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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, *ex rel.* RONDA OSINEK, Plaintiffs, v. KAISER PERMANENTE, FOUNDATION HEALTH PLAN, INC., and THE PERMANENTE MEDICAL GROUP, INC., Defendants.	Consolidated Case No. 3:13-cv-03891 -EMC RELATOR TAYLOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS RELATOR TAYLOR'S THIRD AMENDED COMPLAINT Noticed Hearing Date: May 4, 2023 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor
UNITED STATES OF AMERICA, *ex rel.* JAMES M. TAYLOR, M.D., Plaintiffs, v. KAISER FOUNDATION HEALTH PLAN, INC., KAISER FOUNDATION HEALTH PLAN OF COLORADO, COLORADO PERMANENTE MEDICAL GROUP, P.C., THE PERMANENTE MEDICAL GROUP, INC., and SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP, Defendants.	(Original N.D. Cal. Case No. 3:21-cv-03894-EMC) RELATOR TAYLOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS RELATOR TAYLOR'S THIRD AMENDED COMPLAINT Noticed Hearing Date: May 4, 2023 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

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Relator respectfully provides this Opposition to the Motion of Kaiser Defendants to Dismiss Relator Taylor's Third Amended Complaint ("Mot."). In support thereof, Relator relies upon his Third Amended Complaint ("TAC") and the arguments herein.

Introduction and Procedural History

Dr. Taylor, a physician and certified professional coder who held various high-ranking positions at Kaiser relating to risk adjustment payments and compliance, alleged in detail a nationwide fraud on the Medicare Advantage Risk Adjustment program (the "MA Program") by Kaiser Foundation Health Plan ("KFHP"), Kaiser Foundation Health Plan of Colorado ("KFHP-Colorado"), and Colorado Permanente Medical Group ("CPMG").[1] Relator Taylor filed his initial complaint alleging violations of the False Claims Act (31 U.S.C. § 3729 *et seq.*) ("FCA") in 2014. The Government partially intervened on July 29, 2021.

After two rounds of motions to dismiss, Relator Taylor's theories of fraud remain largely intact: He describes three primary frauds committed by Defendants against the Medicare program that all, at a high level, involve submitting false diagnosis codes to CMS or failing to take corrective action when learning that certain codes were false. Relator Taylor filed his Third Amended Complaint primarily to expand upon the materiality allegations made in his prior complaints. Defendants attack them by flyspecking the language and inventing ambiguities and strawmen, but without identifying a real deficiency. The attacked theories, like the portions of the TAC that Defendants do not challenge, should be permitted to move forward.

Dr. Taylor alleges the following three frauds:

[1] Claims against The Permanente Medical Group, the Southern California Permanente, Kaiser Foundation Health Plan Inc, and claims against Colorado Permanente Medical Group that predate November 15, 2011, were dismissed by the Court's previous orders (Dkt. Nos. 171 and 225).

First, he alleges that Kaiser fraudulently refused, in Colorado and nationally, to investigate or delete diagnosis codes it knew to have consistent, high rates of falsity.[2]

Second, he alleges that Kaiser reviewed the medical records of patients of its external providers in Colorado, then fraudulently and knowingly ignored the results of this chart review that revealed that it had overbilled by submitting codes that violated material coding rules, while acting on the results that gave it additional revenue.

Finally, he alleges that Kaiser knowingly used natural language processing software that, because of its design and Kaiser's implementation, did not assess the validity of previously submitted diagnosis codes and caused the submission of false diagnosis codes.

Each of these independently constitute violations of the FCA, as well as rendered false the attestations Defendants made to CMS regarding the accuracy of their data submissions, which is an additional violation.

Defendants initially moved to dismiss Taylor based on the FCA's first-to-file rule, § 3730(b)(5), citing to the 2013 complaint filed by Ronda Osinek. On May 5, 2022, after argument, this court declined the motion with respect to the majority of Taylor's allegations, allowing the three theories above to proceed.

Defendants then moved to dismiss Relator's Second Amended Complaint, which the court granted in part and denied in part. Dkt. No. 225 or *United States ex rel. Osinek v. Permanente Medical Group, Inc.,* No. 13-cv-03891-EMC, 2022 WL 16943886 (N.D. Cal. Nov. 14, 2022) ("Taylor Order"). In that Order, the Court found that Dr. Taylor adequately pled falsity, relying on *United States ex rel. Swoben v. United Healthcare Ins. Co*., 848 F.3d 1161

[2] Any such allegations as to California have been dismissed by the Court's First-to-File Order (Dkt. No. 171).

(9th Cir. 2015). Taylor Order at *7 ("[The diagnosis codes] were false because Defendants themselves had identified the diagnosis codes as erroneous. Providing more information about precisely why the diagnosis codes were erroneous is not necessary for Defendants in order to defend themselves at this juncture, as the complaint provides sufficient description of the gravamen of the action.").

As to materiality, however, the Court found insufficient detail to assess the question and thus dismissed with leave to amend, other than for diagnosis codes that did not exist as a "clinical matter", which Defendants distinguished (without basis) and had not challenged. Specifically, the Court held that it could not make a materiality assessment because Relator had not provided a description of the *kinds* of errors found in Defendant's data. Taylor Order, at *8. In his Third Amended Complaint, Relator has rectified that and pleaded the types of improper coding knowingly ignored by Defendants, alleging that they are the kinds of inappropriate coding that are material to CMS's payment.

Defendants' new motion raises only two questions: whether that detail is sufficient for the Court to make that assessment, and whether the types of errors Relator has described have "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[3] The answer to both is an unequivocal yes.

Taylor has expressly alleged that Kaiser submitted false codes to CMS and that those submissions directly resulted in overpayments—a plain statement of materiality. Additionally, Taylor pleaded that Kaiser's knowledge of these false codes rendered its required annual attestations false. In his amendment, Relator has added specific allegations regarding the results of nearly a decade of Kaiser's internal "Probe Audits" that were meant to emulate CMS audits of

[3] Quoting the FCA's definition of materiality. 31 U.S.C. § 3729(b)(4).

Medicare Advantage Data, called Risk Adjustment Validation Audits or RADV. TAC ¶¶ 121, 123, 126, 128, 139–40. Through these audits, which applied the CMS standards laid out in its rules, regulations, contracts between the agency and MAOs, the Participant Guide, and the Managed Care Manual, Defendants themselves identified categories of errors that, had they been known to CMS, would have been plainly material to its payment decisions. These include instances when a diagnosis code:

1. Was not supported by the medical record, in violation of the Managed Care Manual, the Participant Guide, CMS rulemaking, and controlling caselaw;[4]
2. Did not affect patient care or treatment, in violation of ICD guidelines, which this Court has acknowledged are binding;[5]

[4] Specifically, this violates the Managed Care Manual ("[MAOs] "must . . . [e]nsure the accuracy and integrity of risk adjustment data to CMS. All diagnosis codes submitted must be documented in the medical record . . . ."). Center for Medicare Management, Medicare Managed Care Manual, Rev. 118 (September 19, 2014), Ch. 7, § 40; the Participant Guide ("[MAOs] must submit risk adjustment data that are substantiated by the patient's medical record."). Centers for Medicare & Medicaid Services, 2003 Regional Risk Adjustment Training For Medicare+Choice Organizations, § 4.1; the most recent CMS rulemaking on the subject, 88 Fed. Reg. 6643, 6646 (Feb. 1, 2023) ("an MAO may only report a diagnosis when that diagnosis is properly supported by the beneficiary's medical records"); and the DC Circuit recent prescription in *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 869 (D.C. Cir. 2021) (''Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer.'').

[5] Specifically, this violates ICD-10 Guidelines § IV.J and ICD-9 Guidelines § IV.K, with which diagnosis codes submitted by MAOs must comply. *See, e.g.*, 45 C.F.R. § 162.1002(a)(1)(i), (b)(1), (c)(2)(i) (establishing the ICD, including the ICD Guidelines, as the national standard for diagnosis coding); 42 C.F.R. § 422.310(d)(1) ("MA organizations 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."); *United States ex rel. Osinek v. Permanente Med. Grp., Inc.* No. 13-cv-03891-EMC, 2022 WL 16925963, at *14 (N.D. Cal. Nov. 14, 2022) ("*Osinek")* ("the Court agrees with the government that Kaiser is required to comply with the ICD Guidelines").

3. Was based on purely probabilistic language in the medical record, in violation of ICD guidelines;[6] or

4. Arose from a non face-to-face encounter in violation of the of the Managed Care Manual.[7]

Id. Defendants' audits identified this as a non-exhaustive list of reasons that they had identified their own diagnosis codes as not comporting with CMS rules, regulations, and guidelines that would be material to the CMS payment decision.

This detail demonstrates why CMS would find the false claims to be material. Every court that has evaluated the materiality of unsupported diagnosis codes to CMS, including diagnosis codes that did not meet ICD standards, has reached the conclusion that they are material. *See United States ex rel. Silingo v. WellPoint, Inc*., 904 F.3d 667, 673 (9th Cir. 2018) ("…if enrollee diagnoses are overstated, then the capitation payments to Medicare Advantage organizations will be improperly inflated"); *Swoben*, 848 F.3d at 1167–68 ("These diagnosis codes contribute to an enrollee's risk score, which is used to adjust a base payment rate."); *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1085-86 (N.D. Cal. 2020) ("When MA Participants submit false risk-adjusting diagnosis codes, CMS pays more money"); *United States ex rel. Poehling v. UnitedHealth Grp., Inc.,* No. CV 16-08697 MWF, 2018 WL 1363487, at *9 (C.D. Cal. Feb. 12, 2018) ("[diagnostic] data is central to the calculation of the amount of money CMS pays to Defendants"); *United States v. Anthem*, 20-cv-2593 (ALC), 2022

[6] Specifically, this violates ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I.

[7] Specifically, this violates the Managed Care Manual. *See* Center for Medicare Management, Medicare Managed Care Manual, Rev. 118 (September 19, 2014), Ch.7 § 40. Long after the audits cited in Relator's TAC were conducted, certain rules on the face-to-face requirement were relaxed in 2020 as a result of the COVID-19 pandemic; these later changes are not relevant here.

WL 4815978, at *6 (S.D.N.Y. Sept. 30, 2022) (denying a motion to dismiss regarding a scheme involving a Defendant's retrospective chart review program, similar to the program at issue in this case); *United States v. Fla. Med. Assocs. LLC.* No. 8:19-cv-1236-KKM-SPF, 2022 WL 4134611, at *7 (M.D. Fla. Sept. 12, 2022) ("[Relator] plausibly alleges materiality given the Amended Complaint's detailed description of how the submission of unsupported and improper risk-adjusting diagnosis codes resulted in overpayments from the government."); *Osinek* 2022 WL 16925963, at 14-15 (finding plausible allegations of materiality due to noncompliance with ICD guidelines); *United States ex rel. Ross v. Indep. Health Corp.,* 12-CV-299S, 2023 WL 24055, at *8-9 (W.D.N.Y. Jan. 3, 2023) (denying a motion to dismiss in a case alleging violations of ICD guidance). In short, had CMS known that Kaiser was submitting false diagnosis codes, or false certifications regarding the accuracy of its data, it would have refused to make risk-adjustment payments or taken other actions to recoup money.

As in their last motion, Defendants attempt to insert an erroneous distinction into the regulations governing the MA program. Citing *nothing* to support their position, Defendants repeatedly point to an invented distinction between diagnoses that are false because they did not exist as a "clinical matter" and those that are false because they violated CMS's prescribed rules, regulations, guidelines, and contract provisions for justifying payment. *See* Mot. at 1, 2, 3, 4, 11, 15, 16. This distinction simply does not exist in the regulatory scheme governing the MA program.

The MA program is built on accurate documentation, not clinical evaluation. Kaiser's failure to point to any authority supporting their supposed distinction highlights that fact. CMS has been consistent that, for a diagnosis code to be acceptable under the MA program, it must meet certain rules and be documented in the medical record. *See* TAC ¶ 73-87. CMS recently

reiterated this rule. In April 2022, the agency reminded MAOs of its longstanding position that "[a] diagnosis code that is not properly documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MA organization." Center for Medicare, Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data (April 15, 2022), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Obligation_to_Submit_Accurate_Data_HPMS_Memo_508_0.pdf. Consistent with this position, CMS's RADV audits, which are meant to recoup money from MAOs for diagnosis that are not adequately supported in the medical record, make no mention of conditions existing as a "clinical matter."[8] Of course, when Defendants were auditing their own data, as opposed to litigating about it, they knew this. In audit after audit, including the audits that led Kaiser to label their own accuracy as needing improvement,[9] Kaiser audited for appropriate documentation, not clinical validity. TAC ¶¶ 121, 123, 126, 128, 139–40.

Relator's allegations are more than enough to support materiality at the pleading stage. Kaiser's motion should be denied.

Factual Background

The Court is undoubtedly familiar with the factual backdrop by this third round of motions, but we reiterate it here for convenience. Through the MA program, CMS allows private health insurers to set up managed care plans to cover Medicare beneficiaries. All told, CMS currently has over 900 contracts with different insurers, known as Medicare Advantage Organizations or MAOs.

[8] CMS audits of MA data, known as "Risk Adjustment Validation Audits," rely solely on the review of medical documentation, not an examination of beneficiaries to evaluate whether conditions existed as a "clinical matter." 42 CFR § 422.310(e). Of course, such a review of whether conditions existed as a "clinical matter," would be impossible.

[9] TAC ¶ 130, 141.

CMS pays a monthly capitation rate for each beneficiary enrolled as a member of an MA plan, known as a "per-member, per-month" payment. This predetermined base payment varies for each MA Plan depending on various factors, primarily demographics (age and sex) and health status.

Individuals with multiple and/or serious health conditions account for more health care costs than healthier members. Accordingly, CMS pays a substantially higher capitation rate for members who have been recently treated for one or more serious, expensive diseases or conditions. *See* 42 U.S.C. § 1395w-23(a)(1)(C). These increased payments are known as "risk adjustment" payments. The only variable that determines a beneficiary's health status is the diagnosis codes an MAO submitted on that beneficiary's behalf. *See* 42 U.S.C. §§ 1395w-23(a)(1)(C)(i), (a)(3); 42 C.F.R. § 422.308(c)(2).[10]

Because diagnosis coding is inherently linked to payment, MAOs are bound by regulation, contract, and mandatory CMS guidance to follow certain rules that dictate the conditions under which they may submit codes for risk adjustment purposes. These rules include requirements that the diagnosis code must be supported by the beneficiary's underlying medical record, must come from an acceptable provider type, must come from a face-to-face medical encounter,[11] and must come from a visit in the relevant timeframe determining that payment, among other requirements.

A violation of any of these requirements renders a code false. The code might have been derived from a visit with an unacceptable provider type, from the wrong year, or simply

[10] Though this opposition focuses on Medicare Part C, Relator is pursuing analogous allegations under Medicare Part D, which covers prescription drugs. Diagnostic coding is also the basis for determining the amount of money insurers receive from the Part D program. *See* TAC ¶¶ 46, 61, 75-77; 42 C.F.R. §§ 423.504 & 423.505.

[11] Certain exceptions to this rule were afforded as a result of the COVID-19 pandemic.

fabricated—or, as the government's various FCA litigations show, many, many other alleged fraud schemes. Because a code triggers payment, each of these violations results in CMS paying more money than if Kaiser had followed the program rules.

Standard of Review

Under Rule 12(b)(6), a district court takes the facts alleged in the complaint as true. *See United States ex rel. Lee v. Corinthian Colls*., 655 F.3d 984, 991 (9th Cir. 2011). The court must draw all reasonable inferences in favor of the plaintiff. *See Turner v. City and Cnty. of San Francisco*, 788 F.3d 1206, 1210 (9th Cir. 2015).

Fraud must be pleaded with particularity under Rule 9(b). For an FCA complaint, that standard is satisfied if the complaint identifies the "who, what, when, where, and how" of the misconduct charged. *Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys.*, *Inc.,* 637 F.3d 1047, 1055 (9th Cir. 2011) (citing *Ebeid ex rel. United States v. Lungwitz,* 616 F.3d 993, 998 (9th Cir. 2010)). But while Rule 9(b) requires particularity for the "circumstances constituting fraud or mistake," its heightened standard is limited to those aspects; all "other facts may be plead generally, or in accordance with Rule 8." *Corinthian Colls*., 655 F.3d at 991, 992.

Argument

Defendants' primary remaining attack on Dr. Taylor's claims is to posit, against the weight of precedent and binding contract and guidance, that codes that are false because they violate the MA Program's rules are somehow not material to CMS. But CMS's rules that must be followed by MAOs when claiming payment are clear, longstanding, and have been held to be the basis of FCA violations by several Courts. Kaiser's materiality arguments should be denied.

I. Relator Adequately Alleges Materiality

Relator alleges that Kaiser submitted improper diagnosis codes that led to false claims for payment and the unlawful retention of overpayments, and that also rendered false the annual

attestations of accuracy that MAOs submit to CMS. In his prior complaints, Relator explained that Kaiser itself had recognized that the coding was improper under CMS rules; in the TAC, as the Court requested, Relator adds additional detail setting out the ways in which the codes violated the CMS rules. Together, they constitute clear pleading of materiality.

The requirement to submit accurate coding is at the heart of the Medicare program, as it directly determines the amount of payment. It is plainly—and definitionally—material. In *Universal Health Servs., Inc. v. United States ex rel. Escobar*, the Supreme Court noted that both the FCA and "common-law antecedents" applied in other federal fraud statutes define materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 579 U.S. 176, 182 (2016) (quoting 31 U.S.C. § 3729(b)(4)). The Court then explained that, under any understanding of this concept, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation'." *Id*. at 193. The Supreme Court's main concern was that FCA liability should not occur "where noncompliance is minor or insubstantial" or be based on "insignificant regulatory or contractual obligations", just because the Government labelled them as conditions of payment and could theoretically decline to pay. *Id.* at 194, 196.

That is not the case here, where both the attestations and the diagnosis codes themselves are essential to the CMS decision to pay Kaiser's capitation payments. Based on the holistic analysis prescribed in *Escobar*, both the risk adjustment attestations and the underlying diagnosis codes themselves are material to CMS payment decisions. The United States has consistently taken this position in FCA cases, and numerous courts have agreed.

Kaiser's central argument on materiality relies on drawing a false distinction between diagnoses codes that did not exist as a "clinical matter" and those that are just in violation of

CMS regulations. *See* Mot. at 1, 2, 3, 4, 11, 15, 16. As discussed above, from the perspective of CMS, a properly coded condition means that the condition exists for the purposes of payment under the MA program. The MA payment system is based on documentation rules because CMS cannot audit the health status of beneficiaries—an impossible task. Defendants point to no authority that makes such a distinction, nor do they explain it.[12] It is simply an attempt to make certain false codes appear immaterial, when CMS has never made any such differentiation.

CMS's recent rulemaking highlights the baselessness of this perceived distinction. On February 1, 2023, CMS released its final RADV rule. RADV audits occurred in prior years but have been on pause during a prolonged rulemaking process. These are the same audits that Kaiser's probe audits were designed to mimic. *See* TAC ¶ 98-100. Consistent with the entire history of the MA program, in that rule, CMS focused on documentation in the medical record, not "clinical accuracy" when describing the standards of the MA program and situations in which the agency plans to recoup money. For instance, CMS plainly references "the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments." 88 Fed. Reg. 6643, 6644 (Feb. 1, 2023). This standard is about documentation, not any sort of clinical judgment.

Likewise, in discussing the purpose of RADV audits, CMS indicates that they are intended to recoup money for risk adjustment payments made on the basis of codes that were not supported in documentation: "Because there is an incentive for MAOs to potentially over-code diagnoses to increase their payments, that is, to code diagnoses not properly substantiated by

[12] Additionally, several categories of errors found in Kaiser's audits, such as improperly coding a history of cancer as acute cancer, are indeed examples of beneficiaries not having the condition in question. *See e.g.,* TAC ¶ 121. Following its false distinction, Kaiser has conceded that such claims are false and material.

medical record documentation, CMS conducts post-payment audits of MAO-submitted diagnosis data." *Id.* at 6645. The final rule also reiterated the principle that MAOs need to comply with CMS rules, including the ICD-10 guidelines. *Id.* at 6646 ("MAOs must submit data that conforms to all relevant national standards, including the … (ICD–10–CM) Guidelines").

Simply put, "Medical records properly support a reported diagnosis when they comply with all CMS data and documentation requirements, which are described in current agency policy documents, including the Medicare Managed Care Manual," not just when a beneficiary suffers from a condition as a "clinical matter." *Id.* at 6646-7.

A. The Allegations Regarding Audit Error Rates Adequately Support Materiality

A diagnosis code that uniquely triggers an HCC[13] directly affects the amount that an MAO is paid by CMS. Thus, the materiality of the diagnosis codes an MAO submits is definitional. They inherently meet the statutory definition of 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).

As explained above, when an MAO submits diagnostic data to CMS systems, CMS systems automatically adjust payments based on that information. Had Kaiser not submitted false diagnosis codes, or had it deleted false diagnosis codes, it would have automatically been paid less by CMS. That is the hallmark of materiality.

[13] Under the MA program, Diagnosis Codes are grouped into Hierarchical Condition Categories, or HCCs, which are broad categories of related conditions e.g., Diabetes with Acute Complications, that are assigned based on the coding of an underlying diagnosis. Each HCC is assigned a coefficient, as are certain aspects of demographics. The sum of these coefficients, on a per beneficiary basis, results in a risk score, which directly translates to the amount paid. In short, a diagnosis code triggers an HCC that triggers an increased payment.

Of course, a crafty lawyer can always find rules that are so minor as to seem immaterial. Kaiser's counsel has done so with requirements about spacing and the use of X as a placeholder. But as Dr. Taylor's TAC makes clear, he is not alleging violations of formatting requirements. His allegations are of falsehoods that get to the heart of the payment system: whether the MAO is claiming a diagnosis code that is properly supported, from face-to-face encounter, and affected care or treatment. Those are the core, material requirements for payment.

Every Court that has examined the issue to date has concluded that accurate diagnostic data is material to CMS payments. *See e.g., Swoben*, 848 F.3d at 1167 (explaining that "[t]he risk adjustment methodology relies on enrollee diagnoses"); *Silingo*, 904 F.3d at 673 ("if enrollee diagnoses are overstated, then the capitation payments . . . will be improperly inflated."); *Ormsby*, 444 F. Supp. 3d at 1085 ("Diagnosis codes are the only factors that CMS uses to determine a beneficiary's health status to calculate Medicare Advantage payments … This establishes that the diagnosis codes are material."); *Poehling*, 2018 WL 1363487, at *9 ("the sole determinant in the calculation of any risk adjustment payments based on a beneficiary's health status" and that CMS adjusts payments upwards or downwards based on addition or deletion of diagnosis codes sufficiently pleads that diagnosis codes are material.).

Relator pleads the reasons listed in Kaiser's own audits that their codes violate CMS rules, including lack of support for a diagnosis in the medical record, the diagnosis arising from an improper visit type, and diagnosis of diseases that have been cured, or are in remission, as active. TAC ¶¶ 121, 123, 126, 128, 139–40.[14] Each of these is a failing that CMS deems material to its payment decision. TAC ¶¶ 264, 268, 272.

[14] A lack of support in the medical record is frequently the basis of HHS-OIG requesting repayment from various MAOs, further demonstrating materiality. *See e.g.,* Off. of Inspector Gen., Dep't of Health and Hum. Servs., Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Co. (H3916) Submitted to CMS (September

Kaiser does little to address this added detail in Relator's complaint, which is more than sufficient for demonstrating the materiality of the violations. Instead, Kaiser simply calls them names ("threadbare recitals", Mot. at 9-10), ignoring that they are drawn from Kaiser's own audits, which identified these categories of errors using criteria from CMS RADV audits.[15] Kaiser knew of the persistent errors—through the eight probe audits cited in the TAC—and thus that they were submitting false diagnoses codes to CMS for payment. Kaiser's audits also demonstrated that this problem was profound amongst its external providers. TAC ¶¶ 112-116. Instead of taking action to correct this fraudulent trend, Kaiser set up a program that would correct errors in diagnosis coding that benefited its bottom line, while ignoring errors that would cost it revenue. TAC ¶¶ 134-160.

This one-way looking, retrospective chart review program that Kaiser operated is extremely similar to programs at issue in three other cases where courts found materiality: *Swoben,* 848 F.3d 1161, *Poehling,* 2018 WL 1363487, and *Anthem,* 2022 WL 4815978. In all three, the Plaintiffs pled a theory nearly identical to the chart review theory Relator puts forth here, and in all three cases, motions to dismiss were denied. Kaiser does nothing to discuss or

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2022), https://oig.hhs.gov/oas/reports/region3/31900001.pdf ("…the diagnosis codes were not supported in the medical records. These errors occurred because the policies and procedures that Highmark had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved…we estimated that Highmark received at least $6.2 million of net overpayments for 2015 and 2016.").

[15] Kaiser's claim that Relator failed to allege what a CMS-conducted RADV has "concluded about diagnosis codes submitted from the Colorado" is without merit. Mot at 12. "To date, CMS has not recovered based on RADV audit findings for audit years after PY 2007." 88 Fed. Reg. 6643, 6646 (Feb. 1, 2023). The audits conducted in 2007 did not include Kaiser Colorado. *See* Center for Medicare, Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet: Payment Year 2007 RADV Audits (June 1, 2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/RADV-Fact-Sheet-2013.pdf.

differentiate these cases, despite all three cases being extensively discussed in the briefing surrounding Kaiser's previous motion. In all three cases, the courts found materiality had been adequately pled, without requiring any more of an explanation of why diagnosis are false than what is provided by Relator in the present case. Relator has alleged the reasons that codes were false and why CMS finds those to be material. That is sufficient.[16]

Faced with this reality, Kaiser hones in on the term "non-exhaustive" before the allegations of the reasons the diagnosis codes were materially false and claims that this somehow makes Relator's pleading insufficient. Mot. at 10-11. But it is simply an acknowledgement that it would be impossible to provide a detailed, fully exhaustive list of the reasons diagnosis codes were false in Kaiser's submissions to CMS. As of January 2023, slightly over 112,000 people are enrolled in Kaiser Colorado's MA plan. That size of enrollment likely results in millions of medical encounters between Kaiser's beneficiaries and their healthcare providers from 2008 to the present.

Defendants seem to want Relator to plead the specifics of every single false claim, but that is simply not the standard. *Swoben* 848 F.3d at 1180 (complaint need not identify representative examples where allege particular details of scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted); *Silingo* 904 F.3d at 677-678 (complaint need not allege representative examples, although that is one

[16] Kaiser also claims that the TAC "does not identify even in general terms what portion of chart-review revenue can be attributed to the alleged fraud." Mot. at 11. This demonstrates a fundamental misunderstanding of Relator's chart review theory. Relator concedes that additional diagnosis found via the program are proper for submission to CMS for additional risk adjustment revenue, provided that those diagnosis fall into CMS rules and requirements governing MA program. The harm to the government comes from previously submitted, false diagnosis codes that are identified as such via the chart review program and Kaiser refused to delete from CMS systems after gaining knowledge regarding their falsehood.

way of complying with 9(b); must provide reliable indicia leading to a strong inference that claims were actually submitted). It would be impossible, and is certainly not a pleading requirement, to account for all reasons why a diagnosis code might be false in a data set of that size.

For example, it is clearly material to CMS that MA beneficiaries see licensed practitioners for their healthcare needs, and diagnoses arising from encounters with providers that have no formal training in medicine, have expired medical licenses, or have been excluded from payment in the Medicare system due to fraud convictions are clearly unacceptable sources of diagnosis codes for MA payments. Any such codes are materially false and triggered FCA liability when they were submitted or left uncorrected once Kaiser had knowledge, such as when discovered through Kaiser's chart review program. It is not surprising that none appeared in Kaiser's audits, which of course were of limited sample sizes, but they remain material. When it discovered these errors in its chart review program, Kaiser should have submitted deletes.

No supposed good faith standard can excuse Kaiser's knowing false claims and retention of false payments. *See* Mot at 11 (citing 64 Fed. Reg. 61893, 61900 (Nov. 15, 1999)). While it is true that not all errors in submissions to CMS give rise to an FCA violation, the fraudulent diagnoses alleged by the Relator are not mere negligent errors; instead they are known false diagnoses that Kaiser's own chart review program has identified as being deficient, and yet Kaiser knowingly did nothing to correct them.[17] The very page of the Federal Register that Kaiser cites draws this distinction: "The knowing submission of false information to HCFA

[17] Kaiser's Motion did not question the adequacy of Relator's pleadings as to the FCA's scienter requirement. Any such argument would now be waived. *See Thrasher v. Clovin,* 611 F. App'x 915, 918 (9th Cir. 2015) ("These arguments are waived because they were not raised in the opening brief.") (Citing *Smith v. Marsh*, 194 F.3d 1045, 1052 (9th Cir.1999))

[CMS's predecessor] can lead to serious criminal or civil penalties." 64 Fed. Reg. 61893 at 61900 .[18]

Contrary to Kaiser's arguments, Relator does not assert that any violation of CMS rules gives rise to liability under the FCA. Mot 13-14. Relator's complaint explains that CMS has standards that must be met for a diagnosis to be an acceptable basis for risk adjustment payments: these include support in the medical record, deriving from a face-to-face encounter, and affecting patient care or treatment. TAC ¶¶ 58-80. Courts have routinely held the same, as the D.C. Circuit recently recognized, "Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer." *Becerra*, 9 F.4th at 868. As discussed above, CMS has laid out these documentation standards as the very basis of the MA program. The substantiation of the diagnosis is critical, given that diagnosis codes translate directly into payment amounts.

[18] Defendants also make a passing reference to CMS having continued payment as suggesting a lack of materiality under *Escobar*, but the Ninth Circuit has already rejected that argument in this context. Mot. at 11-12. When faced with a similar question, it held that a myopic focus on the Government's continued payment should not be used to shield Defendants from liability for their fraud. *See United States ex rel. Campie v. Gilead Scis., Inc*., 862 F.3d 890, 906 (9th Cir. 2017) (stating that "to read too much into the FDA's continued approval [of the drugs after it learned of certain compliance issues] – and its effect on the government's payment decision – would be a mistake" because it would allow the defendant to "use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud"). Additionally, in none of the MA cases cited above has CMS stopped payment, yet all of those cases were allowed to proceed past the pleading stage. *See* string cite *supra,* page 5. Practically speaking, CMS cannot stop payment for two reasons. First, without further investigation, CMS does not know which diagnoses are false and thus how much to withhold. Second, more critically, a stoppage of all payment to Kaiser Colorado would likely result in thousands of Colorado seniors losing their insurance. CMS not triggering this is not an indication of its blessing Kaiser's alleged conduct, merely of a concern for the continued provision of healthcare to vulnerable populations. *See e.g., United States v. Berkeley HeartLab, Inc*., No. 14-cv-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017) ("The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing.").

The examples of improperly formatted data do not give rise to liability under the FCA. In fact, a violation of the rule Kaiser cites example of 481 spaces being required in a certain field does not lead to a wrongful payment from the government to Kaiser; it simply generates an error report. *See* Mot. 14; Dkt. No. 179-1at 403 (Ex. C) ("When data is entered improperly, the plan receives errors as the data is processed through FERAS or RAPS. If errors are discovered in FERAS[19], the file will be returned to the plan.").

Finally, Defendants' materiality arguments do not apply at all to Relator's claims under the "reverse" false claims provision of the FCA, which are an independent theory of liability here. § 3729(a)(1)(G). *Escobar* did not address materiality under this section of the FCA. Relator pleads two frauds under this subsection:

First, Defendants' attestations to CMS that its codes complied with applicable rules were false. Under the false statement provisions of § 3729(a)(1)(G), the inquiry focuses on the materiality of that false statement—here, Defendants' Attestations—on Defendants' "obligation to pay," which includes repaying an overpayment. The materiality of those attestations is discussed in the next section below.

Second, Defendants had an obligation to return overpayments to CMS when they gained knowledge of previously submitted false claims, such as via their one-way look chart review program. Under the second part of § 3729(a)(1)(G), the concealment of an obligation to pay the government, any implied materiality requirement would logically also focus on Defendants' obligation to repay the overpayment. It would not be connected to any false statement, however, as a false statement is not an element of a violation of the second part of § 3729(a)(1)(G). The

[19] FERAS is the Front End Risk Adjustment System, a CMS system that verifies that data submitted to CMS is correctly formatted.

legitimacy of Defendants' coding remains the centerpiece. If it is improper because of requirements that CMS finds material, as Relator alleges, then it gives rise to FCA liability.

In *United States v. Bourseau*, 531 F.3d 1159 (9th Cir. 2008), the Court addressed the application of the pre-FERA version of the reverse false claims provision.[20] Similarly to this case, that case involved interim payments made periodically throughout a year with a final reconciliation payment made based on the Defendants' submission of reports at the end of each year. *Id*. at 1162. The Court explained that the inquiry under the reverse false claims provision was whether the false cost reports were material to avoid or decrease paying money owed the Government or repaying the Government for an overpayment. *Id.* at 1170-71. It concluded that the false reports "concealed and decreased amounts that [the defendants] were obligated to repay to Medicare" even though the cost reports were not reviewed by the Government. *Id*. Here, the known, false diagnosis codes submitted by Defendants inherently increased the amounts paid to Defendants. Kaiser's failure to delete those codes resulted in their retaining overpayments, analogous to the situation in *Bourseau.*

B. Risk Adjustment Attestations Are Material to CMS Payment Decisions

CMS, as an explicit condition of payment, has required the CFO or CEO of each MAO to sign an attestation certifying the accuracy, completeness, and truthfulness of the diagnostic data the MAO submits to CMS. 42 C.F.R. § 422.504(l). Due to the schemes alleged by Relator in the TAC, Kaiser had information showing that their diagnostic data was not accurate, complete, or truthful. That rendered these attestations false at the time Kaiser submitted them. In *Swoben*, the Ninth Circuit called these attestations a "bulwark against fraud." 848 F.3d at 1168. Defendants'

[20] The *Poehling* Court held that *Escobar* did not overturn *Bourseau.* 2018 WL 1363487, at *11-12.

knowingly submitting false diagnosis codes, or failing to delete them once they were discovered, rendered the annual attestations necessarily false. The falsity of the attestation, an explicit condition of payment, is material to CMS's payment decision. The *Anthem* court found false attestations resulting from a one-way looking chart review program material. *Anthem*, 2022 WL 4815978, at *6.

The attestation warns of the serious legal implications of making false representations about the validity of diagnoses. It states that "[t]he MA Organization acknowledges . . . that misrepresentations to CMS about the accuracy of such [risk adjustment] information may result in Federal civil action and/or criminal prosecution." This is a plain statement, executed by Defendants, that evinces materiality to a claim for payment under §§ 3729(a)(1)(A) and (B), or to an obligation to repay under the false statement provisions of § 3729(a)(1)(G).

The known, false diagnosis codes described above render the attestations false. Kaiser's concession that a certain category of false diagnosis codes is material to CMS (the so-called conditions not supported as a "clinical matter") is damning on this point. Even if the court adopted Kaiser's false distinction and did not find other categories of false diagnosis to be material to the CMS payment decision, the presence of this category of false diagnoses in Kaiser's submissions to CMS renders the attestations submitted to CMS false.

C. The NLP Claims Are Also Material

Relator's last theory focuses on Kaiser Colorado's knowing misuse of Natural Language Processing software. TAC ¶ 248-59. Kaiser used NLP that only looked one-way (for additional diagnoses), and the results of that process generated codes that violated the CMS framework described above, yet Kaiser submitted to CMS nonetheless. Audits of the codes generated by the software both by Relator and in Kaiser's Hawaii region showed substantial rates of false diagnoses

being submitted to CMS, but Kaiser Colorado took no steps to prevent the submission of these false codes. TAC ¶ 255-56.

Much like with Relator's chart review claims, and as evidenced by CMS statements in rulemaking, the agency would not have paid Kaiser for diagnoses that do not comply with its rules, regulations, guidelines, and contracts.

Kaiser's arguments basically boil down to two erroneous contentions: that error rates in audits cannot be the basis of FCA liability and that the specific audit here was too small. On the first point, cases at the pleading stage have held exactly the opposite. *See e.g., United States v. Lakeshore Med. Clinic, LTD*., No. 11-CV-00892, 2013 WL 1307013, at *3 (E.D. Wis. Mar. 28, 2013) (denying a Motion to Dismiss where a "defendant ignored audits disclosing a high rate of upcoding" because that "plausibly suggests that defendant acted with reckless disregard for the truth and submitted some false claims."). On the second point, Kaiser first ignores a much larger audit of outputs of the same software in the Hawaii region (TAC ¶ 255), and it fails to argue what sort of audit would be sufficient to get through a motion to dismiss. At this stage, the allegation by an experienced physician and certified coding professional that his audit yielded evidence of substantial false coding is sufficient.

Relator has pleaded his NLP allegations adequately.

II. The Court Should Allow Relator Leave to Amend

Should the Court grant Defendants' Motion, in whole or in part, Relator requests that the dismissal of any of his claims be without prejudice and that he be granted leave to amend[21]. *See*

[21] Kaiser's characterization that this is Relator's fourth chance at pleadings, though technically correct, is a misconstrued characterization. Mot at 16. The TAC is just the second complaint facing a Motion to Dismiss under Rule 12(b)(6). Moreover, the first amendment was made under seal, very quickly after the initial filing, to correct errors in the complaint. There were no substantive changes in that amendment.

Fed. R. Civ. P. 15(a)(2); *see, e.g., Eminence Cap., LLC v. Aspeon, Inc*., 316 F.3d 1048, 1052 (9th Cir. 2003) (holding that dismissal without leave to amend is improper unless the complaint could not be saved by any amendment); *Sloan v. Gen. Motors LLC,* No. 16-cv-07244-EMC, 2019 WL 2775631, at *3 (N.D. Cal. July 2, 2019) (Chen, J.) (Allowing a plaintiff to file a fifth amended complaint, despite the second and third amended complaints being filed in response to rulings on motions to dismiss). Relator has amended only once in response to a motion to dismiss ruling; that should not stand in the way of amendment should the Court dismiss a portion of his claims that can be remedied through additional pleading.

Conclusion

This Court should deny Kaiser's materiality arguments and permit the challenged portions of Relator Taylor's TAC to proceed to discovery. In the alternative, any dismissal of portions of the TAC should be without prejudice and with leave to amend.

DATED: March 3, 2022

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, *ex rel.* RONDA OSINEK, Plaintiffs, v. KAISER PERMANENTE, FOUNDATION HEALTH PLAN, INC., and THE PERMANENTE MEDICAL GROUP, INC., Defendants.	Consolidated Case No. 3:13-cv-03891 -EMC [Proposed] Order Noticed Hearing Date: May 4, 2023 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor
UNITED STATES OF AMERICA, *ex rel.* JAMES M. TAYLOR, M.D., Plaintiffs, v. KAISER FOUNDATION HEALTH PLAN, INC., KAISER FOUNDATION HEALTH PLAN OF COLORADO, COLORADO PERMANENTE MEDICAL GROUP, P.C., THE PERMANENTE MEDICAL GROUP, INC., and SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP, Defendants.	(Original N.D. Cal. Case No. 3:21-cv-03894-EMC) [Proposed] Order Noticed Hearing Date: May 4, 2023 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

[Proposed] Order

This matter coming to be heard on this 4th day of May 2023, upon consideration of MOTION TO DISMISS RELATOR TAYLOR'S THURD AMENDED COMPLAINT, and the Court being fully advised in the premises.

IT IS HEREBY ORDERED the Defendants' Motion is Denied.

Dated:

HON. EDWARD M. CHEN

United States District Judge