UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA ex rel. RONDA OSINEK,

Plaintiff,

v.

PERMANENTE MEDICAL GROUP, INC, et al.,

Defendants.

Case No. 13-cv-03891-EMC

CONSOLIDATED MEMBER CASES

Case No. 16-cv-01558-EMC
Case No. 16-cv-05337-EMC
Case No. 18-cv-01347-EMC
Case No. 21-cv-03124-EMC
Case No. 21-cv-03894-EMC

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS UNITED STATES' COMPLAINT IN INTERVENTION

Docket No. 178

The above-referenced case consists of several consolidated cases that charge Kaiser entities with making false claims for payment to the federal government. The main claims asserted against the Kaiser entities are violations of the federal False Claims Act ("FCA"). Following the Court's order of May 5, 2022, *see* Docket No. 171 (order), the following cases remain:

(1) The United States' complaint in intervention (Docket No. 110);

(2) The first amended complaint in *Osinek* (Docket No. 87);

(3) Parts of the second amended complaint in *Taylor* (Docket No. 118); and

(4) Parts of the first amended complaint in *Bryant* (Docket No. 117).[1]

[1] The Court's order also dismissed the claims in *Bicocca* except to the extent the first amended complaint (Docket No. 16 in Case No. C-21-3124 EMC) pled claims under the California False

Currently pending before the Court are four motions to dismiss filed by the relevant Kaiser entities. The motions are targeted at all of the cases that remain. This order addresses only the motion to dismiss the United States' complaint in intervention. Having considered the parties' briefs, the Court hereby **GRANTS** in part and **DENIES** in part the motion to dismiss.

I. FACTUAL & PROCEDURAL BACKGROUND

In its complaint, the United States alleges as follows.

"Medicare is a federally operated health insurance program." U.S. Compl. ¶ 52. It has four parts:

- Part A, which covers inpatient and institutional care.
- Part B, which covers outpatient care.
- Part C, which is the Medicare Advantage program at issue in this case.
- Part D, which covers prescription drugs.

See U.S. Compl. ¶ 52.

Parts A and B are "traditional" Medicare.

> [T]he Government reimburses healthcare providers using a fee-for-service system, in which providers submit claims to CMS [Centers for Medicare and Medicaid Services] for healthcare services actually rendered, such as a provider officer visit or hospital stay. CMS then pays the providers directly for each service based on payment rates predetermined by the Government.

U.S. Compl. ¶ 53.

A Medicare beneficiary can opt out of traditional Medicare and enroll instead in a Medicare Advantage plan ("MA plan") managed by a Medicare Advantage organization ("MA organization" or "MAO"). *See* U.S. Compl. ¶ 54. "CMS reimburses MA plans differently than traditional Medicare." U.S. Compl. ¶ 57. Specifically, Medicare Advantage uses a "'capitation' payment system." *United States ex rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018). Under that system, "private health insurance organizations provide Medicare benefits in

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Claims Act. *See* Docket No. 171 (Order at 46). However, prior to the Court's order, the plaintiff in *Bicocca* had dismissed those state law claims. *See* Docket No. 159 (notice of voluntary partial dismissal with respect to Counts III and IV of FAC). Accordingly, there is nothing left in *Bicocca*.

exchange for a fixed monthly fee per person enrolled in the program – regardless of actual healthcare usage." *Id.* The fixed monthly fee for an enrollee is set as follows. First, there is a predetermined base payment for each enrollee in a Medicare Advantage plan. *See* U.S. Compl. ¶ 57. Second, the base payment is then adjusted "to account for (1) demographic factors such as age and gender (among others) and (2) health status. This is known as risk adjustment." U.S. Compl. ¶ 58.

Risk adjustment is accomplished by assigning each beneficiary a risk score, which "acts as a multiplier that is applied to the MA plan's base rate to determine the overall monthly payment for the beneficiary." U.S. Compl. ¶ 58. A beneficiary's risk score is determined through a model called the CMS Hierarchical Conditions Category ("HCC") model, which, as indicated above, is based on the patient's demographic factors and health status. *See* U.S. Compl. ¶ 59. "The CMS-HCC model is prospective in the sense that it uses diagnoses made in a base year (the 'service year'), along with demographic information (such as age and gender, among others), to predict costs for Medicare benefits and adjust payments for the following year (the 'payment year')." U.S. Compl. ¶ 60.

With respect to health status, the model relies on diagnosis codes from the International Classification of Diseases ("ICD"). *See* U.S. Compl. ¶ 60. "ICD diagnosis codes are alphanumeric codes used by healthcare providers, insurance companies, and public health agencies to represent medical conditions; every disease, injury, infection, and symptom has its own code." U.S. Compl. ¶ 62. In general, the more severe an enrollee's medical diagnoses are, the greater the risk adjustment is, and the more a MA organization is paid. *See* U.S. Compl. ¶ 2 (alleging that "CMS adjusts these payments for various 'risk' factors that affect expected healthcare expenditures, to ensure that MA Organizations are paid more for sicker enrollees expected to incur higher healthcare costs and less for healthier enrollees expected to incur lower costs"); U.S. Compl. ¶ 3 (alleging that "the amount of payment that CMS made to [a MA organization] for a Medicare Advantage patient depended directly on the diagnoses that [the MA organization] submitted to CMS for that patient").

To participate in Medicare Advantage, a MA organization "must enter into and execute a

written contract with CMS for the MA plans [it] operate[s]." U.S. Compl. ¶ 74. According to the government, both under its contract with CMS and under federal regulations, a MA organization is required to provide CMS with risk adjustment data for its enrollees conforms with not just the ICD diagnosis codes but also the ICD Guidelines. *See, e.g.*, U.S. Compl. ¶¶ 61, 81. "The ICD Guidelines impose numerous requirements and limitations on what diagnoses may be coded in a particular visit and in a particular setting." U.S. Compl. ¶ 82. For example, "[f]or an outpatient visit . . . , the ICD Guidelines only permit the coding of documented conditions that [1] both exist at the visit *and* that [2] 'require or affect patient care treatment or management.'" U.S. Compl. ¶ 83 (emphasis in original; quoting ICD Guidelines).

In its complaint, the United States has sued several Kaiser entities. As alleged, "Kaiser Permanente" is "an integrated health-care consortium comprised of three components: [1] health plans ('Health Plans'); [2] physician medical group practices (referred to as 'Permanente Medical Groups'); and [3] hospitals." U.S. Compl. ¶ 19. The Health Plans are MA organizations, and they contract with the federal government to provide MA plans. In turn, the Permanente Medical Groups contract with the Health Plans to provide medical services to patients who enroll in the plans. *See* U.S. Compl. ¶¶ 20-26. The United States has sued those Health Plans and the Permanente Medical Groups affiliated with California and Colorado (collectively, "Kaiser").

According to the United States,

> Kaiser engaged in a coordinated scheme to unlawfully obtain payments from the Medicare Part C program . . . . Kaiser obtained these payments by systematically altering patient medical records to add diagnoses that either [1] did not exist or [2] were unrelated to the patient's visit with the Kaiser physician. Kaiser altered the patients' medical records to add these diagnoses retrospectively – after the patient medical visit – using a mechanism called an addendum. Often, these addenda were added months or even a year or more after the visit. In many cases, patients were not even told that they supposedly had the diagnoses that Kaiser had added to their medical records. Kaiser knew that it could not lawfully submit diagnoses that were unrelated to the patient's visit, but it nevertheless routinely used these diagnoses to obtain additional payments from Medicare. Between 2009 and 2018, Kaiser added roughly half a million diagnoses using addenda. Kaiser submitted the diagnoses from these addenda to the Centers for Medicare and Medicaid Services ("CMS") and received additional Medicare payments in the range of $1 billion from these diagnoses.

U.S. Compl. ¶ 1; *see also* U.S. Compl. ¶ 7 (referring to practices such as "data mining," "chart review," and "refreshing" that Kaiser used to find diagnoses to add); Opp'n at 7 (discussing the above practices of data mining, chart review, and refreshing).

Based on, *inter alia*, the above allegations, the government has asserted the following causes of action:

(1) Violation of the federal False Claims Act ("FCA") by presenting or causing to be presented false claims for "risk-adjustment payments in the form of improper diagnoses codes for Defendants' Medicare patients, in violation of CMS regulations and policies, which Defendants agreed to and were obligated to comply with." U.S. Compl. ¶ 349; *see also* 31 U.S.C. § 3729(a)(1);\.

(2) Violation of the FCA by "making, using, and causing to be made or used, false records or statements material to false or fraudulent claims resulting in [Defendants'] receiving inflated Medicare payments from CMS to which they were not entitled." U.S. Compl. ¶ 352; *see also* 31 U.S.C. § 3729(a)(1)(B).

(3) Violation of the FCA by conspiring "to submit and cause the submission of false claims and to make, use, and cause to make or use, false records and statements material to false or fraudulent claims to the United States and use false records and statements material to false or fraudulent claims." U.S. Compl. ¶ 357; *see also* 31 U.S.C. § 3729(a)(1)(C).

(4) Payment by mistake.

(5) Unjust enrichment.

II. DISCUSSION

A. Legal Standard

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint that fails to meet this standard may be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6). To overcome a Rule 12(b)(6) motion to dismiss after the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic*

Corp. v. Twombly, 550 U.S. 544 (2007), a plaintiff's "factual allegations [in the complaint] 'must . . . suggest that the claim has at least a plausible chance of success.'" *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1135 (9th Cir. 2014). The court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But "allegations in a complaint . . . may not simply recite the elements of a cause of action [and] must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Levitt*, 765 F.3d at 1135 (internal quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal quotation marks omitted).

B. FCA Claims

1. General Law

"[T]he essential elements of False Claims Act liability are: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 902 (9th Cir. 2017); *see also United States v. Corinthian Colls.*, 655 F.3d 984, 992 (9th Cir. 2011).

With respect to the first element, a claim for payment can be factually false or legally false. "A factually false claim is one in which 'the claim for payment is itself literally false or fraudulent,' such as when the claim 'involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'" *United States ex rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667, 675 (9th Cir. 2018); *see also United States ex rel. Druding v. Druding*, 952 F.3d 89, 96 (3d Cir. 2020) (noting that there is factual falsity "when the facts contained within the claim are untrue").

A legally false claim generally involves a "'knowingly false certification of compliance with a regulation or contractual provision as a condition of payment.'" *United States ex rel.*

Polukoff v. St. Mark's Hosp., 895 F.3d 730, 741 (10th Cir. 2018); *see also United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018) (stating that a claim "is legally false when the claimant lies about its compliance with a statutory, regulatory, or contractual requirement"). "[L]egal falsity can be express, such as a false affirmative statement of compliance with a statutory, regulatory, or contractual prerequisite, or it can be implied – for instance, the absence of a material disclosure that would have prevented compliance with a statutory, regulatory, or contractual prerequisite." *Druding*, 952 F.3d at 96; *see also Silingo*, 904 F.3d at 675-76 (stating that "[e]xpress false certification involves an entity's representation of compliance with the law as part of the process for submitting a claim when it is actually not compliant," while "'[i]mplied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim'").

The Supreme Court addressed the theory of implied false certification in *Universal Health Services v. United States ex rel. Escobar*, 579 U.S. 176 (2016) (hereinafter "*Escobar*"). In *Escobar*, a teenager was a beneficiary of Massachusetts's Medicaid program and was receiving counseling services at a mental health facility in Massachusetts. The teens' parents filed suit after learning that few employees at the facility were actually licensed to provide mental health counseling and that supervision of them was minimal. *See id.* at 183-84. They asserted "an implied false certification theory of liability" – *i.e.*, the defendant "submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for these services." *Id.* at 184-85.

The Supreme Court took note that there is a

> rule that half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations. . . .
>
> So too here, by submitting claims for payment using payment codes that corresponded to specific counseling services, [the defendant] represented that it had provided individual therapy, family therapy,

> preventive medication counseling, and other types of treatment. Moreover, [facility] staff members allegedly made further representations in submitting Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. And these representations were clearly misleading in context. Anyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably – but wrongly – conclude that the clinic had complied with core Massachusetts Medicaid requirements (1) that a counselor "treating children [is] required to have specialized training and experience in children's services," and also (2) that, at a minimum, the social worker possesses the prescribed qualifications for the job. By using payment and other codes that conveyed this information without disclosing [the facility's] many violations of basic staff and licensing requirements for mental health facilities, [the defendant's] claims constituted misrepresentations. By using payment and other codes that conveyed this information without disclosing [the facility's] many violations of basic staff and licensing requirements for mental health facilities, [the defendant's] claims constituted misrepresentations.
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> Accordingly, we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: First, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

Id. at 189-90.

For the second element, *i.e.*, scienter, a person "knowingly" submits false information if he or she "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). A defendant cannot be held liable for an "[i]nnocent mistake" or "mere negligence," *U.S. ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991), but "no proof of specific intent to defraud" is required. 31 U.S.C. § 3729(b)(1)(B).

Regarding the third element of an FCA claim, *i.e.*, materiality, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). "[The] materiality requirement descends from 'common-law antecedents.'" *Escobar*, 579 U.S. at 193.

> Under any understanding of the concept, materiality "look[s] to the

> effect on the likely or actual behavior of the recipient of the alleged misrepresentation." In tort law, for instance, a "matter is material" in only two circumstances: (1) "[if] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not. Materiality in contract law is substantially similar
>
> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.
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> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that 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. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 193.

Thus, under *Escobar*, factors that should be considered on materiality include the following:

> (1) "the Government's decision to expressly identify a provision as a condition of payment"; (2) whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or if, with actual knowledge of the non-compliance, it consistently pays such claims and there is no indication that its practice will change; and (3) whether the "noncompliance is minor or insubstantial" or if it goes "to the very essence of the bargain."

United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 892 F.3d 822, 831 (6th Cir. 2018); *see also United States ex rel. Ling v. City of L.A.*, No. CV 11-974 PSG (JCx), 2018 U.S.

Dist. LEXIS 136589, at *36 (C.D. Cal. July 25, 2018) (identifying the same basic considerations).

2. Government's Liability Theories

As a preliminary matter, the Court considers what the government's theories of liability are and whether those theories are predicated on factual falsity, legal falsity, or both.

As noted above, the gist of the government's complaint is that Kaiser submitted false claims for payment because it "alter[ed] patient medical records to add diagnoses that either [1] did not exist or [2] were unrelated to the patient's visit with the Kaiser physician." U.S. Compl. ¶ 1.

With respect to (1), only factual falsity is implicated. If a diagnosis of a medical condition was claimed but that medical condition did not exist (*i.e.*, the diagnosis was "clinically inaccurate," Reply at 1), then a claim for payment based on that diagnosis is literally false. *See Silingo*, 904 F.3d at 675 ("A factually false claim is one in which 'the claim for payment is itself literally false or fraudulent,' such as when the claim 'involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'"); *Druding*, 952 F.3d at 96 (noting that there is factual falsity "when the facts contained within the claim are untrue").

With respect to (2), there is both factual falsity and legal falsity.[2] There is factual falsity because a claim for payment was based on a diagnosis of a medical condition that did exist, *but* the condition did not "require[] or affect][] patient care, treatment, or management for the visit." U.S. Compl. ¶ 87; *see also* Opp'n at 16-17 (noting that, "when Kaiser submitted for payment inaccurate ICD codes in contravention of the ICD Guidelines, those were factually false claims because they incorrectly described the valid ICD codes for the patient visit"). There is legal falsity because – as claimed by the government – both the CMS/Kaiser contract and federal regulations required Kaiser to comply with the ICD Guidelines, and "the ICD Guidelines only permit the

[2] There does not appear to be anything that would prevent a claim for payment from being both factually false and legally false (in the appropriate circumstances). The Third Circuit has noted that "legal falsity necessarily encompasses situations of factual falsity, for instance, where a physician's lies about medical test results would render certifications for reimbursement inaccurate and non-compliant with regulations." *Druding*, 952 F.3d at 96-97.

coding of documented conditions that [1] both exist at the visit *and* that [2] 'require or affect patient care treatment or management.'" U.S. Compl. ¶ 83 (emphasis in original; quoting ICD Guidelines); *see also Polukoff*, 895 F.3d at 741 (stating that a legally false claim involves a "'knowingly false certification of compliance with a regulation or contractual provision as a condition of payment'").

The government's complaint largely seems to focus on the second theory of liability. *See also* Opp'n at 16 (suggesting that "the Court need not [even] reach Kaiser's argument that the Complaint fails to allege Kaiser submitted 'factually false' claims for non-existent diagnoses" because the second theory of liability – *i.e.*, "Kaiser's submission of diagnoses that did not require or affect patient care, treatment, or management, in violation of the [ICD] Guidelines" – is viable). However, the Court begins with an evaluation of the first theory of liability because, as Kaiser argues, if that theory is indeed viable, it significantly expands the scope of the case. *See* Reply at 1-2 ("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 proof.").

3. Diagnoses That Did Not Exist/Clinically Inaccurate Diagnoses

For the government's first theory of liability – that Kaiser had patient medical records amended to add diagnoses that did not exist (*i.e.*, were clinically inaccurate) – Kaiser makes two arguments: (1) the government has failed to plead factual falsity and (2) the government has failed to plead knowledge of falsity on the part of Kaiser.

a. Falsity

As an initial matter, the Court notes that the government has sufficiently pled three specific instances of clinically inaccurate diagnoses in paragraphs 338, 339, and 210-11 of its complaint.

- In paragraph 338, the government describes an incident relating to "Patient #2." Patient #2 was seen by a Kaiser doctor on 5/30/2012 "for a blood pressure check and to review lab results." U.S. Compl. ¶ 338(a). Six months after the visit, a

Kaiser coder contacted the doctor, informing the doctor that Patient #2 had "'several uncoded diagnoses the region thinks should be picked up'" – including prostate cancer. U.S. Compl. ¶ 338(c). The medical record from the original visit indicated that "Patient #2 had a *history of* prostate cancer (identified with a different ICD history code) and did not have active prostate cancer." U.S. Compl. ¶ 338(d) (emphasis in original). Nevertheless, the doctor responded to the query by creating an addendum to add, *inter alia*, a diagnosis of prostate cancer. *See* U.S. Compl. ¶ 338(e).

- In paragraph 339, the government describes an incident relating to "Patient #3." Patient #3 was seen by a Kaiser doctor on 1/17/2013 for shortness of breath. He was diagnosed with exacerbation of chronic obstructive pulmonary disease ("COPD"). The doctor ordered a chest x-ray to rule out pneumonia. The results of the x-ray showed that Patient #3 did not have pneumonia. *See* U.S. Compl. ¶ 339(a). Approximately eight months later, a Kaiser data quality trainer contacted the doctor, informing him that "'the imaging you ordered showed Positive Aortic Atheroschlerosis'" and asking him to amend his medical notes to "'capture'" AA. U.S. Compl. ¶ 339(c). The doctor responded to the query by adding a diagnosis of AA via an addendum. *See* U.S. Compl. ¶ 339(d). The doctor later created two more addenda, ultimately adding "twelve more diagnoses to Patient #3's medical record." U.S. Compl. ¶ 339(h). One of these diagnoses was for severe obesity equivalent; however, this diagnosis was not justified because it "requires a BMI of at least 35" and Patient #3's BMI at the time of the visit was only 31. U.S. Compl. ¶ 339(i).
- In paragraphs 210-11, the government alleges that, in Colorado, Kaiser used to data mine and query doctors to add hypoxia for patients receiving oxygen; however, after CMS removed hypoxia as a condition from the HCC model, Kaiser queried doctors to add different diagnoses – acute and/or chronic respiratory failure and obesity hypoventilation syndrome. *See* U.S. Compl. ¶ 210. On one occasion, a

> doctor in Colorado "created an addendum to add the diagnosis of obesity hypoventilation syndrome – a breathing disorder found in some *obese* individuals – to a patient who was clearly *not* obese (she was 5'9" and weighed 108 pounds)." U.S. Compl. ¶ 211 (emphasis in original).

However, presumably, the government has not filed suit to seek relief for these three specific instances alone – *i.e.*, it is essentially claiming that Kaiser had a *scheme* to include to include nonexistent diagnoses in patients' medical records. These three specific examples, however, are not enough to make out a plausible case for such a systemic scheme. The complaint does not contain specific allegations which plausibly establish these three instances were emblematic of a wider pattern of similar practices.

On the other hand, the Court concludes that the government has alleged a plausible scheme with respect to one specific disease in particular – *i.e.*, cachexia. In its pleading, the government has alleged as follows: "Cachexia is a complex metabolic syndrome associated with physical wasting, weight loss and muscle atrophy." U.S. Compl. ¶ 207. A diagnosis of cachexia "is based on clinical judgment rather than clinical indicators," U.S. Compl. ¶ 295 – which implicitly makes it more vulnerable to exploitation. According to the government, in 2009, as part of a training, "the N. California Medical Group identified cachexia as one of a few diagnoses that would help them 'Find $100 million dollars in NCal.'"; then, in or about 2011, "the N. California Medical Group created a data-mining algorithm to identify potential cachexia diagnoses," and the results of the algorithm were "sent to physicians with queries for them to addend their patient medical records to add cachexia diagnoses." U.S. Compl. ¶ 295. Queries were "routinely" sent to doctors to add diagnoses of cachexia even "for patients who were merely thin." U.S. Compl. ¶ 296; *cf.* U.S. Compl. ¶ 296 (noting that cachexia "is not simply low body weight"). As a result, "physicians in Northern California added cachexia via addenda over *120 times* more than physicians in Southern California and Colorado, regions that did not have a cachexia initiative." U.S. Compl. ¶ 300 (emphasis in original). Furthermore, audits revealed that "many of these diagnoses were invalid[] because the patient did not . . . have cachexia." U.S. Compl. ¶ 300. Specifically, as part of an audit, "the Clinical Review Team (within [the Encounter Information

Operations office]) found that *over 90%* of the time a physician added the cachexia diagnosis based on a Kaiser query, the documentation is 'either lacking or contradict[s] the definition of Cachexia.'" U.S. Compl. ¶ 321 (emphasis added); *see also* U.S. Compl. ¶ 346(f) (discussing Patient #10, whose doctor created an addendum to add cachexia as a diagnosis even though the doctor stated "'patient has no general debility'" and only "'lost some lbs of weight'"). Based on the above allegations, the government has sufficiently alleged that Kaiser had a scheme to include to include nonexistent diagnoses of cachexia in patients' medical records.

Kaiser protests that the fact that "the medical-record documentation was 'lacking' or inconsistent say[s] nothing about the member's actual health status'" – especially since cachexia is (as alleged) based on clinical judgment rather than clinical indicators. Reply at 7-8. Although Kaiser's argument is not without some merit, at this juncture all reasonable inferences are to be made in the government's favor. If documentation was lacking or if documentation contradicted the definition of cachexia, then it can reasonably be inferred that a diagnosis of cachexia was not justified. Thus, based on the government's allegations, it can reasonably be inferred that a large number of cachexia diagnoses, which were made through addenda, were literally false.

Hence, thus far, the only systemic scheme sufficiently alleged by the government relates to cachexia only. Admittedly, if Kaiser (as alleged) was willing to make clinically false diagnoses for cachexia, one could imagine that Kaiser could easily have had a scheme far broader in scope, reaching any number of medical conditions as well. But at this point, given the allegations in the complaint, it cannot reasonably be inferred that Kaiser's scheme was broader in scope. The government has leave to amend its complaint if it wishes to expand the scope of its allegations on clinically false diagnoses. Identifying scattered anecdotes alone will not suffice.

b. Knowledge

The next issue raised by Kaiser is whether the government has sufficiently pled the element of knowledge. The Court considers this issue only with respect to the allegedly false cachexia diagnoses. As noted above, under the FCA, a person "knowingly" submits false information if he or she "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or

falsity of the information." 31 U.S.C. § 3729(b)(1)(A). A defendant cannot be held liable for an "[i]nnocent mistake" or "mere negligence," *U.S. ex rel. Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991), but "no proof of specific intent to defraud" is required. 31 U.S.C. § 3729(b)(1)(B).

Given that reckless disregard can satisfy the knowledge requirement and that all reasonable inferences are to be made in the government's favor at this early stage, the government has alleged enough with respect to scienter. According to the government, Kaiser higher-ups were warned about sending queries to doctors prompting them to add diagnoses for cachexia. *See, e.g.*, U.S. Compl. ¶ 297 ("After noting that physicians were protesting that naturally thin patients did not have cachexia, Dr. Inna Ravkin (an internal medicine physician in Northern California) warned Karen Graham[3] and Dr. David Bliss[4] in 2011 that the prompting would result in 'inappropriate assignment of this diagnosis."); U.S. Compl. ¶ 298 ("Also in 2011, Dr. Patrick Kan (a CMS Lead) reported to Dr. David Bliss and Karen Graham that 'they [the treating physicians] do not see any physical signs of cachexia.'"); U.S. Compl. ¶ 299 ("And in 2013, Norma Gonzalez (a Senior Consultant for CMS matters) wrote to Danielle Sheetenhelm (Clinical Review Manager) that because she had 'a couple of thousand datamining diagnoses in my area,' it would be 'impossible' to review them all. She further stated that the feedback from the physicians was that the queries were 'garbage.'"). If responsible persons at Kaiser were warned, then Kaiser was on notice and a failure to act in response to indications of inaccurate diagnoses could reasonably be deemed reckless disregard of the falsity of cachexia diagnoses.

Reckless disregard could also be inferred based on allegations that queries were being sent to doctors about cachexia diagnoses simply because the patients at issue were thin. That a cachexia diagnoses is based on a clinical judgment does not mean that Kaiser was justified in prompting doctors about diagnosing cachexia simply because of an underweight patient. It may

[3] As alleged, Ms. Graham was the Managing Director of the N. California Medical Group's Encounter Information Operations office. *See* U.S. Compl. ¶ 119.

[4] As alleged, Dr. Bliss was the N. California Medical Group Regional Director of Documentation and Coding. *See* U.S. Compl. ¶ 248.

be inferred that Kaiser officials were looking for the results Kaiser allegedly obtained.

Finally, the government has alleged that an audit revealed a high error rate with respect to cachexia diagnoses made through addenda but that Kaiser failed to respond. *See* U.S. Compl. ¶ 322 ("Despite this knowledge [about the audit], the N. California Medical Group did not modify its cachexia data-mining algorithm or stop-prompt program for several years."). This further supports a finding of scienter. For false cachexia diagnoses thereafter, one could reasonably infer reckless disregard on the part of Kaiser.

4. Diagnoses Unrelated to Doctors' Visits

As noted above, the government's second theory of liability – that Kaiser altered patient medical records by adding diagnoses that were not related to the doctors' visits – is its main one. And as noted above, this theory of liability implicates both factual falsity and legal falsity. In its papers, Kaiser argues that the government has failed to adequately plead falsity for the second theory of liability. Kaiser further argues that, even if falsity were adequately pled, the government still has not sufficiently pled materiality.

a. Falsity

As an initial matter, the Court notes that Kaiser seems to have ignored the fact that the second theory of liability can be construed as being predicated on factual falsity. *See* Opp'n at 16-17 (noting that, "when Kaiser submitted for payment inaccurate ICD codes in contravention of the ICD Guidelines, those were factually false claims because they incorrectly described the valid ICD codes for the patient visit"). Because the Court agrees with the government that factual falsity is implicated, then that alone is a sufficient basis for the Court to reject Kaiser's argument that falsity has not been sufficiently alleged.

Even if the Court were to consider only legal falsity, Kaiser would fare no better. A legally false claim for payment involves an assertion (either express or implied) that there is compliance with a statute, regulation, or contract. *See, e.g.*, *Escobar*, 579 U.S. at 181 ("[L]iability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances,

liability may attach if the omission renders those representations misleading."). In the case at bar, the government argues that both the CMS/Kaiser contract and federal regulations required Kaiser to comply with ICD Guidelines – and under the ICD Guidelines, a diagnosis can be made on a medical record only if it required or affected patient care treatment or management at the doctor's visit. In response, Kaiser contends that the neither the contract nor regulations required Kaiser to comply with the ICD Guidelines – and therefore the ICD Guidelines are at best "subregulatory" documents that lack the force of law.[5] Kaiser underscores that the Medicare Act contains the following provision:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. § 1395hh(a)(2).[6] In *Azar v. Allina Health Services*, the Supreme Court noted that, under § 1395hh(a)(2), "Congress has told the government that, when it wishes to establish or change a 'substantive legal standard' affecting Medicare benefits, it must first afford the public notice and a chance to comment." *Allina*, 139 S. Ct. at 1808.

i. Contract

As noted above, the government contends as an initial matter that Kaiser is bound by the ICD Guidelines because the CMS/Kaiser contract requires compliance with the Guidelines.

A copy of the CMS/Kaiser contract can be found at Exhibit I to Kaiser's RJN. Article II.A

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[5] To the extent Kaiser has argued that there is no contractual provision or regulation cited by the government that expressly applies to *addenda* of medical records (*i.e.*, the means by which Kaiser allegedly achieved its upcoding), the government correctly contends that this is a red herring. *See* Opp'n at 15 ("[A]n addendum is merely a change to the medical record for a patient visit made after the close of that visit record. Nothing in Kaiser's contracts, the relevant regulations, or the ICD Guidelines indicates that diagnoses added after patient visits are subject to different standards."). Notably, Kaiser somewhat backtracked from this argument in its reply brief. *See* Reply at 10 n.7 ("Defendants agree [that there is no 'addenda exception'], 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.").

[6] "While the APA requires many other agencies to offer public notice and a comment period before adopting new regulations, it does not apply to public benefit programs like Medicare." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019).

of the contract provides as follows: "The MA Organization agrees to operate one or more coordinated care plans . . . and 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.)*." Def.'s RJN, Ex. I (CMS/Kaiser Contract, art. II.A) (emphasis added). The Medicare Managed Care Manual contains a chapter – Chapter 7 – on "Risk Adjustment." *See* Def.'s RJN, Ex. C (CMS/Kaiser Contract Ch. 7). There are twelve sections in Chapter 7. The fourth section (§ 40) covers the "Role and Responsibilities of Plan Sponsors," which include MA organizations. With respect to risk adjustment data submission requirements, § 40 states in relevant part as follows:

> Medicare Advantage Organizations (MAOs) . . . must . . . [e]nsure the accuracy and integrity of risk adjustment data submitted to CMS. All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. *The diagnosis must be coded according to [the ICD Guidelines]*.

Def.'s RJN, Ex. C (CMS Medicare Managed Care Manual, Ch. 7, § 40) (emphasis added); *see also* U.S. Compl. ¶ 81.

Accordingly, based on the Article II.A of the CMS/Kaiser Contract, its incorporation of the CMS Medicare Managed Care Manual, and the Manual's incorporation of the ICD Guidelines, the government argues that a MA organization must comply with the ICD Guidelines in providing risk adjustment data to CMS.

In response, Kaiser makes several arguments, none of which is convincing.

First, Kaiser contends that the government's reliance on Article II.A is flawed:

> The location of [this] clause . . . 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. But the section that addresses ***payment*** is Article IV, which does not reference subregulatory guidance at all and cites only statutes and regulations.

Mot. at 17 (emphasis in original); *see also* Reply at 10-11 (arguing that Article II "concerns plan design" or "plan structure"). But this argument is questionable if only because Kaiser's characterization of Article II is not on point. Article II is titled "Coordinated Care Plan." The article simply lays out broad principles – *e.g.*, Article II.A provides that the MA organization

agrees to operate a coordinated care plan(s) and in compliance with federal law and policies; Article II.B provides that the contract incorporates changes required by statute to be implemented during the term of the contract; Article III.C provides that, other than at the beginning of a calendar year, CMS will not implement regulatory requirements that impose new significant costs or burdens on the MA organization; etc. Nothing about the article is limited or targeted to plan design or plan structure, as Kaiser claims. Indeed, it is notable that Article II.A refers to now a coordinated care plan is to be *operated*.

In any event, just because the reference to compliance with CMS policies (including the Manual which then incorporates the ICD Guidelines) is in Article II and not in Article IV does not mean that compliance with ICD Guidelines is not required for risk adjustment data. As the government correctly contends, although "Kaiser argues that it is not bound by this term because it appears at the beginning of the contract[] rather than in the payment section, . . . there is no such rule of contract law." Opp'n at 11.

Second, Kaiser argues that it would be improper for it to be bound by the ICD Guidelines as a result of two general incorporations by reference (*i.e.*, incorporation of the Manual which then incorporates the Guidelines):

> [T]he government cannot seriously contend that the broad, non-specific language of the contract provision means that the Health Plan Defendants must adhere to every word of the ICD Guidelines simply because they are generally referenced in the [Manual], which itself is referenced in a parenthetical in a single sentence of a CMS contract.

Mot. at 17; *see also* Reply at 11. This argument is unpersuasive, especially in the context of this instant case. Kaiser is a sophisticated entity and incorporation by reference is a common contractual tool. It defies reality to suggest a contract is too complicated for an entity like Kaiser to understand. In any event, ICD Guidelines and their importance to medical procedure is not some obscure bit of minutiae. Further, the government has alleged here that Kaiser was in fact well aware of the ICD Guideline requirement at issue. *See, e.g.*, U.S. Compl. ¶¶ 88-96 (alleging that, "[a]s far back as 2008," Kaiser had issued to all regions a "Program Advisory" which was "'intended to clarify the minimum amount and type of documentation necessary to support the

diagnoses submitted to [CMS] as Medicare Advantage risk adjustment data'"; the Program Advisory specified, *inter alia*, that documentation must comply with the ICD Guidelines). Finally, it is worth noting that, as a practical matter, Kaiser's concerns are essentially addressed through the FCA requirement of materiality (*i.e.*, that the false statement must have been material, causing the government to pay out money). *See Campie*, 862 F.3d at 902.

Third, Kaiser points out that the CMS/Kaiser contract specifies that federal statutes/regulations should prevail if there is a conflict between such and the contract. *See* Def.'s RJN, Ex. I (CMS/Kaiser Contract, art. IX.D) ("In the event that any provision of this contract conflicts with the provisions of any statute or regulation applicable to an MA Organization, the provisions of the statute or regulation shall have full force and effect."). Kaiser then argues that "[a]llowing 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." Mot. at 18 (referring to § 1395hh(a)(2) of the Medicare Act and the Supreme Court's decision in *Allina*). *See, e.g.*, *Allina*, 139 S. Ct. at 1808 (noting that, under § 1395hh(a)(2) of the Medicare Act, "Congress has told the government that, when it wishes to establish or change a 'substantive legal standard' affecting Medicare benefits, it must first afford the public notice and a chance to comment").

The government, however, has provided a strong counter-argument – *i.e.*, that "§ 1395hh(a)(2) does not address the government's ability to contract, nor suggest that contractual terms must first go through notice and comment. The statute applies to the Secretary's rulemaking authority, not his contracting authority." Opp'n at 11. The government also fairly points out that Congress "*mandated* that the Secretary execute contracts with MAOs." Opp'n at 12 (emphasis in original). In fact, Congress even gave some discretion to the Secretary as to contract terms – specifying that "[t]he contract shall contain such other terms and conditions not inconsistent with this part [42 U.S.C. § 1395w-21 *et seq.*] . . . as the Secretary may find necessary and appropriate." 42 U.S.C. § 1395w-27(e)(1). Although there is a statutory limitation that contract terms may not be "inconsistent with this part," the government correctly notes that "§ 13955hh(a)(2) is not . . . in 'this part' (i.e., Part C)." Opp'n at 12. There is no statutory bar to incorporation of the ICD

Guidelines.

Accordingly, the Court rejects Kaiser's argument that the terms of the CMS/Kaiser contract cannot be read to require compliance with the ICD Guidelines.

ii. Federal Regulations

Because the Court concludes that the CMS/Kaiser contract requires Kaiser to comply with the ICD Guidelines, it need not address the government's contention that compliance is also required by federal regulations. However, out of an abundance of caution, the Court has considered the regulatory scheme and concludes it does, in fact, require compliance.

The main regulation that supports the government's position is 42 C.F.R. § 422.310(d)(1). That regulation (which addresses risk adjustment data) provides in relevant part as follows: "MA organizations must submit data that conform to [1] CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to [2] all relevant *national standards*." 42 C.F.R. § 422.310(d)(1) (emphasis added). As the government notes, CMS has adopted the ICD code sets for diseases, including the ICD Guidelines, as a national standard – pointing to 45 C.F.R. § 162.1002. *See, e.g.*, 45 C.F.R. § 162.1002(c)(2)(i) ("The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets: . . . (c) For the period on and after October 1, 2015: . . . (2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (i) Diseases.")[7]; *see also* 42 C.F.R. § 422.504(h)(2) ("The MA organization agrees to comply with – . . . (2) HIPAA administrative simplification rules at 45 C.F.R. part[] . . . 162 . . . .").[8]

In response, Kaiser argues that § 422.310(d)(1) just addresses "the form of data submitted

[7] In 45 C.F.R. § 1002(a)(1)(i) and § 1002(b)(1), the Secretary essentially adopts the ICD code sets (including the ICD Guidelines) for earlier periods of time.

[8] The government points out that the ICD code sets for diseases and the related ICD guidelines are also used in the Medicare fee-for-service context, and therefore there is a fair argument that they should be applied in the MA context as well. *See* Opp'n at 13 (adding that "[a]dherence to the same ICD standard in both traditional Medicare fee-for-service and Medicare Advantage is important because . . . the risk-adjustment model calculates expected costs for MA patients based upon Medicare fee-for-service diagnosis data").

to CMS, not the content.'" Mot. at 16; *see also* Reply at 14. But nothing about § 422.310(d)(1) suggests it is limited to the format of data. Moreover, to the extent Kaiser relies on *United States ex rel. Rasmussen*, No. 17-3273-CV-S-BP, 2020 U.S. Dist. LEXIS 137953 (W.D. Mo. Apr. 29, 2020), that case does little, if anything, to support its position. *Rasmussen* addressed an entirely different subsection of § 422.310 – specifically, § 422.310(g). Furthermore, Kaiser's attempt to make an analogy between the § 422.310(g) and § 422.310(d)(1) falls flat. The text of § 422.310(g) is markedly different from that in § 422.310(d)(1), providing as follows: "*Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and services furnished during the 12-month period before the payment year that is specified by CMS." 42 C.F.R. § 422.310(g). Based on, *inter alia*, this language, the *Rasmussen* court rejected the relator's argument that "a diagnosis can be coded only if the patient received treatment for that condition within the past year." *Rasmussen*, 2020 U.S. Dist. LEXIS 137953, at *17. The court noted: "§ 422.310(g) appears to address the deadline for submitting risk adjustment data. It is not directed toward specifying the procedure for properly coding patients' medical conditions, so it seems to be a poor source for ascertaining such details." *Id.* at *19 n.10.

Finally, the Court should takes into account that it is not just § 422.310(d)(1) that is relevant here. Section 422.310(d)(1) should be read in conjunction with § 422.504(l), *i.e.*, the regulation that requires a MA organization to provide accurate risk adjustment data to CMS. *See* 42 C.F.R. § 422.504(l) ("As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), [etc.] must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests."). While § 422.504(l) requires accuracy from a MA organization, § 422.310(d)(1) essentially provides a benchmark to assess the accuracy of the information provided. Kaiser does not dispute that adherence to the ICD Guidelines facilitates the accuracy of medical information provided. The Ninth Circuit's decision in *United States ex rel. Swoben v. United Healthcare Insurance Co.*, 848 F.3d 1161 (9th Cir. 2016), is not the contrary. *See id.* at 1179 (noting that "nothing in §

422.310(d)[(1)] speaks to a Medicare Advantage organization's obligations to ensure the accuracy of risk adjustment data, [and therefore] it does not modify a Medicare Advantage organization's obligations under [§] . . . 422.504(l)").

b. Materiality

For the reasons stated above, the Court agrees with the government that Kaiser is required to comply with the ICD Guidelines, both as a matter of contract and under the applicable regulations – and thus it has a plausible case of legal falsity (*i.e.*, Kaiser implicitly certified that it had complied with the ICD Guidelines in making a claim for payment). Kaiser argues that, even if this is true, the legal falsity claim must still be dismissed because the government has not adequately alleged that the false statement regarding compliance with the ICD Guidelines was material.

As noted above, under the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court in turn has noted that the FCA is not

> a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

Escobar, 579 U.S. at 193.

In the case at bar, the government has adequately alleged materiality – particularly when the considerations below are taken collectively. First, as the government explains,

> submitting accurate ICD diagnosis codes is material because CMS makes risk-adjustment payments based directly on the codes submitted by MAOs. . . . An ICD code that violates the ICD Guidelines because the condition had nothing to do with a patient visit is not an accurate ICD code . . . .

Opp'n at 21. Under MA, risk adjustment payments in the aggregate are obviously substantial. Misrepresentations which affect those payments can undoubtedly have a substantial financial effect on the MA program. Health risk assessments are a core element of the program.

Second, the CMS Medicare Managed Care Manual makes explicit the importance of complying with the ICD Guidelines, including the ones that are the focus of the government's case. The Manual notes as follows:

> Medicare Advantage Organizations (MAOs) . . . must . . . [e]nsure the accuracy and integrity of risk adjustment data submitted to CMS. All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to [the ICD Guidelines].

Def.'s RJN, Ex. C (CMS Medicare Managed Care Manual, Ch. 7, § 40); *see also* U.S. Compl. ¶ 81. And notably, Kaiser's own internal documents (*e.g.*, its Program Advisories on risk adjustment) recognized the need to comply with the ICD Guidelines, including the ones that are the focus of the government's case here. *See, e.g.*, U.S. Compl. ¶ 90 (noting that Kaiser's 2008 Program Advisory specified, *inter alia*, that risk adjustment data must be obtained as a result of a face-to-face visit and that the doctor must have considered or addressed the coded diagnosis during the encounter); *see also Escobar*, 579 U.S. at 193 (noting that "[w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.").

Finally, as indicated above, the magnitude of the noncompliance weighs in favor of materiality, as the government has asserted that Kaiser has "reap[ed] thousands of dollars for each inaccurate diagnosis code and hundreds of millions of dollars for its scheme." Opp'n at 23; *see also* U.S. Compl. ¶ 335 (alleging that "false claims inflated CMS's reimbursements to the Kaiser Health Plans by hundreds of millions of dollars"). *See, e.g., United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1022 (9th Cir. 2018) (indicating that noncompliance can be deemed minor or insubstantial where there is no real monetary impact – "[f]or instance, were a school to offer admissions representatives cups of coffee or $10 gift cards for recruiting higher numbers of students, there would be no viable claim under the False Claims Act").

5. Statute of Repose/Statute of Limitations

Kaiser argues that, even if the government has adequately pled FCA causes of action, those claims should still be trimmed because part of the claims are time barred. Below is the relevant provision from the FCA:

> (b) A civil action under section 3730 [31 U.S.C. § 3730] may not be brought –
>
> (1) more than 6 years after the date on which the violation of section 3729 [31 U.S.C. § 3729] is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
>
> whichever occurs last.
>
> (c) If the Government elects to intervene and proceed with an action brought under [section] 3730(b) [31 U.S.C. § 3730(b)], the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) [31 U.S.C. § 3730(b)] to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

31 U.S.C. § 3731(b)-(c).

Kaiser contends that the provision above contains not just a statute of limitations but also a statute of repose.

> Statutes of limitations and statutes of repose both are mechanisms used to limit the temporal extent or duration of liability for tortious acts. Both types of statute can operate to bar a plaintiff's suit, and in each instance time is the controlling factor. There is considerable common ground in the policies underlying the two types of statute. But the time periods specified are measured from different points, and the statutes seek to attain different purposes and objectives. . . .
>
> In the ordinary course, a statute of limitations creates "a time limit for suing in a civil case, based on the date when the claim accrued." Measured by this standard, a claim accrues in a personal-injury or property-damage action "when the injury occurred or was discovered." . . .
>
> A statute of repose, on the other hand, puts an outer limit on the right to bring a civil action. That limit is measured not from the date on which the claim accrues but instead from the date of the last culpable act or omission of the defendant. A statute of repose "bar[s] any suit that is brought after a specified time since the

> defendant acted (such as by designing or manufacturing a product), even if this period ends before the plaintiff has suffered a resulting injury." The statute of repose limit is "not related to the accrual of any cause of action; the injury need not have occurred, much less have been discovered." The repose provision is therefore equivalent to "a cutoff," in essence an "absolute . . . bar" on a defendant's temporal liability, C. J. S. §7, at 24.

CTS Corp. v. Waldburger, 573 U.S. 1, 8 (2014).

Although the Supreme Court in *CTS* underscored the distinction between a statute of limitations and a statute of repose, it also recognized that "general usage of the legal terms [statute of limitations and statute of repose] has not always been precise" – *e.g.*, "Congress has used the term 'statute of limitations' when enacting statutes of repose," and "petitioner does not point out an example in which Congress has used the term 'statute of repose.'" *Id.* at 13-14; *see also Fed. Hous. Fin. Agency v. Nomura Holding Am., Inc.*, 873 F.3d 85, 113 (2d Cir. 2017) (noting that, "although Congress has indisputably created statutes of repose in the past, it 'has never used the expression "statute of repose" in a statute codified in the United States Code'"). Even after *CTS*, the Supreme Court itself has not always been precise about the use of the terms, including in a FCA case. In *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507 (2019), the Court stated as follows:

> The False Claims Act contains two limitations periods that apply to a "civil action under section 3730" – that is, an action asserting that a person presented false claims to the United States Government. The first period requires that the action be brought within 6 years after the statutory violation occurred. The second period requires that the action be brought within 3 years after the United States official charged with the responsibility to act knew or should have known the relevant facts, but not more than 10 years after the violation. Whichever period provides the later date serves as the *limitations period*.

Id. at 1510 (emphasis added).

In the instant case, Kaiser maintains that, although § 3731(b) of the FCA contains a statute of limitations, it also contains a statute of repose – specifically in (b)(2) – due to the following language: "but in no event more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b)(2).

Kaiser then argues that, because the government did not file its complaint until October 25,

2021, the statute of repose dictates that the government's claims are valid only to the extent they are based on conduct occurring on or after October 25, 2011. Thus, according to Kaiser, the government's attempt to implicate conduct as far back as 2009 should be rejected. *See* U.S. Compl. ¶ 1 ("Beginning sometime prior to 2009 and continuing through at least 2018, Kaiser engaged in a coordinated scheme to unlawfully obtain payments from the Medicare Part C program, also called Medicare Advantage.").

Kaiser acknowledges that the FCA contains a relation back provision in § 3731(c). It also recognizes – implicitly – the government's contention that, under § 3731(c), it can claim relation back to the *Osinek* complaint (filed in 2013) or the *Taylor* complaint (filed in 2014), and then, because *Osinek* was filed in 2013 and *Taylor* in 2014, § 3731(b)(1) would allow the government to wrap in conduct six years earlier – *i.e.*, from 2007 and 2008. But Kaiser contends that the government rely on § 3731(c) because that provision in the FCA only mentions relation back and the statute of limitations, not the statute of repose. In support of this argument, Kaiser relies on *United States v. Scan Health Plan*, No. CV 09-5013-JFW (JEMx), 2017 U.S. Dist. LEXIS 174308 (C.D. Cal. Oct. 5, 2017) [hereinafter *Swoben II*]. There, the court held as follows:

> [T]he 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." In fact, Congress added the relation-back provision [to the FCA] in 2009, as part of the same legislation in which it 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. As one False Claims Act expert testified during the Senate's consideration of those changes, without 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. at *27-28.

But at least one court has expressly disagreed with the analysis in *Swoben II*. Its reasoning was that "subsection (c)'s relation-back provision does not distinguish between 'statutes of limitation' and the 'statute of repose,'" and so " the Court concludes that subsection (c) refers to the various timing restrictions contained in subsection (b), the statute of repose included." *United States ex rel. Ling v. City of L.A.*, No. CV 11-974 PSG (JCx), 2018 U.S. Dist. LEXIS 136589, at

*70-71 (C.D. Cal. July 25, 2018).

Arguably, both the analysis in *Ling* and that in *Swoben II* are problematic in that they rely on terminology used in § 3731(c) but neither Congress nor the Supreme Court has been precise in their use of the term "statute of limitations" or "statute of repose." Given the ambiguity of the terms as they appear in this statute, the more fundamental question is whether as a matter of principle it would be improper to apply relation back where there is a statute of repose (as opposed to a statute of limitations). On this question, the government correctly argues that it would not because relation back does not alter a limitations period or repose period, nor does it even toll one. Rather relation back simply pinpoints *when a claim is filed*. *See* Opp'n at 25. This was the basic point that the Third Circuit made when considering whether the FCA's statute of repose prevented relation back under Federal Rule of Civil Procedure 15(c) (*i.e.*, instead of relation back under § 3731(c) of the FCA): "[T]olling extends the repose period, while relation back *keeps the repose period intact*." *SEPTA v. Orrstown Fin. Servs.*, 12 F.4th 337, 351 (3d Cir. 2021) (emphasis added). The Third Circuit's analysis is convincing.

Accordingly, the Court reject Kaiser's argument that the government's claims cannot reach back to conduct from 2009 given the application of relation back.

6. Summary

For the foregoing reasons, the government's FCA claims largely survive Kaiser's 12(b)(6) challenge. The FCA claims are not viable only to the extent the government has argued factual falsity on a systemic basis because diagnoses were made for nonexistent conditions. The government has not pled enough to support this factual falsity claim with one exception – *i.e.*, that there was a scheme to amend patient records to add a clinically inaccurate diagnosis of cachexia. The government has leave to amend its complaint for this factual falsity theory. Any amended complaint shall be filed by December 12, 2022. Kaiser shall then have until January 3, 2023 to file a response, whether an answer or a motion.

C. Claims for Payment by Mistake and Unjust Enrichment

Aside from the FCA claims, the government has also asserted the following causes of action: payment by mistake and unjust enrichment. According to Kaiser, these are common law

claims that should be dismissed for two reasons: (1) the claims are "derivative of the flawed FCA claims"[9] and (2) with respect to the Health Plans (who contracted with CMS to provide the MA plans), "quasi-contractual claims are unavailable" because of the express contract between the Health Plans and CMS. Mot. at 24. Kaiser adds that, even as to the Permanente Medical Groups (who contracted with the Health Plans to provide services to patients), "it is not clear how the government could have quasi-contract claims" because the government alleges that the Permanente Medical Groups "must 'comply with' the Health Plan Defendants' 'contractual obligations to CMS.'" Mot. at 25.

The Court rejects Kaiser's first argument because, as discussed above, the FCA claims largely survive.

Kaiser's second argument presents a closer call. Kaiser does have authority to support its position. For example, in *United States v. First Choice Armor & Equipment*, 808 F. Supp. 2d 68, (D.D.C. 2011), the district court noted as follows:

> The defendants argue that the government cannot simultaneously proceed on its FCA claims and its claims of payment by mistake and unjust enrichment. Rule 8(d)(2) allows a plaintiff to plead alternative theories of liability. Accordingly, "at the motion-to-dismiss stage, courts in this district . . . have permitted the government to proceed with claims alleging FCA violations as well as claims for unjust enrichment or payment by mistake." However, "it does not appear that the D.C. Circuit has [wavered] from the rule that 'there can be no claim for unjust enrichment when an express contract exists between the parties.'" Allegations in a complaint that an express contract existed between the parties, therefore, preclude a plaintiff from proceeding on alternative theories of FCA liability and unjust enrichment or payment by mistake.

Id. at 77-78; *see also United States ex rel. Doughty v. Or. Health & Scis. Univ.*, No. 3:13-CV-01306-BR, 2017 U.S. Dist. LEXIS 55083, at *18 (D. Or. Apr. 11, 2017) ("[T]he basis for Plaintiff-Relators' claims for payment by mistake and unjust enrichment arise from the express contracts the government alleged in its Complaint. In fact, Defendant could only have been

[9] In its reply, Kaiser acknowledges that a FCA claim requires a knowing false representation, while payment by mistake and unjust enrichment do not. However, it argues that, if there is no falsity, then there can be FCA claim, not a cause of action for payment by mistake or unjust enrichment.

enriched unjustly and payments to Defendant could only have been mistaken if the express contracts did not set out specific rates and methods for charging costs. . . . The Court, therefore, concludes Plaintiff-Relators have not stated claims for unjust enrichment or payment by mistake.").

Nevertheless, Kaiser's position is problematic given that the government has not simply alleged the violation of the CMS/Kaiser contract but also the violation of federal regulations. In other words, if the Court or the trier of fact were to find that Kaiser's failure to comply with the ICD Guidelines was not a violation of the CMS/Kaiser contract, then why should the government not be able to proceed with a quasi-contractual theory at that point? *Cf. United States ex rel. Costa v. Baker & Taylor, Inc.*, No C-95-1825-VRW, 1998 U.S. Dist. LEXIS 23509, at *36 (N.D. Cal. Mar. 20, 1998) ("In the present case, plaintiffs believe that their contracts with defendants are valid. In the unlikely event that the court should find these contracts invalid, however, plaintiffs have included claims for unjust enrichment and payment by mistake.").

More important, the government persuasively argues that, even if a quasi-contract claim might ordinarily be barred where an express contract exists, its claim is unique precisely because the government is involved.

> When a payment is erroneously or illegally made, as is alleged here, "it is in direct violation of . . . the Constitution." To correct for this violation, the United States may exercise its "[well]-established right to sue for money wrongfully or erroneously paid from the public treasury," *a right arising separate and apart from statute, regulation, or contract*.

Agility Public Warehousing Co. K.S.C.P. v. United States, 969 F.3d 1355, 1365 (Fed. Cir. 2020); *see also United States v. Wurts*, 303 U.S. 414, 415 (1938) ("The Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid. 'No statute is necessary to authorize the United States to sue in such a case. The right to sue is independent of statute, ..."); *id.* at 416 ("The Government's right to recover funds, from a person who received them by mistake and without right, is not barred unless Congress has 'clearly manifested its intention' to raise a statutory barrier."); *United States ex rel. Robinson-Hill v. Nurses' Registry & Home Health Corp.*, No. 5:08-145-KKC, 2015 U.S. Dist. LEXIS 68222, at *8

(E.D. Ky. May 27, 2015) ("The United States' common law claims for fraud, unjust enrichment, and payment by mistake also survive Mr. House's death. 'The Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid.'").

III. CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Kaiser's motion to dismiss the government's complaint. The Court grants the motion only to the extent that the government has failed to plead a FCA claim based on a scheme by Kaiser to alter patient medical records by adding clinically inaccurate diagnoses on a general or systemic basis. The government, however, has adequately alleged a general scheme to add clinically inaccurate diagnoses for cachexia (specifically). It has also adequately alleged a FCA violation based on Kaiser adding clinically accurate diagnoses but for which no treatment was provided at the time of the doctors' visits. The FCA claims are not time barred. As for the claims for payment by mistake and unjust enrichment, they are allowed to proceed.

The government has leave to file an amended complaint by December 12, 2022. If the government files an amended complaint, then Kaiser shall file a response by January 3, 2023. If no amended complaint is filed by December 12, 2022, then Kaiser shall answer the original complaint in intervention by January 3, 2023.

This order disposes of Docket No. 178.

IT IS SO ORDERED.

Dated: November 14, 2022

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California