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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

NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES

Hearing Date: TBD (Dkt. No. 129)
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

NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES

Hearing Date: TBD (Dkt. No. 129)
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

NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES

Hearing Date: TBD (Dkt. No. 129)
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

NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES

Hearing Date: TBD (Dkt. No. 129)
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 **NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES** Hearing Date: TBD (Dkt. No. 129) 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 **NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES** Hearing Date: TBD (Dkt. No. 129) Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

NOTICE OF MOTION AND MOTION

TO THE COURT, ALL PARTIES, AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that, as convenient to the Court pursuant to the Court's scheduling order, Dkt. No. 129 at 2, in the courtroom of the Honorable Edward M. Chen (Courtroom 5) of the above-entitled Court, located at 450 Golden Gate Avenue, San Francisco, California 94102, Kaiser Foundation Health Plan, Inc.; Kaiser Foundation Health Plan of Colorado; The Permanente Medical Group, Inc.; Southern California Permanente Medical Group; and Colorado Permanente Medical Group, P.C. (collectively, "Defendants") will and hereby do move this Court to dismiss the United States' Complaint-in-Intervention, Dkt. No. 110, under Federal Rule of Civil Procedure 12(b)(6).

Defendants bring this Motion on the grounds that the government has failed to adequately allege any claims against Defendants. For the False Claims Act ("FCA") claims brought against Defendants based on legal falsity, the government has failed to allege falsity and materiality. For the FCA claims brought against Defendants based on factual falsity, the government has failed to allege falsity and knowledge. All FCA claims that predate October 25, 2011 are time-barred under the FCA's statute of repose and must be dismissed on that basis as well. Finally, the government cannot maintain its common-law quasi-contract claims where it alleges the existence of a valid contract between the parties.

The Motion is based on this Notice of Motion, the accompanying Memorandum of Points and Authorities, the Request for Judicial Notice and for Incorporation of Documents by Reference, the Declaration of David Deaton in support of the Request for Judicial Notice and for Incorporation of Documents by Reference, any reply memorandum, and such other written and oral argument as may be presented to the Court.

Dated: June 21, 2022

Respectfully submitted,

By: /s/ *K. Lee Blalack, II*

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

For more than eight years, the government has investigated Defendants'[1] Medicare Advantage risk-adjustment business, leaving no stone unturned. It has issued broad subpoenas that touch on virtually every aspect of Defendants' diagnosis-coding practices across two states. See Dkt. No. 124-1, Exs. A–D. And it has had the benefit of scrutinizing millions of pages of Defendants' records. Dkt. No. 150 at 7. The government's narrow complaint—based primarily on Defendants' alleged violation of a few sentences in informal, nonbinding diagnosis-coding guidelines—demonstrates how little it has to show for these efforts.

The government's case focuses exclusively on one type of medical record documentation: amendments or "addenda" to medical records that occur after provider-patient visits.[2] The complaint alleges that when Defendants used addenda to record diagnosis codes for Medicare Advantage members[3] and report those codes to the U.S. Centers for Medicare and Medicaid Services ("CMS"), Defendants knowingly violated purported coding requirements that appear in subregulatory third-party and CMS documents. While CMS has approved the use of addenda, it has developed little guidance on how to code diagnoses from addenda. In fact, the guidelines at the heart of the government's case do not mention addenda at all. And they were not even issued through notice-and-comment rulemaking. In other words, the government seeks to hold Defendants liable for hundreds of millions of dollars in damages for an alleged failure to follow alleged coding requirements that say nothing about the type of documentation at issue in this case and that Congress did not enact, CMS did not promulgate, and the U.S. Department of Justice

[1] "Defendants" are Kaiser Foundation Health Plan; Kaiser Foundation Health Plan of Colorado; The Permanente Medical Group; Southern California Permanente Medical Group; and Colorado Permanente Medical Group.

[2] A medical record addendum is an addition to the medical record made after a doctor-patient encounter and used to correct an otherwise incomplete or incorrect medical record. *See* Request for Judicial Notice ("RJN"), Ex. B at 51 (CMS, *Medicare Program Integrity Manual* ch. 3.3.2.5 (endorsing addenda to ensure correctness and completeness in medical-record documentation)).

[3] "Members" refers to the individual Medicare beneficiaries who are enrolled in the Medicare Advantage program and receive their healthcare coverage through a private insurer known as a Medicare Advantage Organization ("MAO"). Members become patients when they receive medical care covered by the Medicare Advantage program.

cannot enforce. The complaint alleges no viable theory of fraud and must be dismissed.

First, the government does not allege that Defendants submitted or caused the submission of any "false" claims for payment to the government, as required to sustain the government's FCA causes of action. The government's primary theory of falsity is one of legal falsity, claiming that when Defendants submitted diagnosis-code data based on addenda to CMS, they falsely certified compliance with legally binding coding guidance. But not one of the guidance documents that the government cites, such as CMS's Medicare Managed Care Manual ("MMCM"), imposes any requirements for addenda-based coding. And all are subregulatory—they were not issued by CMS through notice-and-comment rulemaking and are not otherwise legally binding through regulation or contract. As a matter of law, such informal documents that do not address addenda practices cannot form the basis for an FCA action about addenda practices. In addition, the government pleads no plausible allegations that adherence to these purported coding requirements was "material" to CMS's payment decisions.

Second, the government's secondary theory of falsity—one based on factual falsity—also fails to satisfy the operative pleading requirements. In a few scattered paragraphs of its 364-paragraph complaint, the government alleges that Defendants submitted to CMS some diagnosis codes for addended medical conditions that "did not exist"—*i.e.*, the claims were factually false. But the government's complaint contains only threadbare recitals of factual falsity, which fall far short of the particularity required in fraud cases. Nor does the complaint contain any plausible allegations that Defendants submitted such false codes "knowing they were false."

Third, the government's long delay in bringing this case further limits its FCA claims. The FCA's ten-year statute of repose prohibits the government from bringing any claims based on purported FCA violations that occurred more than ten years before it filed its complaint, requiring the Court to dismiss all government FCA claims that predate October 25, 2011.

Finally, the government's common-law claims for unjust enrichment and payment by mistake fail as well. These equitable, quasi-contract claims are derivative of the flawed FCA claims and cannot survive in the face of a valid contract, which the complaint itself alleges exists.

For these reasons, the Court should dismiss the government's complaint in its entirety.

II. BACKGROUND

A. Medicare Advantage and Risk-Adjustment Payments

In the 1960s, the federal government established Medicare, a groundbreaking insurance program geared toward ensuring healthcare coverage for the country's aging population. *See United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018). Traditional Medicare consists of Medicare Part A, which covers inpatient hospital care, and Medicare Part B, which covers outpatient medical care. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 872 (D.C. Cir. 2021). Medicare Part C, now known as Medicare Advantage, allows beneficiaries to elect to receive their Medicare benefits from private MAOs, such as Kaiser Foundation Health Plan. *Id.* CMS administers both traditional Medicare and Medicare Advantage.

Under traditional Medicare, the government uses a fee-for-service reimbursement model; it compensates healthcare providers directly for every service rendered to Medicare beneficiaries. *Id.* at 873. For example, Medicare pays healthcare providers a specified amount for an office visit with a patient and another for a diagnostic x-ray, both under a fee schedule. Healthcare providers have no incentive to avoid delivering services that may be duplicative, inefficient, or expensive—the more services they perform, "the more money they earn." *See Silingo*, 904 F.3d at 672.

Congress enacted the predecessor to Medicare Advantage, the Medicare+Choice program, in the 1990s as an alternative to traditional Medicare to help the government manage the complicated task of insuring Medicare beneficiaries.[4] *See* 42 U.S.C. §§ 1395w-21–1395w-28; 70 Fed. Reg. 4588, 4657. The Medicare Advantage program allows Medicare beneficiaries to choose to receive their Medicare-reimbursed insurance benefits from private managed care or health maintenance organizations, also known as MAOs. *See* 70 Fed. Reg. 4588, 4589–90.

Unlike in traditional Medicare, CMS payments to MAOs do not change based on services provided to members. *Silingo*, 904 F.3d at 672. MAOs instead contract with the government to bear the financial risk of insuring members in return for a prospective, fixed monthly per-member

[4] In 2006, Congress revised Medicare+Choice and renamed it Medicare Advantage. The private healthcare plans that participated in the program became known as MAOs. *See* 42 U.S.C. §§ 1395w-21–1395w-28. For ease of reference, this Motion will refer to Medicare+Choice as "Medicare Advantage" and healthcare plans that participated in Medicare+Choice as "MAOs."

payment to anticipate the cost of care. *See* 42 U.S.C. § 1395w-23. Congress sought "to harness the power of private sector competition to stimulate experimentation and innovation that would ultimately create a more efficient and less expensive Medicare system." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 685 F.3d 353, 363 (3d Cir. 2012). This insurance-based model encourages MAOs to actively manage members' healthcare to promote long-term health and avoid expensive services down the road that would increase the costs of care.

Under the original Medicare Advantage reimbursement model, CMS set fixed per-member monthly payments regardless of individual members' health status. *See* 65 Fed. Reg. 40,170, 40,245–46. CMS would reimburse MAOs the same amount for a member suffering from a chronic medical condition such as diabetes as it would for a member with no known chronic illnesses. *See id.* This model unintentionally incentivized MAOs to enroll healthier individuals—who would generally require fewer services and cost MAOs less—over less healthy individuals. *See* 63 Fed. Reg. 34,968, 35,048. To combat this incentive, Congress introduced the "risk-adjustment" model central to this case when it created the current Medicare Advantage program. *See id.* at 35,005, 35,048.

Under the risk-adjustment model, CMS adjusts monthly per-member payments to MAOs based on variables that CMS has concluded will help predict future healthcare costs, including medical diagnoses and demographic factors, such as age and gender. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i), (a)(3); 42 C.F.R. § 422.308(c)(2). The purpose of the model is to incentivize MAOs to enroll all eligible individuals—irrespective of age, gender, or health status—by compensating MAOs for the financial risk they face from future healthcare costs of any given member. *See id.*; *Becerra*, 16 F.4th at 873–74. MAOs report data on the health status of members to CMS using "diagnosis codes," which are numeric or alphanumeric codes based on medical conditions documented by healthcare providers in medical records. *See Silingo*, 904 F.3d at 672. Healthcare providers typically record member diagnoses after member visits and send the corresponding codes to the members' Medicare Advantage plans. *Id.*; *see also* 42 U.S.C. § 1395w-23(a)(1)(C)(i). The plans then report the codes to CMS, which uses them to calculate payment rates for each member. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

The D.C. Circuit recently offered this example of how the reporting of medical conditions affects MAOs' payments: "a 72-year-old woman living . . . with diabetes without complications (relative factor 0.118), and multiple sclerosis (relative factor 0.556)" has a particular risk score keyed to her age, gender, other demographic factors, and medical diagnoses. *Becerra*, 16 F.4th at 874–75. Both medical conditions raised her risk score by a "relative factor," but multiple sclerosis resulted in a higher increase in that score because CMS had previously determined that treating that condition costs the traditional Medicare program more than treating ordinary diabetes without complications. *See id.* In other words, some medical conditions will result in higher risk scores and, in turn, higher CMS payments to Medicare Advantage plans because those conditions are associated with comparatively higher average medical costs than other conditions.

Because CMS compensates MAOs on a prospective basis, CMS requires diagnosis data to be reported anew each year for every Medicare Advantage member, even for chronic medical conditions that never resolve. *See id.* The risk-adjustment model thus encourages MAOs to document and report to CMS as many of their members' medical conditions as possible each year to ensure that the MAOs have the resources to care for their members. As a general matter, "CMS has acknowledged that there is nothing 'inappropriate, unethical or otherwise wrong with [healthcare providers] taking full advantage of coding opportunities to maximize Medicare payment that is supported by documentation in the medical record.'" *Integra Med Analytics LLC v. Providence Health & Servs.*, 854 F. App'x 840, 844 n.4 (9th Cir. 2021) (citations omitted).

CMS also requires by regulation that MAOs certify based on "best knowledge, information, and belief" that their risk-adjustment data submissions are "accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*). But CMS recognized that "encounter data [containing risk-adjustment data] come into [MAOs] in great volume and from a number of sources, presenting significant verification challenges for the organizations." 65 Fed. Reg. 40,170, 40,268. MAOs need not ensure that every piece of data is accurate; rather they must make "good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted." *Id.*

B. CMS's Limited Guidance for Diagnosis Coding Based on Addenda

The risk-adjustment model was a momentous development for healthcare providers,

requiring a sea change in medical record documentation and billing practices. Before risk adjustment, healthcare providers could focus documentation on services provided; they did not need to document every diagnosis during each patient visit because only procedures and tests were reimbursed. But the risk-adjustment model, with its prospective focus, made it necessary to document all medical conditions every year because a member's medical condition might not otherwise be considered in the risk-adjustment payment calculation. While a member's hardening of the arteries, also known as aortic atherosclerosis, may not require treatment in the current year, for example, the diagnosis results in a higher payment from CMS because, based on CMS's own calculations, the condition makes it more likely that the member will require more costly care the next year. This new model presented a major new administrative challenge for healthcare providers and MAOs. *See* 63 Fed. Reg. 34,968, 35,006; 65 Fed. Reg. 40,170, 40,268.

Despite this challenge, CMS has offered virtually no instruction to MAOs and healthcare providers on proper documentation and diagnosis coding for medical record addenda. The government cites two CMS documents that approve of addenda as a way to document medical conditions, but provide little instruction on how to use addenda. In a subregulatory risk-adjustment participant guide, CMS recognized that a healthcare provider's medical record "is not a static document" and may be amended through addenda after the healthcare provider meets with a member to add information to the medical record. RJN, Ex. A at 149 (CMS, *2008 Risk Adjustment Data Technical Assistance Participant Guide* § 6.4.2). CMS acknowledged that when "addenda are made, corrections or additions to the diagnoses reported to [MAOs] may be recommended, particularly if the HCC assignment is impacted"—*i.e.*, the assignment that allows CMS to compute the reimbursement impact of the diagnosis data. *See id.* CMS also has advised in a different subregulatory manual that addenda should comply with technical recordkeeping principles, such as certain signature and date requirements. *See* RJN, Ex. B at 51–52 (CMS, *Medicare Program Integrity Manual* ch. 3.3.2.5).

But beyond citing documents that approve of addenda, the government has pointed to no documentation or diagnosis-coding guidance for "accurate, complete, and truthful" risk-adjustment data derived from addenda. The lack of coding guidance for addenda is striking given

that addenda are a specific type of medical record documentation separate from the process of documenting medical conditions and services at the same time as the face-to-face encounter. *See id.* By definition, although addenda relate to an encounter, as amendments to a medical record, they occur after the encounter.

The government's complaint instead focuses on two coding statements that do not discuss addenda at all—statements that appear in the International Classification of Diseases ("ICD") Official Guidelines for Coding and Reporting ("ICD Guidelines") and CMS program manuals, such as the MMCM that in turn references the ICD Guidelines. RJN, Ex. C at 4 (CMS, MMCM, ch. 7, § 40 (Rev. 118, Sept. 19, 2014)).

The ICD Guidelines are drafted collaboratively by CMS and the National Center for Health Statistics and provide rules "to accompany and complement the official conventions and instructions provided within the" ICD itself. RJN, Ex. D at 1 (ICD Guidelines). The ICD establishes a standard set of diagnosis codes that CMS uses as the source of numeric and alphanumeric diagnosis codes for certain healthcare transactions. *See* 45 C.F.R. §§ 162.1000, 162.1002. The ICD Guidelines do not reference addenda, are not specific to the risk-adjustment model, and say nothing about how they should be applied for risk-adjustment purposes in the Medicare Advantage program. *See generally* RJN, Ex. D (ICD Guidelines).

Instead, in a single sentence of 100-plus pages of coding guidance, the ICD Guidelines advise healthcare professionals to code "all documented conditions that coexist at the time of the encounter/visit and that require or affect patient care, treatment or management." *Id.* at 108. For instance, an x-ray taken after a patient leaves an examination room might show that a medical condition existed "at the time of" the visit and "require[s] or affect[s]" patient care, treatment, or management. *See id.* But neither the ICD Guidelines nor CMS has explained—by regulation or subregulatory guidance—what it means for a diagnosis to "require or affect" care, treatment, or management with respect to documenting medical conditions in addenda.

CMS subregulatory documents such as the MMCM also introduced a new concept for risk adjustment. Specifically, CMS program manuals advise that diagnoses submitted for risk-adjustment purposes be documented "as a result of a face-to-face visit" or "in a medical record

that was based on a face-to-face health service encounter between a patient and a healthcare provider" (the purported "face-to-face" requirement). *See, e.g.*, RJN, Ex. C at 4 (MMCM); RJN, Ex. A at 158 (CMS, *2008 Risk Adjustment Data Technical Assistance Participant Guide* § 7.1.5). Again, CMS did not issue these statements in any regulation, explain what "as a result of" or "based on" a face-to-face encounter means, or clarify how the principle applies to the specific circumstance of documenting medical conditions in addenda.

The few CMS documents reflecting the agency's application of these subregulatory instructions indicate that the instructions should be applied leniently given the prospective nature of the risk-adjustment model. For example, CMS has explained that diagnosis coders in the Medicare Advantage context "should be aware of the background and prospective nature of the [risk-adjustment] payment process including its basis on chronic conditions, and dependence on validating chronic conditions for an annual payment on just the review of one record." Dkt. No. 150 at 10 (quoting *CMS 2014 RADV Reviewer Guidance* at 5 (May 8, 2014)). But CMS has not provided further guidance as to how broad statements plucked from the ICD Guidelines and CMS manuals should be applied to coding via addenda.

C. The Government's Intervention Complaint

Relator Ronda Osinek filed a sealed *qui tam* action against "Kaiser Permanente" almost nine years ago, raising allegations about Defendants' Medicare Advantage risk-adjustment practices. The government spent the next eight years investigating Defendants as several other relators filed suits similar to Osinek's against Defendants and other affiliated entities. The government finally decided to intervene in the underlying *qui tam* actions on July 29, 2021, and brought its complaint on October 25, 2021. Dkt. Nos. 65, 110.

The complaint names three regional medical groups that deliver healthcare to patients: The Permanente Medical Group (which delivers healthcare in Northern California), Southern California Permanente Medical Group, and Colorado Permanente Medical Group (together, the "Medical Group Defendants"). *See* Compl. ¶¶ 23–27. It also names the nonprofit Kaiser Foundation Health Plan and Kaiser Foundation Health Plan of Colorado (together, the "Health Plan Defendants"), which contract with CMS to provide Medicare Advantage plans in California

and Colorado, respectively. *Id.* ¶¶ 20–22. Together with other health plans, hospitals, and medical groups, Defendants operate under the trade name Kaiser Permanente. *See id.* ¶¶ 19, 28. Defendants employ tens of thousands of healthcare providers and deliver healthcare to over a million individuals enrolled in the Medicare Advantage program in Colorado and California. *See id.* ¶¶ 23–26. Through an integrated healthcare delivery system, Defendants coordinate to improve patient outcomes through preventive care, evidence-based treatments, technologies, and information-sharing across the organizations. *See id.* ¶¶ 28–29, 31.

As noted, the government's complaint focuses exclusively on Defendants' use of medical record addenda for Medicare Advantage members. The complaint centers on two types of purportedly inappropriate addenda-related practices:

First, the government accuses Defendants of adding medical conditions to medical records "unrelated" to the member's visit with the healthcare provider. *Id.* ¶¶ 1, 126. This theory is the complaint's primary focus and turns on the government's view of the ICD Guidelines' instruction to "[c]ode all documented conditions," RJN, Ex. D at 108, and what the government argues is a requirement to submit to CMS diagnoses documented "as a result of a face-to-face visit." Compl. ¶ 80. In asserting this theory of fraud, the government does not allege that Defendants invented "face-to-face" visits or systematically falsified clinically inaccurate diagnoses. The government does not contest that Defendants in fact ***conducted face-to-face visits*** with members and then made addenda to the medical records for those visits to reflect ***clinically accurate diagnoses*** that were relevant to CMS's risk-adjustment payments. *See id.* ¶¶ 4, 98, 122.

Second, the government contends in a few scattered paragraphs that Defendants recorded some medical conditions that "did not exist." *Id.* ¶¶ 1, 11, 97, 126. Other than these conclusory assertions, the government does little to explain how Defendants fabricated medical conditions.

Based on these allegations, the government contends that Defendants violated the FCA and conspired to violate the FCA. *Id.* ¶¶ 347–58. The government also brings common-law quasi-contract claims of unjust enrichment and payment by mistake. *Id.* ¶¶ 359–64.

III. LEGAL STANDARD

To survive dismissal under Federal Rule of Civil Procedure 12(b)(6), the government's

complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Dismissal is proper where there is a "lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). While well pleaded facts can be accepted as true, the Court need not "'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011).

The government's fraud allegations also must comply with the heightened pleading standard of Rule 9(b), which requires a party to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The allegations must be "specific enough to give [a defendant] notice of the particular misconduct which is alleged to constitute the fraud so that [the defendant] can defend against the charge and not just deny that [it has] done anything wrong." *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (quotations omitted).

IV. ARGUMENT

The government has failed to allege a viable claim. The FCA creates liability only for those who "knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval" to the U.S. government. 31 U.S.C. § 3729(a)(1). The FCA is not "an all-purpose antifraud statute." *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). It is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016). And it is not a tool to clarify vague or ambiguous administrative documents. *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1029 (D. Nev. 2006). FCA liability is appropriate only where "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 579 U.S. at 181.

Here, the government's complaint must be dismissed. The government does not point to any legally binding coding requirements that Defendants violated and that can support its FCA claims. Nor has it shown why the alleged violations of subregulatory guidance are material to CMS's payment decision. The government also has not plausibly alleged that Defendants knowingly submitted diagnosis codes for nonexistent medical conditions to CMS—their

conclusory allegations otherwise do not state a claim. The FCA's ten-year statute of repose further prevents the government from bringing FCA claims that accrued before October 2011. And the tacked-on claims for unjust enrichment and payment by mistake fail for the same reasons as the FCA claims and, in any case, cannot survive in the face of valid contracts between CMS and the Health Plan Defendants. These defects require dismissal of the entire complaint.

A. The Court Should Dismiss the Government's FCA Claims Based on a Theory of Legal Falsity for Failure To Plead Falsity and Materiality

1. The Government Fails To Plead Falsity

The government fails to plead falsity in support of its FCA claims premised on a theory of legal falsity. "Evidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (quotations omitted). "The FCA does not define false. Rather, courts decide whether a claim is false or fraudulent by determining whether a defendant's representations are accurate in light of applicable law." *United States v. Bourseau*, 531 F.3d 1159, 1164 (9th Cir. 2008). FCA claims must be pleaded with the particularity required by Rule 9(b), so the falsity allegations must give a defendant "notice of the particular misconduct which is alleged to constitute the fraud charged" and "supply reasonable indicia that false claims were actually submitted." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010) (quotations omitted).

As noted, the thrust of the government's complaint centers on a theory of legal falsity. A legally false claim occurs "when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). Here, the complaint asserts that many of the addended diagnosis codes are false because the processes used to generate them did not comply with purported legal requirements. Compl. ¶¶ 5, 10–11, 97, 127, 304, 334–36. From the government's view, Defendants implicitly (and falsely) certified that they complied with this allegedly binding coding guidance when they submitted diagnosis codes to CMS. But this theory fails because it depends on unenforceable subregulatory documents and irrelevant regulations and contract terms that do not address addenda.

a. Subregulatory Documents Do Not Require Compliance with Coding Guidance

The government bases it claims on subregulatory documents that "do not have the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) (quotations omitted). Indeed, they can "***never*** form[] the basis for an enforcement action" because they do "not impose any legally binding requirements on private parties." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (quotations omitted) (emphasis added). Enforcement actions "must" be based on "a legislative rule" that is the product of "notice and comment." *Id*. DOJ's own policy and procedures manual agrees and requires enforcement actions to be based on "failure to comply with a binding obligation." RJN, Ex. J at 2 (DOJ, Justice Manual § 1-19.000); *see also United States ex rel. Yannacopoulos v. Gen. Dynamics*, 2007 WL 495257, at *3 (N.D. Ill. Feb. 13, 2007) (failure to comply with administrative guidance documents that "were not promulgated pursuant to any rulemaking power of the agency . . . does not establish an FCA violation").

Congress has prohibited CMS from establishing Medicare payment requirements based on subregulatory documents. The Medicare Act mandates notice and comment for any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. § 1395hh(a)(2). In *Azar v. Allina Health Services*, the Supreme Court clarified that when the Medicare Act "does not speak directly to [an] issue and thus leaves a gap for the agency to fill," the government "can't evade its notice-and-comment obligations" when filling that gap. 139 S. Ct. 1804, 1817 (2019) (marks omitted).

Although the Supreme Court did not define "substantive legal standard," the D.C. Circuit has defined that term to include, "at a minimum," "a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'" *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017). "If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a 'substantive legal standard.'" *Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019), *aff'd*, 17 F.4th 376 (3d Cir. 2021).

Allina's rationale applies with equal force in the FCA context. In *Polansky*, a relator brought FCA claims alleging that a defendant defrauded Medicare and Medicaid by causing

hospitals to falsely bill inpatient care as outpatient care. *Id.* at 918–19. The relator relied on a policy found in CMS manuals that did not go through notice-and-comment rulemaking. *Id.* at 932–33. The policy at issue was a substantive legal standard because it "determined entitlement to reimbursement" and "delineates the circumstances in which a hospital is entitled to higher [] reimbursement." *Id.* at 935. *Allina* "compel[led] the conclusion that there can be no FCA liability," and the court dismissed the FCA claims. *Id.* at 936.

Here, the Medicare Act and *Allina* foreclose the government's theory of legal falsity. Based on the government's framing, the coding documents at issue directly impact Defendants' right to reimbursement and therefore represent a substantive legal standard. *See id*. Indeed, the government's theory of legal falsity assumes that compliance with certain coding documents is a precondition to payment from CMS. *See, e.g.*, Compl. ¶¶ 261, 331. But CMS cannot premise an MAO's right to payment on compliance with a substantive legal standard that was not the product of formal rulemaking. *Polansky*, 422 F. Supp. 3d at 937.

CMS has not met *Allina*'s requirements here. The government fails to identify any binding rule that establishes the obligations it seeks to enforce:

ICD Guidelines. The government cannot maintain an FCA claim based on its assertion that Defendants were not entitled to payments for diagnosis codes derived through addenda that did not conform to the ICD Guidelines' statement to "[c]ode all documented conditions that coexist at the time of the encounter/visit and that require or affect patient care, treatment or management." Compl. ¶¶ 5, 81–83, 87; RJN, Ex. D at 108. The ICD Guidelines were not created through notice-and-comment rulemaking and do not address addenda. Nor is there any regulation associated with Medicare Advantage that incorporates the ICD Guidelines as binding requirements for addenda specifically. The government must identify some law or regulation requiring compliance with the ICD Guidelines for them to be a potential basis for an FCA violation.[5] It cannot.

[5] To be clear, Defendants do not agree with the government's interpretation of the ICD Guidelines and other coding documents. This Motion, however, focuses on whether the ICD Guidelines and other documents cited by the government are legally binding requirements the violation of which can sustain this FCA action. Defendants reserve the right to challenge the government's interpretation of such documents later in the case and after further discovery.

Medicare Managed Care Manual. The government also cannot maintain an FCA claim based on the MMCM's purported requirement that CMS diagnosis codes must be documented "as a result of a face-to-face visit" and its observation that diagnoses should be coded according to the ICD Guidelines. *See* Compl. ¶¶ 80–81. The MMCM, like the ICD Guidelines, does not reference addenda and was not issued through notice-and-comment rulemaking, so its violation cannot result in FCA liability either. *See Polansky*, 422 F. Supp. 3d at 936.

CMS Participant Guide. The government's reliance on a 2013 CMS Participant Guide that discusses how "[d]iagnoses must result from a face-to-face visit" to be reported to CMS is similarly insufficient. *See* Compl. ¶¶ 69, 84; RJN, Ex. E at 12 (CMS, 2013 Participant Guide). Like the MMCM and the ICD Guidelines, the Participant Guide does not refer to addenda, nor is it a regulation promulgated by notice-and-comment rulemaking.

AHIMA Practice Briefs. The government cannot premise an FCA claim on "practice briefs" issued by the American Health Information Management Association ("AHIMA"), a private professional organization. *See* Compl. ¶ 191; RJN Exs. F-H (AHIMA Practice Briefs). The government asserts that Defendants were not entitled to payments based on diagnosis codes that resulted from allegedly improper medical record queries, which are "communication tool[s] or process[es] used to clarify documentation in the health record for accurate code assignment." Compl. ¶ 129. Defendants allegedly sent queries to healthcare providers that did not comply with AHIMA's query advice, which in turn led providers to record medical conditions in addenda in violation of the purported "face-to-face" requirement and ICD Guidelines. *Id*. ¶¶ 185, 191–211.

While these practice briefs recognize that queries can result in valid addenda that are by definition added after a face-to-face encounter, they do not address coding in the Medicare Advantage context and are not issued by a government entity, much less the product of any notice-and-comment process. The government does not and cannot cite a single statutory or regulatory provision requiring MAOs to follow AHIMA practice briefs.

Internal Company Policies. The government asserts that Defendants are not entitled to payments for diagnosis codes that violated Defendants' own internal advice on the timing of addenda. *Id.* ¶¶ 276–77. As with AHIMA practice briefs, the cited internal documents are non-

governmental, and there is no statutory or regulatory provision requiring Defendants to follow voluntarily adopted policies as a condition of payment from CMS.

b. Data Formatting and Certification Regulations Do Not Require Compliance with ICD Guidelines When Coding from Addenda

The few regulations the government cites that were adopted through notice-and-comment rulemaking also cannot form the basis for the government's fraud claims because they do not require Defendants to comply with the ICD Guidelines when coding from addenda.

The government's reliance on 45 C.F.R. §§ 162.1000 and 162.1002 is misplaced. *See id.* ¶ 81. These sections do not concern medical record addenda. Nor do they apply to risk-adjustment data derived from addenda. HHS promulgated Part 162 over two decades ago to address a "lack of standardization" in the electronic transfer of healthcare data that made it difficult for healthcare providers and health plans to "achieve efficiency and savings." 65 Fed. Reg. 50,312; *see also* 42 U.S.C. § 1320d-2; 63 Fed. Reg. 25,272–73. Part 162 identifies "standard medical data code sets"—including the code sets established in ICD Guidelines—to be used in nine categories of "covered transactions."[6] 65 Fed. Reg. 50,312, 50,317, 50,323; 45 C.F.R. §§ 162.1000, 162.1101–1902.

Part 162 is irrelevant here. It does not adopt general coding principles or refer to addenda; it adopts only "code sets"—*i.e.*, the set of numeric and alphanumeric codes that correspond to diagnoses. *See supra* at 4. In other words, while Part 162 may require MAOs to use particular codes to communicate diagnoses to CMS, the regulation does not prescribe when a medical condition can be coded or diagnosed. In addition, risk-adjustment data derived from addenda sent from a private health plan to a government entity, such as CMS, is ***not*** one of the covered categories of data. *See supra* at 15 n.6. Part 162's regulatory history explains that data sent from a private managed care organization to a state Medicaid agency—equivalent to an MAO sending

[6] These include: (1) healthcare claims or equivalent encounter information from healthcare providers to health plans; (2) eligibility for a health plan; (3) referral certification and authorization; (4) healthcare claim status; (5) enrollment and disenrollment in a healthcare plan; (6) healthcare electronic funds transfers and remittance advice; (7) health plan premium payments; (8) coordination of benefits; (9) Medicaid pharmacy subrogation. 45 C.F.R. § 162.1101–1902.

CMS data—"***does not need to be a standard transaction***." 65 Fed. Reg. 50,312, 50,318 (emphasis added); *see id.* at 50,317 ("Data submissions or exchanges for purposes other than those designated in this regulation . . . do not require use of the standards.").

The government's reliance on 42 C.F.R. §§ 422.504(*l*), 422.504(h)(2), and 422.310(d)(1) is similarly misplaced. These regulations address MAOs' submission of risk-adjustment data to CMS. Under § 422.504(*l*), CMS requires an individual officer or employee of an MAO to make good-faith efforts to certify that risk-adjustment data submissions to CMS are "accurate, complete, and truthful" to that officer or employee's best knowledge, information, and belief. 42 C.F.R. § 422.504(*l*); 65 Fed. Reg. 40,170, 40,268. But that provision says nothing about whether MAOs need to comply with the ICD Guidelines or the purported "face-to-face" requirement when coding based on medical conditions documented in addenda.

Section 422.504(h)(2) states only that "[t]he [MAO] agrees to comply with . . . HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164." This regulation creates an obligation to follow other regulations, none of which creates a relevant limitation on which medical conditions healthcare providers can diagnose in addenda.[7]

Section 422.310(d)(1) likewise does not impose any substantive coding requirements on MAOs that submit codes from addenda. It provides that MAOs "must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards." 42 C.F.R. § 422.310(d)(1). This regulation is about the form of data submitted to CMS, not the content—it is "not directed toward specifying the procedure for properly coding patients' medical conditions." *See United States ex. rel. Rasmussen v. Essence Grp. Holdings Corp.*, 2020 WL 4381771, at *6 n.10 (W.D. Mo. Apr. 29, 2020).

[7] Of 45 C.F.R.'s three parts, the government asserts that only Part 162 contains any payment limitations applicable to MAOs' submissions to CMS. *See* Compl. ¶ 81. But as explained, it does not. *See supra* at 15. Along with Part 162, Parts 160 and 164 make up the HIPAA Administrative Simplification Regulations. Part 164 requires covered entities to "[e]nsure the confidentiality, integrity, and availability of all electronic protected health information" and "[p]rotect against . . . threats or hazards to the security or integrity of such information." 45 C.F.R. § 164.306(a). Part 160 provides definitions and procedures to ensure compliance with Parts 162 and 164. *See, e.g.*, 45 C.F.R. § 160.103 (definitions), § 160.308 (compliance reviews), §§ 160.402–04 (civil penalties). Neither Part contains provisions about addenda coding.

c. CMS's Contracts Do Not Require Compliance with ICD or Other Guidelines When Coding from Addenda

Finally, the government cannot rely on CMS's contracts with the Health Plan Defendants to support its legal falsity theory.[8] *See* Compl. ¶ 75. The contracts state: "The [MAO] agrees to operate one or more coordinated care plans . . . 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.)." RJN, Ex. I at 2 (CMS-MAO contract). Again, none of the "applicable" statutes, regulations, and policies mentions coding from addenda.

In any event, the government cannot seriously contend that the broad, non-specific language of the contract provision somehow means that the Health Plan Defendants must adhere to every word of the ICD Guidelines simply because they are generally referenced in the MMCM, which itself is referenced in a parenthetical in a single sentence of a CMS contract. If that were true, then MAOs' right to payment would hinge on compliance with every past, present, and future policy document that CMS releases in any form—even one as informal as a CMS handout from an industry conference that CMS later uploaded to its website without notice. But as the Supreme Court has said about Congress, agencies usually do "not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—[they] do[] not . . . hide elephants in mouseholes." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1626–27 (2018) (quotations omitted).

The location of the clause also confirms that the contract does not require MAOs to comply with nonbinding guidance in order to receive payment from CMS. The clause appears in Article II of the contract, which describes the network and benefit structures of a coordinated care plan. RJN, Ex. I at 2. But the section that addresses ***payment*** is Article IV, which does not reference subregulatory guidance at all and cites only statutes and regulations. *Id.* at 6–7.

CMS likewise cannot skirt its statutory notice-and-comment obligations by including requirements to follow subregulatory documents in contracts of adhesion. The contract prohibits that workaround. It mandates that if any provision "conflicts with the provisions of any statute or regulation applicable to an [MAO], the provisions of the statute or regulation shall have full force

[8] The complaint does not allege any contracts between CMS and the Medical Group Defendants.

and effect." *Id.* at 16. The Medicare Act requires notice and comment for any "substantive legal standard." 42 U.S.C. § 1395hh(a)(2). Allowing CMS to create contractual obligations that are not reflected in the Medicare Act or any regulations guts Congress's intent to require notice-and-comment rulemaking for gap-filling guidance. *See Allina*, 139 S. Ct. at 1816.

Such a workaround would also make bad policy. The purpose of notice-and-comment rulemaking is to allow affected parties to be heard and to ensure agencies engage in reasoned and well-informed decision-making before promulgating rules with the force and effect of law. *See Perez*, 575 U.S. at 96. Permitting CMS to avoid its obligations through standard agreements whose terms are not negotiated is inconsistent with the Medicare Act.

* * *

The crux of the government's complaint is that Defendants did not follow a web of subregulatory and nongovernmental coding documents when coding from addenda. One would need to sift through hundreds of thousands of pages of subregulatory materials to find the items that the government now cites as the basis for a fraud claim. And even then, those materials do not reference the type of documentation on which the government has staked its case. Defendants should not be subjected to liability for the alleged failure to comply with nonbinding subregulatory passages when coding from addenda. The Supreme Court has recognized that such documents can never support an enforcement action, *Kisor*, 139 S. Ct. at 2420, and this Court should dismiss the government's FCA claims that are premised on a theory of legal falsity.

2. The Government Fails To Plead Materiality

The Court must dismiss the government's claims premised on a theory of legal falsity for an independent reason—the complaint lacks any plausible allegations that Defendants' purported failure to comply with subregulatory guidance was "material" to CMS's payment decision.

Materiality requires more than a falsely certified compliance with guidance documents—rather, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 579 U.S. at 192. Materiality means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

Id. at 192–93 (quotations omitted). The "materiality standard is demanding," *id.* at 194, and the FCA includes "a heightened standard for pleading materiality," *United States v. Comstor Corp.*, 308 F. Supp. 3d 56, 85 (D.D.C. 2018). "[M]ateriality is satisfied . . . only where compliance is 'a *sine qua non* of receipt of state funding.'" *Ebeid*, 616 F.3d at 998 (citations omitted). The Supreme Court has rejected the view "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation." *Escobar*, 579 U.S. at 195.

Courts routinely dismiss claims premised on conclusory materiality allegations. In *United States v. Vora*, for example, the government alleged that "Medicare would not pay" for the services at issue "if it knew the claims violated the Medicare laws, regulations, and program instructions." 2022 WL 89177, at *5 (W.D. Ky. Jan. 7, 2022) (alterations omitted). The government "simply incant[ed] [the materiality] element's legal language without adding any factual support." *Id.* The complaint did not allege that any legal requirements the defendant purportedly violated were "conditions of payment." *Id.* at *4. It did not allege anything about "the consistency of the government's refusal or non-refusal to pay claims subject to such regulatory violations." *Id.* And it did not allege whether the violations were "minor, insubstantial, or essential"—all considerations *Escobar* said mattered to materiality. *See id.* (citing *Escobar*, 579 U.S. at 193 n.5, 194–95). The court thus dismissed claims premised on an implied-certification theory. *Id.* at *7; *see also, e.g.*, *Knudsen v. Sprint Commc'ns Co.*, 2016 WL 4548924, at *12 (N.D. Cal. Sept. 1, 2016) (dismissing complaint given relator's "conclusory statement" about compliance with a specific contract provision being material).

Here, the government has not pleaded materiality with the requisite particularity. As in *Vora*, the materiality allegations are conclusory, such as: "If CMS had known [of the alleged false certifications], CMS would have refused to make risk-adjustment payments based on the improper coding and/or taken other appropriate actions." Compl. ¶ 354; *see also id.* ¶¶ 350, 353, 357, 360. There are no allegations that CMS ever has refused to pay claims for failure to follow the guidance at issue, or that CMS communicated to Defendants—or any MAO—that compliance with the guidance cited was central to reimbursement. The government "has given the Court no

basis to conclude that" Defendants' alleged failure to comply with the subregulatory guidance "would be material to the payment decision[.]" *Vora*, 2022 WL 89177, at *5.

The most specific materiality allegation in the complaint asserts that, because Kaiser Foundation Health Plan of Colorado redacted certain diagnoses that had been added to members' health records following allegedly improper queries, "Kaiser was aware that its improper query and addenda issues were material to CMS." Compl. ¶ 330. But this allegation fails to establish materiality. First, Kaiser Foundation Health Plan of Colorado's conduct says nothing about whether compliance was material ***to CMS*** or whether ***CMS*** would have declined to pay had it been aware of the allegedly leading queries. Second, this allegation focuses narrowly on compliance with query "practice briefs" issued by AHIMA, which the government has not alleged is a condition to payment (and, in any case, such briefs are not binding, *see supra* at 14).

If facts existed to support materiality, the government is well positioned to know and plead them since it is the payor here and has scrutinized Defendants' Medicare Advantage reimbursements for the past eight years. But it has failed to plead materiality sufficiently, and the Court should dismiss the claims premised on an implied-certification theory.

B. The Court Should Dismiss the Government's FCA Claims Based on a Theory of Factual Falsity for Failure To Plead Falsity and Knowledge

1. The Government Fails To Plead Falsity

The government also fails to plead that Defendants submitted any factually false claims to CMS. A factually false claim is "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). Under Rule 9(b)'s particularity requirement, the government "must allege the who, what, when, where, and how of the misconduct charged, including what is false or misleading about a statement, and why it is false." *See United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016) ("*Swoben*") (quotations omitted). The complaint states that Defendants addended medical records with medical conditions that "did not exist." Compl. ¶¶ 1, 11, 97; *see also id.* ¶¶ 126, 155. But these conclusory allegations fail to identify the "who, what, when, where, and how" required by Rule 9(b). The government fails, for instance, to allege

what medical conditions were added to medical records that members did not have, who invented these conditions, or what methods Defendants used to add these conditions to the records.

The methods that the government does discuss all relate to the government's theory of legal—not factual—falsity. For example, the complaint alleges that Defendants addended medical conditions even if they were not addressed during the face-to-face visit. *See, e.g.*, *id.* ¶ 4. But that does not mean a condition does not exist; it means only that Defendants allegedly did not follow the government's view of the purported "face-to-face" requirement. The complaint lacks any specific factual allegations that Defendants knowingly addended medical conditions that members did not have. "Broad allegations that include no particularized supporting detail do not suffice" to meet Rule 9(b)'s requirements. *Swoben*, 848 F.3d at 1180.

Although the government alleges that some members whose medical records reflected an addended cachexia (wasting syndrome) diagnosis "did not even have cachexia," Compl. ¶ 300, these allegations still fail to meet Rule 9(b)'s requirements. The government itself alleges that a diagnosis of cachexia is "based on clinical judgment rather than clinical indicators." *Id.* ¶ 295. By the government's own admission, the healthcare provider has sole discretion to decide whether a member has cachexia. Yet the government does not state that a single healthcare provider exercised improper clinical judgment in documenting cachexia. Instead, the government relies on alleged conjecture by Defendants' employees that certain queries that Defendants sent ***could*** lead to the inappropriate assignment of a cachexia diagnosis. *See, e.g.*, *id.* ¶ 297. This rank speculation does not plausibly allege that Defendants fabricated cachexia diagnoses.

2. The Government Fails To Plead Knowledge

The government's FCA claims based on a theory of factual falsity independently fail because the government does not allege that Defendants ***knew*** that they submitted diagnosis codes to CMS for medical conditions that members did not have.

The FCA attaches liability to "the knowing presentation of" and the knowing making or using of a statement material to a false claim. *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996); *see also* 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B), (b)(1). The scienter element is "critical" to establishing liability under the FCA. *United States ex rel. Hochman v.*

Nackman, 145 F.3d 1069, 1073 (9th Cir. 1998). And it is "rigorous." *Escobar*, 579 U.S. at 192. Without a "knowingly false or misleading representation," a violation of a regulatory provision "does not amount to fraud." *Anton*, 91 F.3d at 1267 (quotations omitted). Instead, scienter requires a showing that the defendant made statements that were "intentional, palpable lie[s]." *Id.* While knowledge can be alleged generally in the pleadings, an FCA plaintiff must identify some "facts" that "support [the] conclusory allegation that defendants knowingly submitted false claims." *United States ex rel. Modglin v. DJO Glob. Inc.*, 48 F. Supp. 3d 1362, 1405 (C.D. Cal. 2014), *aff'd sub nom. United States v. DJO Glob., Inc.*, 678 F. App'x 594 (9th Cir. 2017).

Here, the complaint contains no allegations that Defendants submitted diagnosis codes to CMS for medical conditions that Defendants ***knew*** their members did not have. Every knowledge allegation relates to legal—not factual—falsity. For example, the government alleges that an audit revealed coding errors including "[a]ddendum made greater than 1 month later," "[diagnosis] not in encounter," and "[n]o link in encounter." Compl. ¶ 314. But the complaint does not allege that Defendants ***knew*** coded diagnoses did not exist ***at all***.[9]

C. The FCA's Statute of Repose Requires the Court To Dismiss FCA Claims Premised on Alleged Violations that Occurred Before October 25, 2011

The FCA's ten-year statute of repose requires dismissal of the government's claims that predate the complaint by ten years—*i.e.*, October 25, 2011. *See* 31 U.S.C. § 3731(b). The government seeks to prosecute alleged FCA violations beginning "sometime prior to 2009," more than 13 years ago. Compl. ¶ 1. The statute of repose prevents litigation of such stale claims.[10]

The FCA makes clear that "in no event" may an FCA action be brought "more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b). The "in no event" clause is the FCA's "ten-year statute of repose." *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1218 (9th Cir. 1996); *United States ex rel. Wood v. Allergan, Inc.*, 2020 WL

[9] While the complaint alleges that some employees in Colorado raised concerns about how prompts for the medical condition cachexia ***could*** lead healthcare providers to an "inappropriate assignment of the diagnosis," *id.* ¶ 297, there are no allegations that the providers improperly diagnosed cachexia ***and*** that Defendants then submitted diagnosis codes knowing the diagnoses were incorrect.

[10] Defendants reserve the right to make other limitations-based defenses later in the litigation based on information learned in discovery.

3073293, at *3 (S.D.N.Y. June 10, 2020). A statute of repose "puts an outer limit on the right to bring a civil action." *CTS Corp. v. Waldburger*, 573 U.S. 1, 8 (2014). Here, the FCA's statute of repose prohibits the government from bringing FCA claims based on claims for payment submitted prior to October 25, 2011. *Houpt v. Wells Fargo Bank, N.A.*, 800 F. App'x 533, 534 (9th Cir. 2020) (FCA claims accrue when the request for payment is submitted).

The government may argue that its complaint "relates back" to the 2013 filing date of the first *qui tam* complaint such that pre-October 25, 2011 claims are timely. But the FCA's plain language, its legislative history, and the purpose of repose periods all foreclose that result.

The text of the FCA makes clear that the government cannot circumvent the statute of repose by relating its complaint to an earlier-filed *qui tam* complaint. The FCA includes both a two-tiered statute of limitations and a statute of repose. *United States v. Scan Health Plan*, 2017 WL 4564722, at *8 (C.D. Cal. Oct. 5, 2017) ("*Swoben II*"). The FCA's statute-of-limitations provisions immediately precede the repose provision in § 3731(b). And the FCA's relation-back provision states that "***[f]or statute of limitations purposes***," any "Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action . . . ." 31 U.S.C. § 3731(c) (emphasis added). In other words, the government's complaint can relate back to an earlier-filed complaint for only "statute of limitations purposes"—not for repose purposes. *Id.* The "in no event" language of the FCA's repose provision also explicitly disclaims exceptions of any kind. 31 U.S.C. § 3731(b).

The FCA's legislative history confirms the plain-text reading. The statute of repose predates the relation-back provision, which Congress did not add until 2009. *See* Pub. L. 111-21, § 4(b) (2009). Congress "considered consolidating the separate statutes of limitations and repose into a single ten-year statute of limitations before rejecting that consolidation as insufficiently protective of defendants' interests in repose." *Swoben II*, 2017 WL 4564722, at *8 (citing Pub. L. 111-21, § 4(b), 123 Stat. 1623 (2009)). Congress explicitly limited relation back to "statute of limitations purposes"—so "it follows that Congress did not intend the relation back mechanism to alter or affect the protection established under the [existing] repose provision." Boese & Baruch, *Civil False Claims & Qui Tam Actions* § 5.04 n.349 (5th ed., 2022 Supp.).

Finally, an exception-free statute of repose aligns with the doctrine's purpose. Unlike statutes of limitations, which test the diligence of the plaintiff in bringing suit, statutes of repose protect the defendant from indefinite liability and place an ***absolute bar*** on a defendant's liability. *CTS Corp.*, 573 U.S. at 8, 10. For this reason, statutes of repose are not subject to equitable tolling and other extensions that may apply to statutes of limitations. *Id.* at 10.

Swoben II applied the FCA's statute of repose in an identical procedural situation. 2017 WL 4564722, at *8. There, the government filed an FCA complaint with claims older than ten years. *Id.* Relying on the FCA's text, its legislative history, and the purpose of repose periods, the court enforced the statute of repose and held that "the Government[] cannot rely on the relation back doctrine contained in Section 3731(c) because Section 3731(c) is specifically limited to 'statute of limitations purposes.'" *Id.* (quoting 31 U.S.C. § 3731(c)). "[W]ithout a repose period, the 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." *Id.* (quotations omitted).[11]

The situation here is indistinguishable, and this Court should dismiss the government's FCA claims that predate October 25, 2011.

D. The Court Should Dismiss the Government's Quasi-Contract Claims

Finally, the Court should dismiss the government's claims for unjust enrichment and payment by mistake for two reasons. First, the common-law claims are derivative of the flawed FCA claims and fail for the same reasons. Compl. ¶¶ 359–64; *United States v. Aegis Therapies, Inc.*, 2015 WL 1541491, at *14 (Mar. 31, 2015) (dismissing claims for unjust enrichment and payment by mistake because they were "purely derivative" of dismissed FCA claims).

Second, as asserted against the Health Plan Defendants, the common-law claims fail as a matter of law because the complaint alleges the existence of a contract between the parties. Equitable remedies for such quasi-contractual claims are unavailable where an express contract

[11] While another judge in the Central District broke with *Swoben II* and allowed the government to bring FCA claims predating the complaint by more than ten years, *United States ex rel. Mei Ling v. City of Los Angeles*, 2018 WL 3814498, at *22 (C.D. Cal. July 25, 2018), that decision ignores the clear delineation between statutes of limitations and repose, *CTS Corp.*, 573 U.S. at 8 ("each has a distinct purpose and each is targeted at a different actor").

defines the rights between the parties. *See Paracor Fin., Inc. v. Gen. Elec. Cap. Corp.*, 96 F.3d 1151, 1167 (9th Cir. 1996) ("[U]njust enrichment is an action in quasi-contract, which does not lie when an enforceable, binding agreement exists defining the rights of the parties."). Where a plaintiff has "affirmatively pled that [the parties] entered into a contract, [the plaintiff] cannot assert an unjust enrichment or quasi-contract claim against [the defendant] as a matter of law." *Luxul Tech. Inc. v. NectarLux, LLC*, 2015 WL 4692571, at *7 (N.D. Cal. Aug. 6, 2015) (dismissing quasi-contract claims with prejudice on the pleadings).

Here, the government alleges the existence of binding contracts between the Health Plan Defendants and CMS. *See, e.g.*, Compl. ¶¶ 20–22, 78–79. And while the government does not allege a contractual relationship between CMS and the Medical Group Defendants, it does allege that they must "comply with" the Health Plan Defendants' "contractual obligations to CMS." *Id.* ¶ 77. Given these allegations, it is not clear how the government could have quasi-contract claims against the Medical Group Defendants either. Accordingly, the Court must dismiss the quasi-contract claims here with prejudice. *See United States v. First Choice Armor & Equip., Inc.*, 808 F. Supp. 2d 68, 77 (D.D.C. 2011) ("Allegations in [the government's] complaint that an express contract existed between the parties [] ***preclude*** a plaintiff from proceeding on alternative theories of FCA liability and unjust enrichment or payment by mistake." (emphasis added)); *United States ex rel. Reeves v. Mercer Transp.*, 253 F. Supp. 3d 1242, 1255–56 (M.D. Ga. 2017) (similar); *Lee v. Canada Goose US*, 2021 WL 2665955, at *9 (S.D.N.Y. June 29, 2021) (similar).

Nor can the quasi-contract claims be maintained in the alternative. A plaintiff may proceed on quasi-contract claims in the alternative only if those claims are "supported by, ***at the very least***, an allegation that there is no valid contract." *United States v. Kellogg Brown & Root Servs., Inc.*, 800 F. Supp. 2d 143, 160 (D.D.C. 2011) (emphasis added). There is no allegation here against the Health Plan Defendants.

V. CONCLUSION

For the foregoing reasons, the Court should dismiss the government's complaint in full.

Dated: June 21, 2022

Respectfully submitted,

By: /s/ *K. Lee Blalack, II*

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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

[PROPOSED] ORDER GRANTING MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION

Hearing Date: TBD (Dkt. No. 129)
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 **[PROPOSED] ORDER GRANTING MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: TBD (Dkt. No. 129) 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 **[PROPOSED] ORDER GRANTING MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: TBD (Dkt. No. 129) 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 **[PROPOSED] ORDER GRANTING MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION** Hearing Date: TBD (Dkt. No. 129) 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

[PROPOSED] ORDER GRANTING MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION

Hearing Date: TBD (Dkt. No. 129)
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

[PROPOSED] ORDER GRANTING MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION

Hearing Date: TBD (Dkt. No. 129)
Time: 1:30 PM
Judge: Hon. Edward M. Chen
Courtroom: 5, 17th Floor

[PROPOSED] ORDER

With good cause shown, Defendants' Motion to Dismiss the United States' Complaint-in-Intervention is GRANTED. The Court dismisses the Complaint-in-Intervention in its entirety.

IT IS SO ORDERED.

DATED:

_____
HONORABLE EDWARD M. CHEN
UNITED STATES DISTRICT JUDGE