*the* national standard." *See* Opp'n at 13 (emphasis in original). But the ICD Guidelines themselves are lengthy, containing myriad coding guidelines that apply in all different types of situations, and there are also multiple sets of ICD codes, which the Opposition recognizes. *See id.* at 12. Even using the United States' framing, it is completely unclear what the "one ICD standard" is.

The United States fails to cite any other regulation that even mentions the ICD Guidelines, let alone explicitly establishes the ICD Guidelines and its "require or affect" provision as a "national standard" that MAOs must follow. While the Opposition cites various snippets from rulemaking history that mention the ICD Guidelines, none of these bind MAOs. *Id.* at 12–14. The rulemaking on which the United States relies is from the background section of proposed rules. *See* 83 Fed. Reg. 54982, 55037; 74 Fed. Reg. 54634, 54674; 79 Fed. Reg. 1918, 2001. And every one of these proposed rules is about CMS's risk-adjustment audits and related appeals—not MAOs' right to payment for providing healthcare coverage to members. CMS cannot lawfully mandate the use of the ICD Guidelines by citing to proposed rules, and it cannot premise an MAO's right to payment on the background section of a proposed rule about audits.

[12] In the Motion, Defendants rely on *Rasmussen*, 2020 WL 4381771, at *6, for its persuasive distinction between (1) a format for submitting data to CMS and (2) a standard for documenting medical conditions. Mot. at 16. There, the relator argued that a condition could be diagnosed only if a patient had received treatment during the previous year based on 42 C.F.R. § 422.310(g), *Rasmussen*, 2020 WL 4381771, at *6, which is part of the regulation that the United States now cites to support its argument in this case. *Rasmussen* observed that the better reading of the cited provision was that it "appears to address the deadline for submitting risk adjustment data" and that it was "not directed toward specifying the procedure for properly coding patients' medical conditions." *Id.* at n.10. That reasoning applies with equal force here: subsection 422.310(d)(1), on which the United States relies in this case, mandates the format of the risk-adjustment data submitted to CMS; it does not specify standards for diagnosing members' medical conditions.

See Allina, 139 S. Ct. at 1816.

2. Materiality

To adequately allege materiality here, the Supreme Court's decision in *Escobar* requires the United States to make a simple allegation supported by specific facts: that CMS ***would not have paid*** Defendants had it known about the purported violation of the ICD Guidelines. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016); *United States v. Scan Health Plan*, 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017) ("*Swoben II*") (dismissing FCA claims where the United States failed to plead that "CMS would have refused to make risk adjustment payments . . . if it had known the [claims were false]").

The Complaint does not make the required materiality allegations. Instead, the Complaint hedges, suggesting that "CMS would have refused to make risk-adjustment payments based on the improper coding ***and/or*** taken other appropriate actions to ensure that Defendants did not receive or retain risk-adjustment payments to which they were not entitled." Compl. ¶ 350 (emphasis added). Using such qualified language does not satisfy the FCA's rigorous materiality standard; the "key allegation" for materiality is that the alleged violation would "have a direct impact on CMS' risk adjustment payments." *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, 2018 WL 1363487, at *9 (C.D. Cal. Feb. 12, 2018). But the United States leaves open the possibility that CMS might have taken some "other appropriate action," such as bringing an FCA enforcement action like this one. Indeed, the Opposition contends that its "efforts to recover [] payments ***through this lawsuit*** is further evidence that [CMS] views compliance with the ICD Guidelines to be material." Opp'n at 22 (emphasis added). The United States cites no authority for this remarkable proposition, which is patently false. As a matter of law, the United States' decision to bring an FCA lawsuit is not sufficient to establish materiality—otherwise, the materiality element would lose all meaning in every case in which the United States filed FCA claims, "working an end-run around *Escobar*." *United States ex rel. Mei Ling v. City of Los Angeles*, 2018 WL 3814498, at *20 (C.D. Cal. July 25, 2018).

The Opposition also insists that the Complaint satisfies materiality because diagnosis codes are central to CMS's payment decision, Opp'n at 21, but that is not the relevant question.

As Defendants' Motion explained, it is not enough for the United States to allege that diagnosis codes are important to CMS in the abstract. Mot. at 18–20. Rather, the United States must allege and then prove that a violation of the requirement at issue would influence CMS's payment decision. *See Escobar*, 579 U.S. at 181 (holding that the "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision"). Here, that means the United States must allege facts to show that Defendants' purported violation of the particular part of the ICD Guidelines at issue was material to CMS's payment decision. The Opposition's need to hedge its materiality allegation with "and/or" language evidences that it cannot make the required showing here.

The Opposition points to certain factual allegations that the United States argues support materiality. None does. The United States alleges that Defendants' internal advisories required compliance with the ICD Guidelines and that KFHP redacted certain diagnosis codes following an audit, but that does not establish materiality. *See* Opp'n at 22 (citing Compl. ¶¶ 90–95, 270–75, 330). These allegations say nothing about whether "the defendant knows that ***the Government consistently refuses to pay*** claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *United States ex rel. Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1213 (9th Cir. 2019) (emphasis added) (quotations and citations omitted). The key inquiry for materiality is what ***CMS*** would have done—not what Defendants thought or did. The Complaint does not allege even a single example where CMS refused to pay risk-adjusted claims due to noncompliance with the ICD Guidelines. And the Opposition does not cite a single case where allegations about the defendant's conduct alone established materiality.[13]

As the Motion explained, the omission of clear materiality allegations is glaring. The United States is in the best position to allege concrete facts showing that CMS would have refused to pay Defendants had it known about Defendants' alleged noncompliance with the single

[13] As evidence of materiality, the United States relies on CMS guidance documents that generally refer to the ICD Guidelines. Opp'n at 21–22, 22 n.13. It is not enough to point to such generic guidance documents, because they say nothing about whether CMS would have paid Defendants had it known that the diagnosis codes submitted to CMS reflected medical conditions that were accurate but were not coded in compliance with the ICD Guidelines.

sentence of the ICD Guidelines. Yet neither the Complaint nor the Opposition alleges any facts showing that CMS has previously declined payment to an MAO or sought to recoup prior payments based on noncompliance with the cited provision of the ICD Guidelines. The United States simply cannot make the straightforward materiality allegation that *Escobar* requires here.

C. The FCA's Statute of Repose Bars Part of the United States' Lawsuit

The United States urges the Court to ignore the FCA's ten-year statute of repose based on a misreading of Supreme Court precedent and the text of the FCA itself. The Court should reject this misguided attempt to evade the repose period and dismiss the United States' FCA claims that predate the Complaint by ten years.

The Opposition's suggestion that the FCA does not have a statute of repose conflicts with the text of the statute and a chorus of caselaw. *See* Opp'n at 24–25. To imply that the FCA lacks a statute of repose, the United States incorrectly interprets *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1510 (2019), which referred in dicta to the FCA's entire limitation provision as a "statute of limitations." *Cochise* considered only "how to calculate the limitations period for *qui tam* suits in which the United States does not intervene," not whether the FCA contained a statute of repose. *Id*. Following *Cochise*, courts have continued to conclude that the FCA contains a statute of repose based on the statute's clear statement that an action under 31 U.S.C. § 3730 can "in no event" be brought "more than 10 years after the date on which the [FCA] violation is committed." 31 U.S.C. § 3731(b)(2); *see, e.g.*, *United States ex rel. Tracy v. Emigration Improv. Dist.*, 2021 WL 1192493, at *3 (D. Utah Mar. 30, 2021) ("Section 3731(b)(2) ***creates a statute of repose*** and not a statute of limitations." (emphasis added)); *United States ex rel. Wood v. Allergan, Inc.*, 2020 WL 3073293, at *3 (S.D.N.Y. June 10, 2020) ("Section 3731(b) is, in part, . . . ***a statute of repose***." (emphasis added)). Even the *Mei Ling* decision cited in the Opposition concludes that the FCA "features a 'ten-year statute of repose,' after which no FCA claim can be brought." 2018 WL 3814498, at *22 (citations omitted). These holdings align with the Ninth Circuit's undisturbed observation of the FCA's ten-year statute of repose. *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1218 (9th Cir. 1996).

The only question before the Court, then, is whether to calculate the ten-year repose

period from the date of the United States' complaint or the partially intervened *qui tam* complaints. Only two courts have reached this issue, and they have come to different conclusions. *Compare Swoben II*, 2017 WL 4564722, at *8 (holding that the FCA's statute of repose is calculated from the date of the United States' complaint), *with Mei Ling*, 2018 WL 3814498, at *22 (holding that the statute of repose is calculated from the date of the underlying *qui tam* complaint). For all the reasons explained in the Motion, the *Swoben II* court reached the correct result supported by the FCA's plain-text meaning, the legislative history, and the purpose of repose to provide an outer limit to a defendant's liability.[14] *See* Mot. at 23–24.

That purpose is front and center here, where the United States spent eight years investigating the underlying *qui tam* actions and now seeks to hold Defendants liable for conduct that occurred as early as 2009. The Opposition argues that Defendants' reading of the repose provision is flawed because the statute then would "not even provide repose to an FCA defendant" since relators can still bring claims that predate a government suit. Opp'n at 26. This argument makes sense only if the purpose of repose is to protect the ***United States'*** interest in bringing fraud claims. But that is the opposite of what the statute of repose is meant to do—to protect ***defendants*** from potentially unlimited liability. *Swoben II*, 2017 WL 4564722, at *8. If the United States can pause relator litigation for as long as it chooses with virtually no impact on the scope of claims it can bring, it will have no incentive to timely investigate claims. Relators do not have the United States' wide-ranging investigatory abilities and they do not have any mechanism to delay litigation of their claims like the United States does. Pre-litigation investigations can endure for more than a decade—exposing FCA defendants to potentially unlimited liability for years-old conduct. *See id.* (observing that "without a repose period, the

[14] While the Opposition criticizes the *Swoben II* court's citation to legislative history, Opp'n at 26 n.19, that court relied on legislative history to establish that Congress understood the difference between the FCA's statutes of repose and limitations when it drafted the FCA's relation-back provision—a distinction that confirms the plain-text reading of that provision and allows relation back only for "statute of limitations purposes." *Swoben II*, 2017 WL 4564722, at *8. The Supreme Court's decision in *Mead Corporation* does not undermine such reliance. *See Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989). There, the Court refused to read anything into the fact that a final version of a bill did not include a word that had appeared in a former version of a bill, because it would be inappropriate to "attach decisive significance to the unexplained disappearance of one word from an unenacted bill." *Id.* Here, by contrast, the cited legislative history sheds light on the language and structure of current FCA provisions.

relation-back provision would have forced defendants 'to defend themselves for actions that occurred 12, 15 or even 20 years ago, depending on how long a qui tam case remains under seal'" (citations omitted)). At some point, the United States must decide whether it plans to bring a lawsuit and pursue further discovery under the Federal Rules of Civil Procedure—it should not be allowed to avoid those rigors by extending its investigation period indefinitely (or in this case for eight years) without any protection of Defendants' interests.

D. The Court Should Dismiss the United States' Common-Law Claims

The Court should dismiss the common-law claims for two reasons. First, because they are derivative of the FCA claims, they fail for the same reasons the FCA claims do. Mot. at 24. The United States argues that not all elements of an FCA claim are the same as the elements of its common-law claims, citing *United States v. Mead*, 426 F.2d 118, 125 (9th Cir. 1970). But *Mead* merely observed that "[k]nowledge of falsity is not a requisite for recovery under the mistake doctrine." *United States v. Mead*, 426 F.2d 118, 125 n.6 (9th Cir. 1970). Here, the United States' FCA claims fail for reasons other than defective knowledge allegations—the Complaint also fails to allege falsity for all the reasons described herein, *supra* at 5–8, 10–14, and in the Motion. If Defendants' claims for payment to CMS were not false, then there has been no unjust enrichment or payment by mistake. Accordingly, the quasi-contract claims fall with the FCA claims. *See United States v. Aegis Therapies, Inc.*, 2015 WL 1541491, at *14 (S.D. Ga. Mar. 31, 2015).

Second, the United States cannot allege common-law claims based on a quasi-contract theory where it also alleges the existence of a valid contract. Mot. at 24–25. While the Opposition disputes this legal principle, citing to its inherent authority to recover erroneously paid funds, *see* Opp'n at 27–28, it fails to identify a single case where a court allowed the United States to proceed on quasi-contract claims in the face of an enforceable contract between the parties covering the conduct at issue. All of the cases cited in the Opposition are distinguishable from the situation here:

- *Wurts*—the United States' primary case—addressed the United States' right to recover an erroneously paid tax refund. *United States v. Wurts*, 303 U.S. 414, 415 (1938). The case did not involve a contract between the parties. *Id.*
- *Heidt* addressed the United States' right to seek repayment for overpayments to an

army officer—again, there were no allegations of an enforceable contract. *Heidt v. United States*, 56 F.2d 559, 560 (5th Cir. 1932).

- *Lahey* involved the United States' attempt to recover payments for tests that were billed to Medicare at twice the rate they were billed to private physicians. *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 5, 13 (1st Cir. 2005). Though the First Circuit determined that the Medicare Act itself did not curtail the United States' ability to seek these funds under a quasi-contract theory, it did not reach the question whether the existence of an enforceable contract similarly impacted that ability. *Id.* at 13–17.
- *Kingman* is irrelevant because, there, the United States explicitly denied the existence of a contract between the parties. *Kingman Water Co. v. United States*, 253 F.2d 588, 589 (9th Cir. 1958) ("The Government denies that any such contract was made[.]").
- *DiSilvestro* was not a case brought by the United States; it was brought by a military veteran seeking the return of funds withheld to cover erroneously paid benefits. *DiSilvestro v. United States*, 405 F.2d 150, 153 (2d Cir. 1968).
- And *Agility* did not involve quasi-contract claims; instead, the government sued under the Debt Collection Act for overpayments under an existing contract. *Agility Pub. Warehousing Co. K.S.C.P. v. United States*, 969 F.3d 1355, 1365–66 (Fed. Cir. 2020).

By contrast, the Motion cites multiple cases rejecting the United States' attempt to bring common-law claims alongside FCA claims where it also alleges the existence of an enforceable contract between the parties—the precise situation here.[15] Mot. at 25 (collecting cases).

While the Opposition argues that the United States' inherent authority to seek improperly paid funds allows it to pursue quasi-contract remedies, that argument makes sense only if quasi-contract claims were the United States' only path to relief. But they are not, as the government's own case has made clear. The United States seeks to recover funds that were allegedly obtained fraudulently under a statute designed for that very purpose: the FCA. The United States has chosen to bring two common-law claims here, with all of the well-established limitations that come with such claims. The Court should apply the common-law rules adopted by those courts that have considered the same issue presented here and dismiss the common-law claims.

III. CONCLUSION

For the foregoing reasons, and the reasons explained in the Motion, the Court should dismiss the Complaint in its entirety.

[15] The United States argues that, at the least, the Court should not dismiss the common-law claims brought against the Medical Group Defendants, which did not contract with CMS. Opp'n at 29. But the United States has no response to Defendants' argument that those claims are barred because the Complaint alleges that the Medical Group Defendants must comply with the Health Plan Defendants' "contractual obligations to CMS." Mot. at 25; Compl. ¶ 77. The one case cited by the Opposition for its argument did not appear to have any similar allegations. *See United States v. First Choice Armor & Equip., Inc.*, 808 F. Supp. 2d 68, 78 (D.D.C. 2011).

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Respectfully submitted,

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