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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. RONDA OSINEK,

Plaintiff,

v.

KAISER PERMANENTE, et al.,

Defendants.

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

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

Hearing Date: May 4, 2023
Time: 1:30 PM
Judge: Hon. Edward M. Chen
Courtroom: 5, 17th Floor

(CAPTION CONTINUED)

UNITED STATES OF AMERICA ex rel. GLORYANNE BRYANT and VICTORIA HERNANDEZ, Plaintiff, v. KAISER PERMANENTE, et al., Defendants.	Case No. 3:18-cv-01347-EMC **NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES** 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, Plaintiff, v. KAISER PERMANENTE, et al., Defendants.	Case No. 3:21-cv-03894-EMC **NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-INTERVENTION; MEMORANDUM OF POINTS AND AUTHORITIES** Hearing Date: May 4, 2023 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

NOTICE OF MOTION AND MOTION

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

PLEASE TAKE NOTICE that, on May 4, 2023, at 1:30 p.m., or as soon thereafter as counsel may be heard, in the courtroom of the Honorable Edward M. Chen (Courtroom 5) of the above-entitled Court, located at 450 Golden Gate Avenue, San Francisco, California 94102, Kaiser Foundation Health Plan, Inc.; Kaiser Foundation Health Plan of Colorado; The Permanente Medical Group, Inc.; Southern California Permanente Medical Group; and Colorado Permanente Medical Group, P.C. (collectively, "Defendants") will and hereby do move this Court to dismiss the United States' First Amended Complaint-in-Intervention, Dkt. No. 240, under Federal Rule of Civil Procedure 12(b)(6).

Defendants bring this Motion on the grounds that the amended complaint's new allegations fail to adequately allege any claims against Defendants under the False Claims Act ("FCA"). The United States has failed to allege falsity, knowledge, and materiality for its new allegations. The United States also has failed to state a conspiracy claim premised on its new allegations because the amended complaint does not sufficiently allege the existence of an agreement among Defendants to diagnose members with medical conditions contradicted by information in the medical record, or to diagnose members with nonexistent conditions. Lastly, the United States' new allegations are also insufficient to state a claim against any Defendant except for Kaiser Foundation Health Plan and The Permanente Medical Group, because the new allegations indiscriminately lump together all five Defendants without adequately specifying how each Defendant contributed to the alleged fraud scheme. In sum, the Court should dismiss all claims for relief premised on the new allegations in the amended complaint.

The Motion is based on this Notice of Motion, the accompanying Memorandum of Points and Authorities, any reply memorandum, and such other written and oral argument as may be presented to the Court.

Dated: February 2, 2023

Respectfully submitted,

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

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I. INTRODUCTION

In ruling on Defendants'[1] initial motion to dismiss, the Court held—with one minor exception—that the United States failed to allege that Defendants perpetrated a systemic scheme to submit clinically false diagnosis codes to the Medicare Advantage program.[2] Dkt. No. 223 ("Order") at 14. The Court granted the United States leave to amend its complaint "to expand the scope of its allegations on clinically false diagnoses." *Id.* But rather than cure its initial pleading failures, the United States' amended complaint introduces an entirely new, watered-down theory that does nothing to support allegations of clinical falsity.

The United States now contends that Defendants diagnosed Medicare Advantage members with medical conditions that were "contradicted" by information in the members' medical records, peppering its amended complaint with upward of ***forty*** generalized references to "contradictions," "contradictory" information, and "contradicted" diagnoses.[3] By contrast, the United States adds only ***two*** specific examples of diagnoses that allegedly did not exist, both of them for the same medical condition.

The new theory in the amended complaint is distinct from a clinical falsity theory. A medical record that contains information that might contradict a diagnosis does not equate to a clinically false diagnosis. A medical record may contain information that contradicts a diagnosis code for a host of reasons that have absolutely nothing to do with fraud. A diagnosis can be clinically accurate even when contradictory information is present in the medical record if, for

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

[2] The Court allowed the United States to proceed on clinical falsity allegations concerning a purported scheme to misdiagnose cachexia in Northern California. Order at 14.

[3] "Members" refers to the individual Medicare beneficiaries who are enrolled in the Medicare Advantage program and receive their healthcare coverage through a private insurer known as a Medicare Advantage Organization. Members become patients when they receive medical care covered by the Medicare Advantage program. Thus, for purposes of this Motion, the terms "members," "beneficiaries," and "patients" are synonymous unless otherwise stated.

example, the record contains a typographical error such as a misrecorded weight or there has been a change in the patient's circumstance such as the reappearance of cancer after remission.

The Court should reject the United States' new theory, as the amended complaint fails to allege several elements of the False Claims Act ("FCA") and the derivative common-law claims.

First, the United States has again failed to plead falsity. The Court granted the United States leave to amend its complaint to plead a fraudulent ***scheme*** by Defendants to diagnose medical conditions that did not exist and submit corresponding diagnosis codes to the U.S. Centers for Medicare & Medicaid Services ("CMS"). As explained, the United States does not allege any such scheme because its new theory is not based on clinical falsity at all. The United States asserts instead that a contradiction between a diagnosis and information in the medical record must be indicative of fraud, but ignores the many plausible alternative explanations for such contradictions other than fraud. The United States contends that Defendants' use of datamining algorithms and queries led to the submission of diagnoses to CMS that were contradicted by the medical record, but the United States concedes that healthcare providers exercised their clinical judgment when making the decision to diagnose their patients. The United States scatters conclusory assertions of a widespread fraud across three markets for over a decade, but then cites only two new examples of diagnoses that allegedly did not exist, both for the same medical condition. Simply put, the United States has not plausibly alleged ***facts*** showing that thousands of individual healthcare providers knowingly diagnosed Medicare Advantage members with medical conditions that did not exist.

Second, the United States has not alleged scienter in support of its new theory. The United States primarily bases scienter on the allegations regarding datamining algorithms and coding queries. But because the United States has not plausibly alleged that flaws in algorithms and queries actually resulted in the submission to CMS of clinically false diagnosis codes by thousands of individual healthcare providers—or even of "contradictory" information—the United States has not plausibly alleged that Defendants knew of those clinically false diagnoses.

Third, the United States fails to allege materiality for its new theory. The amended complaint contains no factual allegation that CMS would have refused to pay Defendants simply

because it received a diagnosis code that was contradicted by some information in the medical record, as opposed to a diagnosis code for a condition that in fact did not exist.

Fourth, the United States cannot pursue an FCA conspiracy claim based on its new allegations because the amended complaint does not sufficiently allege the existence of an agreement among Defendants to diagnose members with medical conditions contradicted by information in the medical record—much less an agreement to diagnose members with nonexistent conditions.

Finally, if the Court does conclude that the new allegations satisfy the United States' pleading burdens, the Court should at least limit those allegations to claims for relief against Kaiser Foundation Health Plan ("KFHP") and The Permanente Medical Group ("TPMG"). Except for some specific allegations against KFHP and TPMG, the new allegations indiscriminately lump together all five Defendants without adequately specifying how each Defendant contributed to the allegedly fraudulent scheme.

By pleading "contradictions" between diagnoses and medical records and by relying on perceived flaws in datamining algorithms and coding queries, the United States attempts to avoid directly accusing thousands of healthcare providers of misdiagnosing their patients with medical conditions that do not exist. But that is precisely what a clinical falsity theory requires, especially when the amended complaint alleges that healthcare providers had the final say regarding the diagnoses that were recorded for their patients. To allege a systemic fraud premised on submitting clinically inaccurate diagnoses to CMS, the United States must plead facts showing that thousands of individual healthcare providers knowingly diagnosed their patients with nonexistent medical conditions. The United States appears unwilling to accept that burden and its serious implications for discovery. The Court must limit the complaint accordingly.

II. BACKGROUND

A. The United States' Complaint-In-Intervention

Relator Ronda Osinek filed a sealed *qui tam* action against "Kaiser Permanente" almost ten years ago, raising allegations about Defendants' Medicare Advantage risk-adjustment

practices.[4] The United States devoted the next eight years to investigating Defendants, as several other relators filed copycat suits against Defendants and other Kaiser Permanente-affiliated entities. During this time period, Defendants responded to multiple subpoenas, witness examination requests, letters, and emails on a wide range of topics and produced nearly 4.7 million pages of documents to the United States. *See* Dkt. No. 150 at 7. The United States finally decided to partially intervene in the underlying *qui tam* actions on July 29, 2021, and filed its complaint on October 25, 2021. Dkt. Nos. 65, 110.

The complaint named as defendants three regional medical groups that render healthcare services to Medicare Advantage members: TPMG (which delivers healthcare services in Northern California), Southern California Permanente Medical Group ("SCPMG"), and Colorado Permanente Medical Group ("CPMG"). *See* Compl. ¶¶ 23–27. It also named the nonprofit KFHP and Kaiser Foundation Health Plan of Colorado ("KFHP-CO"), which contract with CMS to provide Medicare Advantage plans in California and Colorado, respectively. *Id.* ¶¶ 20–22.

The original and amended complaints focus exclusively on healthcare providers' use of medical record addenda to record diagnoses for Medicare Advantage members. The original complaint centered on two types of purportedly inappropriate addenda-related practices. First, it accused Defendants of violating applicable diagnosis-coding requirements by adding existing medical conditions to medical records "unrelated" to the member's visit with the healthcare provider. *Id.* ¶¶ 1, 98, 126. Second, it contended that Defendants recorded some medical conditions in those addenda that "did not exist." *Id.* ¶¶ 1, 11, 97, 126. In other words, the United States alleged that Defendants violated the FCA in two different ways: submitting diagnosis codes that were allegedly false (1) because they did not comport with certain diagnosis-coding guidance and (2) because the member did not have the underlying medical condition diagnosed by the healthcare provider. Defendants moved to dismiss both FCA theories.

B. The Court's Dismissal Order

As relevant here, the Court dismissed the United States' claims for relief based on

[4] Because the Court is familiar with the structure of the Medicare Advantage program, *see* Order at 2–4, Defendants do not describe it again here.

clinically inaccurate diagnoses.[5] Order at 14. The Court acknowledged that while the United States alleged three specific instances of clinical falsity, the complaint had failed to allege "a plausible case for . . . 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." *Id.* at 13.

The Court concluded, however, that the United States had adequately alleged a scheme to add clinically inaccurate cachexia diagnoses to medical records, pointing to specific allegations of a coordinated effort in Northern California to "[f]ind $100 million dollars" by amending medical records to add cachexia diagnoses via addenda, which allegedly resulted in a diagnosis rate for cachexia that was "120 times" higher than in other Kaiser Permanente-affiliated regions. *Id.* In so holding, the Court also highlighted specific allegations about an internal audit showing that over 90 percent of cachexia diagnoses did not have support in the medical record. *Id.* at 14.

Because the complaint failed to include particularized allegations about a scheme to submit diagnosis codes for other medical conditions that members did not actually have, the Court dismissed the United States' claims for relief related to all other clinically inaccurate medical conditions. *Id.* at 14, 28. The Court granted the United States leave to amend its complaint to allege a systemic scheme to add clinically inaccurate diagnoses to medical records other than cachexia. *Id.* at 14.

C. The United States' Amended Complaint[6]

Rather than cure the complaint's deficiencies and add new allegations about a scheme to diagnose medical conditions that members did not have, the United States offers an entirely new theory of falsity: that Defendants submitted diagnosis codes to CMS for medical conditions that were "contradicted" by information in the medical record. *See, e.g.*, Dkt. No. 240 (First Amended Complaint ("FAC")) ¶ 131. In advancing this new theory, the amended complaint

[5] The Court did find that the United States adequately alleged FCA claims based on purported violations of certain diagnosis-coding guidance. *See* Order at 10, 28. As such, this Motion does not address any of those allegations in the amended complaint.

[6] For the Court's convenience, **Exhibit A** to the Declaration of Kyle M. Grossman includes a redline comparing the United States' amended complaint with the original complaint.

largely repeats the allegations of the original complaint with a few scattered additions.

The new allegations focus on purportedly flawed datamining algorithms that resulted in queries to healthcare providers about diagnoses that were contradicted by other information elsewhere in the members' medical records. *See, e.g.*, *id.* ¶ 141 ("These programs and their algorithms, however, often failed to properly account for inconsistent information, especially in the medical record for the visit at issue."). But the allegations under this new theory add no new examples of any specific diagnosis codes submitted to CMS resulting from these purportedly flawed algorithms. Of the many millions of diagnosis codes submitted during the relevant time period, the amended complaint adds only two specific examples of members who were diagnosed with malnutrition based on the purportedly flawed algorithms. *Id.* ¶¶ 175–76. One of these members was documented to be obese and "well nourished," and the other merely had "no clinical indicators" of malnutrition. *Id.* Elsewhere in the amended complaint, the United States describes multiple healthcare providers who received purportedly flawed queries yet made an accurate diagnosis based on their review of the medical record. *See id.* ¶¶ 220, 274, 309–11. Importantly, as with the original complaint, the amended complaint makes clear that the individual healthcare providers made the ultimate decision regarding whether to add a diagnosis to the medical record via addenda, not Defendants. *Compare* FAC ¶ 128 (explaining that physicians "add [] diagnoses to the patients' medical records using addenda"), *with* Dkt. No. 110 ¶ 123 (same). Nowhere does the United States allege that someone other than a healthcare provider added diagnoses to medical records.

III. LEGAL STANDARD

To survive dismissal under Federal Rule of Civil Procedure 12(b)(6), the amended complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This standard requires "more than a sheer possibility" that Defendants have acted unlawfully—the United States must plead "factual content that allows the court to draw the reasonable inference that [Defendants] [are] liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In evaluating plausibility, "courts must also consider an 'obvious alternative explanation' for [the] defendant's behavior." *Eclectic Props. E., LLC v.*

Marcus & Millichap Co., 751 F.3d 990, 996 (9th Cir. 2014) (quoting *Iqbal*, 556 U.S. at 682). Dismissal is proper where there is a "lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). While well-pleaded facts must be accepted as true, the Court need not "'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (citations omitted).

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

IV. ARGUMENT

Defendants' initial motion to dismiss emphasized that it was imperative for the Court to decide at the pleadings stage whether the United States can prosecute allegations of clinical falsity because discovery about such allegations will be broad and voluminous. And in ruling on the motion, the Court recognized that if such a theory were viable, it would "significantly expand[] the scope of the case." Order at 11. It remains no less imperative for the Court to scrutinize the new allegations here. If the United States may proceed to discovery on a broad clinical falsity theory against Defendants, the United States must prove the existence of a "contradiction" or nonexistent medical conditions in the medical records for each of the tens of thousands of Medicare Advantage members at issue. And Defendants will be entitled to discovery on the diagnostic judgment of each healthcare provider for each of the diagnosis codes put at issue by the United States as well as the clinical condition of each and every member. This massive documentary and testimonial record will require not only enormous fact discovery but also expert analysis of every single medical record in dispute.

The United States again fails to justify the enormous effort it will take to prove and defend

a case premised on a systemic scheme to diagnose members with medical conditions that do not exist. The United States supports its new theory with only two specific examples and bases it on the faulty premise that a diagnosis must necessarily be false when the patient's medical record contains information that conflicts with the diagnosis. The new allegations not only fail to allege three crucial elements of an FCA claim—falsity, knowledge, and materiality—but they also fail to allege an agreement to support the United States' FCA conspiracy claim. The Court should dismiss all claims for relief premised on these new allegations.

A. A Diagnosis Is Not Clinically False Simply Because the Patient's Medical Record Contains Information That May Be Inconsistent with the Diagnosis

Though the Court gave the United States leave to amend its complaint "to expand the scope of its allegations on ***clinically false diagnoses***," *id.* at 14 (emphasis added), the United States instead introduces a new theory: not that Defendants diagnosed medical conditions that members ***did not actually have***, but instead that diagnoses were "***contradicted by*** the patient's medical record." FAC ¶ 131 (emphasis added) (striking "did not even exist" and replacing with "were not current conditions and were contradicted by the patient's medical record").

These theories are distinct. When a member does not have the diagnosed medical condition, the associated diagnosis code is false on its face, regardless of what the medical record shows. Even if the diagnosis does not contradict any information in the medical record, it is still false because the member does not have the medical condition described by the diagnosis. Conversely, a contradiction between the diagnosis and information in the medical record does not on its own establish falsity. Where the medical record contradicts the diagnosis, the contradiction could suggest any number of innocuous things—for example, there may have been a change of medical circumstances or a simple typographical error in the record. Indeed, contradictory information in the medical record may be the best reason to query a healthcare provider to clarify which of the contradictory indicators should be credited for purposes of diagnosis coding. The query guidance document upon which the United States relies explicitly indicates that a query should be used "when the health record documentation [i]s ***conflicting***, imprecise, incomplete, illegible, ambiguous, or ***inconsistent***." Dkt. No. 179-1, Ex. H at 1 (emphases added).

Consider the example of a cancer diagnosis. Cancers are often active, go into remission, and then unfortunately may become active again. A note in the medical record that a patient has a "history of" cancer, for instance, technically "contradicts" an active cancer diagnosis, but it does not plausibly suggest that the patient in question does not have cancer or that the associated diagnosis is clinically false. Similarly, malnutrition is often associated with weight loss or a low weight, but a medical record of a patient with malnutrition may contain contradictory information about the patient's weight if that individual has varied in weight or if a patient's weight has been misrecorded in the record. Just because the patient may have experienced some weight variations does not mean that the patient does not have malnutrition if malnutrition is diagnosed by a healthcare provider.

That the United States now relies on allegations of "contradictory" information without pleading a systemic scheme by healthcare providers to diagnose medical conditions that did not actually exist strongly suggests that the facts obtained during its eight-year investigation would not support such a serious charge.

B. The New Allegations Do Not Adequately Allege Any FCA Violations

The FCA creates liability only for those who "knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval" to the U.S. government. 31 U.S.C. § 3729(a)(1). The FCA is not "an all-purpose antifraud statute." *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). FCA liability is appropriate only where "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016). The amended complaint's new allegations fail to allege the key elements of an FCA claim: falsity, knowledge, and materiality.

1. The United States Fails to Plead Clinical Falsity

The United States' new allegations fail to plead a plausible scheme by Defendants to submit clinically inaccurate diagnosis codes to CMS. "Evidence of an actual false claim is the *sine qua non* of a False Claims Act violation." *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002) (quotations omitted). "The FCA does not

define false. Rather, courts decide whether a claim is false or fraudulent by determining whether a defendant's representations are accurate in light of applicable law." *United States v. Bourseau*, 531 F.3d 1159, 1164 (9th Cir. 2008). FCA claims must be pleaded with the particularity required by Rule 9(b), so the falsity allegations must give a defendant "notice of the particular misconduct which is alleged to constitute the fraud charged" and "supply reasonable indicia that false claims were actually submitted." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010) (quotations omitted).

The amended complaint's new allegations fail to establish clinical falsity for two reasons. First, the United States' new theory of falsity is not a theory of clinical falsity at all because it is not reasonable to infer that a "contradiction" between a diagnosis and information in the medical record necessarily supports the conclusion that the patient does not have the diagnosed condition. Second, the United States has failed to plausibly allege with specific facts a systemic ***scheme*** by thousands of healthcare providers to falsely diagnose their patients with medical conditions that do not actually exist or even medical conditions contradicted by the medical record.

a. The United States Does Not Allege a Plausible Theory of Clinical Falsity

The United States now alleges that Defendants violated the FCA by submitting diagnosis codes to CMS that were "contradicted" by the members' medical records, *see, e.g.*, FAC ¶¶ 1, 9, but this theory is not a plausible theory of clinical falsity.

For starters, it is not a theory of falsity at all. By focusing its new allegations on "contradictions" in medical records rather than on medical conditions that did not exist, the United States would have the Court believe that all the United States must do to prove falsity under the FCA is show a contradiction in the medical record. *See, e.g.*, *id.* ¶ 1 (contending that Defendants "could not lawfully submit diagnoses that were . . . contradicted by the patient's medical record[]"). That cannot be true as a matter of common sense for all of the reasons explained above. And the amended complaint cites no statute, regulation, or other binding guidance that prohibits Medicare Advantage Organizations from submitting diagnosis codes that are contradicted in some way by some other information in the medical record. Such a limitation

would be impractical and would create perverse incentives: an error in the medical record or a change in the member's health conditions would prevent Medicare Advantage Organizations from submitting diagnosis codes for valid and truthful medical conditions. It could also change the practice of care for the worse, as healthcare providers would be hesitant to document potentially important clinical observations for fear that they could be construed as inconsistent with diagnoses in the medical record and lead to fraud charges against themselves or their employers.

To the extent the United States suggests that a "contradiction" is ***indicative of*** clinical falsity, rather than a theory of fraud itself, then the United States has not plausibly alleged clinical falsity for similar reasons—specifically, it has not ruled out plausible nonfraudulent explanations for the contradiction. "When faced with two possible explanations, only one of which can be true and only one of which results in liability, plaintiffs cannot offer allegations that are merely consistent with their favored explanation but are also consistent with the alternative explanation. ***Something more is needed***, such as facts tending to exclude the possibility that the alternative explanation is true, in order to render plaintiffs' allegations plausible." *In re Century Aluminum Co. Secs. Litig.*, 729 F.3d 1104, 1108 (9th Cir. 2013) (emphasis added) (quotations omitted). In the FCA context, the Ninth Circuit has held that it could not infer that a relator satisfied the falsity element where the relator failed to rule out the "'obvious alternative explanation' that no false claims occurred." *Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1057 (9th Cir. 2011) ("In light of [relator's] failure to identify any particular false claims or their attendant circumstances, as well as the 'obvious alternative explanation' that no false claims occurred, we will not draw the unwarranted and implausible inference that discovery will reveal evidence of such false claims.").

Here, the Court cannot plausibly infer that a diagnosis is clinically false merely because the corresponding medical record contains some "contradictory" information. As noted, there are many inferences the Court can draw on an apparent contradiction between the medical record and a diagnosis—for example, that there was an error in the medical record, a change in the member's medical condition, or an inaccurate diagnosis code. Depending on the specific factual

circumstances, it ***may*** be appropriate in ***some*** situations to infer that the diagnosis code is clinically inaccurate. But in many situations, such an inference would be unreasonable and the contradiction on its own does "not rule out [the] obvious alternative explanation[s]." *Integra Med Analytics LLC v. Providence Health & Servs.*, 854 F. App'x 840, 844–45 (9th Cir. 2021) ("Integra offers only a *possible* explanation—that doctors lied about underlying medical conditions—to explain a statistical trend that is consistent with a plausible alternative (and legal) explanation. . . . We need not accept the conclusion that defendant engaged in unlawful conduct when its actions are in line with lawful rational and competitive business strategy." (emphasis in original; quotations omitted)). Indeed, the healthcare provider's assignment of the diagnosis is one of the most important parts of the medical record. If there is a contradiction between the diagnosis and, say, a bodyweight measurement, the plausible inference would be that the measurement is wrong, not that the diagnosis is clinically wrong.

Consider the example of an obesity diagnosis where the member's weight was recorded in the medical record as 113 pounds, but the member was in fact 311 pounds. If the facts show that the member had been diagnosed with obesity in seven separate encounters with three different healthcare providers, it would be unreasonable to infer that the obesity diagnosis was inaccurate. The nonfraudulent inference—that the entry of 113 pounds was an error—is far more reasonable than the inference that the diagnosis itself was false. And if it is the case that the diagnosis was correct, then the medical record does not contain a clinically false diagnosis, even if the record does have some other inaccurate detail. COVID-19 is not a risk-adjusting medical condition, but it shows how changes in a member's health over time may create apparent contradictions that are not indicative of clinical falsity. A note in the medical record that a member had recovered from COVID-19 followed by a diagnosis of COVID-19 does not standing alone support the inference that the later-in-time diagnosis was false. The nonfraudulent inference is much stronger: the member had COVID-19 a second time. In both examples, and many more like them, the contradiction alone would not suffice to rule out the plausible, nonfraudulent alternative inferences. But the United States has failed to consider and plead that there is no nonfraudulent explanation for the alleged "contradictions," and as such, its new falsity theory must fail under

well-established pleading standards in the Ninth Circuit. *See id.*; *Century Aluminum*, 729 F.3d at 1108; *Cafasso*, 637 F.3d at 1057.

These examples illustrate another fundamental problem with the United States' generalized allegations of "contradictions": without more specific factual allegations about how the medical record contradicts a contested diagnosis, Defendants cannot begin to determine which diagnosis codes fall within the scope of the amended complaint. *See Bly-Magee*, 236 F.3d at 1019 (allegations of fraud must be specific enough to give "notice of the particular misconduct which is alleged" (quotations omitted)). Does the United States' new theory include those medical conditions that can be cured and then reappear? How far back in time must the contradiction exist between the diagnosed condition and the medical record? Would a diagnosis for obesity be false if a low weight had been documented a year before? Five years before? Medical records and clinical diagnoses are not static; they change over time with the health of the member. So if the United States intended to assert FCA claims based on the submission of clinically false diagnosis codes, it was obligated to explain with specificity what it meant by "contradiction" and how the "contradiction" supports the inference of falsity for each specific alleged diagnosis. *See Ebeid*, 616 F.3d at 998 (plaintiff must plead with particularity "the who, what, when, where, and how of the misconduct" and "set forth what is false or misleading about a statement, and why it is false" (quotations omitted)). Broad, generalized assertions that different diagnoses "contradicted" the medical record will not suffice under Rules 8 and 9(b).[7]

b. The United States Again Fails to Allege a Systemic Scheme

The United States' new allegations fall flat for another reason: they do not show the existence of a ***scheme*** to defraud the Medicare Advantage program. The amended complaint adds three categories of allegations: (1) assertions of "flaws" in datamining algorithms that resulted in coding queries to healthcare providers about risk-adjusting medical conditions that had

[7] While the Court previously concluded that allegations about contradictory information in medical records supported an inference that members did not have cachexia, *see* Order at 14, the Court did not hold that an allegation of a contradiction standing on its own sufficiently alleged clinical falsity. Rather, the Court reached its conclusion in the context of other specific factual allegations about efforts to diagnose cachexia in Northern California. *See id.* at 12–13.

not previously been recorded by the providers; (2) allegations of clinically inaccurate malnutrition diagnoses for two members; and (3) complaints from healthcare providers who disagreed with the applicability of specific queries regarding the medical conditions of certain members. None of these allegations, even when accepted as true on a motion to dismiss, supports the inference that Defendants and the thousands of healthcare providers affiliated with them embarked on a systemic scheme to diagnose clinically inaccurate medical conditions that were later submitted to CMS.

Algorithm Flaws. The United States alleges that the datamining algorithms that Defendants used to generate coding queries to healthcare providers were flawed, but the allegations do not plausibly suggest that Defendants submitted clinically inaccurate diagnosis codes to CMS on a systemic basis. Specifically, in two new paragraphs, the United States alleges that: (1) where a member was previously overweight but had lost weight, the algorithm would continue to suggest obesity-related diagnoses for queries to healthcare providers; and (2) Defendants often generated the queries early in the year and, therefore, the queries did not always reflect the most up-to-date information on the medical condition of the member. FAC ¶¶ 141–42. But as the amended complaint makes clear, a query is not a diagnosis submission to CMS. It is merely "a communication tool used to clarify documentation in the health record." *Id.* ¶ 10.[8] The amended complaint contains no allegations, much less particularized facts, that a diagnosis suggested in a query is automatically added to the medical record; only a healthcare provider can do so. *See id.* ¶¶ 10, 135, 137. A healthcare provider's professional judgment separates a query from a diagnosis, so a flawed query does not necessarily equate to a flawed diagnosis. For this reason, the Ninth Circuit has found that the allegation that a provider's "staff incentivized doctors to use language conducive to coding higher-paying secondary diagnoses through their documentation tips and queries" cannot alone support the conclusion "that doctors recorded unsupported medical conditions." *Integra*, 854 F. App'x at 844. And the amended complaint lacks any factual allegations suggesting any scheme to rely on algorithms to addend

[8] Defendants do not necessarily agree with this characterization of the term "query," but accept the allegation as true for purposes of this Motion.

medical conditions to medical records without the healthcare provider first reviewing the query and then exercising professional judgment to add the diagnosis. To the contrary, the United States' allegations repeatedly affirm that the healthcare providers recorded the contested diagnoses in the addenda—not the algorithms. FAC ¶¶ 221, 225, 285, 288, 363.

Malnutrition Examples. The United States also adds just two examples of members diagnosed with malnutrition despite clinical indicators that the members did not have malnutrition. *Id.* ¶¶ 175–76. But the United States fails to allege when these diagnoses were recorded or in what region, blatantly ignoring Rule 9(b)'s requirement to allege the "when" and "where" of the purported fraud. Moreover, as the Court previously concluded, isolated examples of diagnoses that contradict the medical record do not support the inference of a widespread scheme to falsify diagnoses. Order at 14 ("Identifying scattered anecdotes alone will not suffice."). A contradiction between the medical record and the diagnosis—even one that results in a clinically false diagnosis—is not evidence of a widespread scheme to defraud. That is particularly true of these two examples, both of which focus on malnutrition rather than on a range of medical conditions. Notably, cachexia is a "complex metabolic syndrome" that results in "loss of muscle and physical wasting," meaning that it results in weight loss due to undernourishment. FAC ¶ 224. Thus, the United States has barely departed from its original cachexia allegations with these two new examples.

The amended complaint asserts claims for relief against multiple Defendants across two states over the course of more than a decade implicating tens of thousands—potentially millions—of individual members. The United States must do far more than cite two standalone diagnoses of the ***same medical condition*** that themselves do not clear Rule 9(b)'s hurdles to support allegations of a wide-ranging scheme to defraud the Medicare Advantage program.

Healthcare Providers Responding Accurately to Queries. Finally, the United States adds several anecdotes about healthcare providers receiving queries, relying on their own professional judgment, and responding accurately to the queries. Again, these allegations do not show any scheme to diagnose medical conditions that "contradict" information in the medical record, let alone a scheme to diagnose conditions that do not exist.

The United States alleges that a healthcare provider received a query related to whether a member had thrombocytopenia (*i.e.*, a medical condition related to low blood-platelet count) and then noted in the medical record that the member had a history of thrombocytopenia. *Id.* ¶ 220. The United States makes no allegations that the healthcare provider's notes were inaccurate or that they contradicted anything in the medical record. *Id.* To the contrary, the amended complaint alleges that the healthcare provider's diagnosis was accurate and asserts that Defendants incorrectly submitted a diagnosis code for active thrombocytopenia when the correct diagnosis was history of thrombocytopenia. *Id.* This is the only example the United States provides where Defendants allegedly submitted a diagnosis code for a medical condition that was not diagnosed by a healthcare provider. Such allegations do not support the inference of a systemic ***scheme*** to diagnose clinically inaccurate medical conditions. Quite the opposite: They show that this healthcare provider relied on her own professional judgment to diagnose the member's medical condition and the amended complaint credits the provider's diagnosis as accurate. At most, these allegations show that in this one instance an incorrect diagnosis code was submitted to CMS, for reasons that are not alleged, where the code was inconsistent with the clinical diagnosis recorded by the provider. But, even when accepted as true, the submission of a single erroneous diagnosis code to CMS is not evidence of a widespread scheme to diagnose medical conditions that contradict the medical record or that do not exist.

The United States also alleges that a healthcare provider "complained" about being prompted to add a diagnosis of aortic atherosclerosis, *id.* ¶ 274, but this allegation also fails to establish a scheme to submit nonexistent diagnoses to CMS. The allegation says nothing about any diagnosis that was assigned by the provider or submitted to CMS. The United States alleges that the healthcare provider disagreed with the suggested diagnosis, *see id.*, but does not allege that Defendants either submitted the diagnosis anyway or somehow forced the healthcare provider to make the objectionable diagnosis. Again, if anything, this allegation shows that healthcare providers applied their independent professional judgment to determine whether a diagnosis was appropriate after receiving a coding query. Such an allegation can hardly be said to support the new theory advanced by the United States in the amended complaint.

The United States similarly describes a handful of other healthcare providers who received queries with which they disagreed and about which they complained, *id.* ¶¶ 310–11; but, again, the amended complaint lacks any allegations that the providers recorded the objectionable diagnoses in the medical records or that Defendants submitted those diagnoses to CMS over the objections of the providers. Instead, these examples show what healthcare providers typically do in response to all queries: review the suggested diagnosis, assess the member's existing medical record and the provider's own recollection of the encounter, and apply professional judgment to determine whether to add the diagnosis code to the medical record. These allegations illustrate precisely why the Court cannot plausibly infer that Defendants submitted clinically inaccurate diagnosis codes based on the mere identification of a flaw in a datamining algorithm or resultant query.

Finally, the contrast between the amended complaint's new allegations and the cachexia allegations that the Court previously found sufficient to allege clinical falsity demonstrates that the new allegations are lacking. The cachexia allegations are far more specific. The United States identified a specific initiative at TPMG with a specific monetary goal, compared the rate of cachexia diagnoses at TPMG with other regions, and alleged the diagnosis rate was "120 times" higher at TPMG. *See* FAC ¶¶ 315–21, 348 (emphasis removed). The Court concluded that these allegations, ***combined with*** allegations of a contradiction between the cachexia diagnoses and the member's medical record, supported the inference of a scheme to submit clinically inaccurate cachexia diagnoses. Order at 13–14. But the new allegations offer no similar specificity and fail to support the inference that there were any similar initiatives for other medical conditions and by Defendants outside of Northern California.[9]

2. The United States Fails to Plead Knowledge

The amended complaint also fails to establish FCA liability because the United States adds no allegations showing that Defendants acted "knowingly" in the submission to CMS of

[9] The United States' conclusory assertion that its cachexia allegations are "emblematic" of a larger scheme, FAC ¶ 314, do not suffice given that Rule 9(b) requires the United States to plead the specific facts of the alleged fraud.

diagnosis codes for medical conditions that did not actually exist or even that "contradicted" the members' medical records. FCA liability does not attach to every false claim for payment. The United States must allege that Defendants acted with the requisite scienter: that they had "actual knowledge" that the diagnosed medical conditions did not exist or at least that the diagnosis codes contradicted the medical record, "act[ed] in deliberate ignorance of" that fact, or "act[ed] in reckless disregard of" that fact. 31 U.S.C. § 3729(b)(1). The scienter element is "critical" to establishing liability under the FCA. *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998). And the required showing is "rigorous." *Escobar*, 579 U.S. at 192. While knowledge can be alleged generally in the pleadings, an FCA plaintiff must identify some "facts" that "support [the] conclusory allegation that defendants knowingly submitted false claims." *United States ex rel. Modglin v. DJO Glob. Inc.*, 48 F. Supp. 3d 1362, 1405 (C.D. Cal. 2014), *aff'd sub nom. United States v. DJO Glob., Inc.*, 678 F. App'x 594 (9th Cir. 2017).

The United States attempts to allege knowledge with references to (i) certain of the Defendants' internal documents and (ii) audits conducted by certain Defendants. Both categories of allegations fall short. First, the United States alleges that "[i]nternal documents indicate that Kaiser was aware that its risk adjustment initiatives were generating inaccurate diagnoses, including identifying, for example, that refresh reports would ask for a diagnosis to be refreshed even though it was only captured as a history of the condition." FAC ¶ 178. As explained *supra* at 14–15, however, asking a healthcare provider whether a diagnosis should be added to the medical record is not equivalent to submitting that same diagnosis to CMS, and it certainly says nothing about the individual healthcare provider's conduct or exercise of independent professional judgment to record the diagnosis in question. Without more facts supporting the inference that Defendants knew this purported flaw in the refresh process carried through to submissions of specific false diagnosis codes to CMS, an allegation about potential problems with a refresh report does not show actual knowledge of, deliberate indifference to, or reckless disregard of the submission of clinically false diagnoses. That is particularly true where, as here, other allegations show that problems with queries and refresh lists did not carry over to the CMS submissions themselves, such as allegations that healthcare providers rejected diagnoses

suggested in queries that they thought were not clinically supported. *See supra* 15–17; FAC ¶¶ 220, 274, 310–11. In other words, knowing that an algorithm would result in a query asking a healthcare provider about refreshing a diagnosis that is no longer active is in no way equivalent to knowing that licensed and trained healthcare providers ***diagnosed*** conditions that were no longer active or that those additional diagnosis codes were actually submitted to CMS. Asking healthcare providers about the applicability of a certain diagnosis, even if the query is flawed, is simply not a false claim to CMS.

Second, the new audit allegations similarly do not assert that Defendants had knowledge of a systemic scheme to submit clinically false diagnosis codes to CMS, or even diagnosis codes that were "contradicted" by the medical record. The United States focuses on an internal audit of addended diagnoses in 2015, but acknowledges that the audit "did not expressly categorize diagnoses where the medical record contradicted the existence of the condition." FAC ¶ 337. The United States alleges that the auditors identified a single medical condition—morbid obesity—that was diagnosed despite body mass index measurements that were "inconsistent" with the diagnosis. *Id.* The audit categorized these errors as "No link in encounter." *Id.* The United States does not allege that the members at issue ***did not have*** morbid obesity. It is not reasonable to infer that Defendants would be on notice that healthcare providers were diagnosing medical conditions that members did not have based solely on audit results suggesting there was no link in the encounter. As the United States' complaint shows, "no link in encounter" could indicate any number of potential issues other than a nonexistent medical condition, including perceived non-compliance with certain coding provisions, such as the ICD Guidelines.

And while the United States asserts that auditors found "contradictions" in Northern California medical records in another audit from 2016, for all the reasons explained *supra* at 8–9, such a finding would not reasonably put anyone on notice that the contradictions corresponded to medical conditions that did not actually exist as a clinical matter—particularly where the United States fails to allege any facts about what these contradictions were, how that information was communicated, or what medical conditions were found to be contradicted by the medical record.

3. The United States Fails to Plead Materiality

The Court must dismiss the United States' newly added allegations for a separate reason: they fail to allege that CMS would have refused risk-adjusted payments to Defendants for diagnosis codes merely because of a "contradiction" in the medical records associated with those diagnosis codes. The FCA's "materiality standard is demanding," *Escobar*, 579 U.S. at 194, and the FCA includes "a heightened standard for pleading materiality," *United States v. Costar Corp.*, 308 F. Supp. 3d 56, 85 (D.D.C. 2018). The Supreme Court has rejected the view that "any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation." *Escobar*, 579 U.S. at 195. "[M]ateriality is satisfied . . . only where compliance is 'a *sine qua non* of receipt of state funding.'" *Ebeid*, 616 F.3d at 998 (citations omitted). "[M]ateriality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 579 U.S. at 193 (quotations omitted).

In the Medicare Advantage context, courts in the Ninth Circuit have dismissed the United States' FCA claims where the United States has failed to allege "that CMS would have refused to make risk adjustment payments if it had known [that the alleged claims] were false." *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, 2018 WL 1363487, at *10 (C.D. Cal. Feb. 12, 2018); *see also United States v. Scan Health Plan* ("*Swoben II*"), 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017) (holding that United States failed to plead materiality where it did not plead "that [CMS] would not have paid these claims had it known of these violations" (quotations omitted)). Because the United States appears to allege that Defendants violated the FCA by submitting diagnoses that contradict the medical record—regardless of whether the member has the diagnosed condition—the United States must allege that CMS would have refused to make risk-adjustment payments had it known about the alleged contradictions in the medical records.

The United States does not plead facts supporting an inference of materiality.[10] Nowhere

[10] In their initial motion to dismiss, Defendants did not advance a materiality challenge against the United States' FCA claims about the submission of clinically inaccurate diagnosis codes. *See* Dkt. No. 178 at 18–20. Defendants agree that CMS would not pay Defendants based on

does the United States allege that CMS would have declined to pay for any diagnosis code that is merely "contradicted" by some information somewhere in the medical record. *See Poehling*, 2018 WL 1363487, at *10; *Swoben II*, 2017 WL 4564722, at *6. And there is good reason to infer that CMS would not deny payment on that basis alone: a mere contradiction could be evidence of an error in the medical record unrelated to the diagnosis itself or a change in the patient's medical condition. *See supra* at 8–9. Without allegations to the contrary, the Court cannot plausibly infer that CMS would necessarily deny payment whenever there is an error in the medical record or a member experiences a change in medical circumstances.

C. The United States Fails to Allege an Agreement Among Defendants to Support Its FCA Conspiracy Claim

The amended complaint also does not sufficiently allege an FCA conspiracy claim against Defendants. A conclusory allegation that Defendants "conspired" with one another does not support an FCA conspiracy claim if it is "unsupported by specific allegations of any agreement or overt act." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005); *United States v. Toyobo Co.*, 811 F. Supp. 2d 37, 50–51 (D.D.C. 2011) (dismissing FCA conspiracy claim against certain defendants where complaint lacked factual allegations supporting the inference that the alleged conspirators had entered into any agreements for the purpose of getting the government to pay a claim). The amended complaint alleges in conclusory fashion that the two health plan Defendants "conspired with" the three medical group Defendants, FAC ¶¶ 386–88, but it does not contain specific facts that would support a plausible inference that the health plan Defendants and medical group Defendants had an agreement to submit diagnosis codes to CMS for medical conditions that did not exist or even just diagnoses that were contradicted by some information in the medical record.

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diagnosis codes for a nonexistent condition. *See* Dkt. No. 203 at 12. However, because the United States' new allegations focus on "contradictory" information in the medical record rather than diagnoses for medical conditions that do not exist, the new allegations are properly subject to a materiality challenge under *Escobar*. If the United States' theory is instead that the contradictions are merely evidence that Defendants submitted clinically inaccurate diagnosis codes to CMS, then, as explained above, this theory fails because the United States has not pleaded falsity or knowledge. *See supra* at 10–19.

D. The United States' Clinical Falsity Theory Does Not Apply to KFHP-CO, CPMG, and SCPMG

In the event that the Court concludes that the amended complaint sufficiently alleges a knowing and material fraud, the Court should not allow the United States to proceed on its clinical falsity theory against all five Defendants. In asserting this theory, the United States largely fails to differentiate among Defendants—which comprise both health plans and medical groups spanning two states—and does not include sufficiently specific allegations about KFHP-CO, CPMG, and SCPMG. At the very least, the Court should limit the United States' new falsity theory to claims for relief against KFHP and TPMG only.

Rule 9(b) "does not allow a complaint to merely lump multiple defendants together." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007). Plaintiffs must "differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding [its] alleged participation in the fraud." *United States v. United Healthcare Ins. Co.* ("*Swoben*"), 848 F.3d 1161, 1184 (9th Cir. 2016) (quotations omitted). While courts do allow collective allegations where each defendant has an identical role and functions in the exact same manner, collective allegations are not permitted where the defendants presumably did not engage in the exact same conduct. *See Hausauer v. City of Mesa*, 2020 WL 2735970, at *3 (D. Ariz. May 26, 2020) (dismissing claims where plaintiff "repeatedly lumps [defendants] together as a collective whole" although defendants "presumably did not each engage in the exact same conduct").

Here, the amended complaint's new allegations do not sufficiently allege that the health plan Defendant KFHP-CO or the medical group Defendants CPMG and SCPMG engaged in a knowing scheme to diagnose members with medical conditions that did not exist and then send corresponding diagnosis codes to CMS. The amended complaint's new allegations generally attribute conduct to "Kaiser," which is defined to include all five Defendants, and does not distinguish between the defendants, even though the Defendants had different roles in the healthcare system and operated in different geographic regions. *See* FAC at 1 (defining "Kaiser"); *see id.* ¶¶ 2 (alleging that "***Kaiser*** falsely submitted diagnosis codes for conditions that

the patient did not actually have"), 10 (alleging that "***Kaiser*** would query physicians to add conditions whose existence at the time was contradicted by the medical record") (emphases added).[11]

But virtually none of the new allegations refers to a specific Defendant's conduct in Colorado or Southern California, and thus do not implicate KFHP-CO, CPMG, or SCPMG. Where the new allegations do refer to a particular defendant, they typically reference KFHP or TPMG. For instance, in the new allegation about the thrombocytopenia diagnosis, the United States alleges that the "Health Plan"—*i.e.*, KFHP—submitted a diagnosis code for thrombocytopenia despite a TPMG healthcare provider noting that the patient had a history of the medical condition. *Id.* ¶ 220. Similarly, the new malnutrition examples focus on how ***KFHP*** "submitted the diagnosis code for malnutrition and received a risk-adjustment payment." *Id.* ¶¶ 175–76. Other allegations criticize prompts that ***TPMG*** sent to providers. *See id.* ¶ 308. Even the cachexia allegations that did pass muster in the original complaint only concerned conduct in ***Northern California***—not in Colorado or Southern California. *See id.* ¶¶ 315–21, 348. In fact, the amended complaint alleges that the cachexia addenda rates in Southern California and Colorado were significantly smaller than in Northern California because Southern California and Colorado did not have a similar initiative. *Id.* ¶ 321 ("[P]hysicians 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." (emphasis removed)).

E. The Court Should Deny Leave to Amend

Finally, the Court should not permit leave to amend. A "district court may exercise its discretion to deny leave to amend due to . . . repeated failure to cure deficiencies by amendments previously allowed[.]" *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892 (9th Cir. 2010)

[11] *See also, e.g.*, *id.* ¶¶ 134 (alleging that "***Kaiser*** generated [missed-opportunity] lists without accounting for contradictory information in the medical record of the visit"), 137 (alleging that "***Kaiser's*** risk-adjustment initiatives often . . . fail[ed] to properly account for contradictory information in a patient's medical file"), 141 (alleging that "***Kaiser's*** programs many times would identify obesity-related diagnoses for the patient notwithstanding that the patient had lost weight") (emphases added).

(quotations omitted). The United States' repeated failure to adequately allege its theory of clinical falsity despite an eight-year investigation into Defendants' Medicare Advantage risk-adjustment practices warrants dismissal of the new allegations with prejudice. The United States has access to millions of pages of Defendants' internal documents and audits along with members' medical records and diagnoses codes submitted by Defendants to CMS. In other words, it has all the information it would need to amend its factual allegations and adequately plead a fraudulent scheme whereby thousands of individual healthcare providers diagnosed Medicare Advantage members with medical conditions that did not exist and then KFHP and KFHP-CO submitted those clinically false diagnoses codes to CMS. Yet the United States has now twice failed to allege a systemic scheme by Defendants to diagnose conditions that do not exist. Such a repeated failure "is a strong indication that the [United States has] no additional facts to plead." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1007 (9th Cir. 2009) (quotations omitted).

V. CONCLUSION

For the foregoing reasons, the Court should grant the Motion and dismiss all claims for relief premised on the new allegations in the amended complaint. The Court should not permit the United States to proceed on either a theory of fraud based on "contradictions" in the medical record, or a systemic scheme to diagnose clinically false diagnoses other than cachexia in Northern California.

Dated: February 2, 2023

Respectfully submitted,

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

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. RONDA OSINEK,

Plaintiff,

v.

KAISER PERMANENTE, et al.,

Defendants.

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

DECLARATION OF KYLE M. GROSSMAN IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-INTERVENTION

Hearing Date: May 4, 2023
Time: 1:30 PM
Judge: Hon. Edward M. Chen
Courtroom: 5, 17th Floor

(CAPTION CONTINUED)

UNITED STATES OF AMERICA ex rel. GLORYANNE BRYANT and VICTORIA HERNANDEZ, Plaintiff, v. KAISER PERMANENTE, et al., Defendants.	Case No. 3:18-cv-01347-EMC **DECLARATION OF KYLE M. GROSSMAN IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-INTERVENTION** 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, Plaintiff, v. KAISER PERMANENTE, et al., Defendants.	Case No. 3:21-cv-03894-EMC **DECLARATION OF KYLE M. GROSSMAN IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS UNITED STATES' FIRST AMENDED COMPLAINT-IN-INTERVENTION** Hearing Date: May 4, 2023 Time: 1:30 PM Judge: Hon. Edward M. Chen Courtroom: 5, 17th Floor

I, Kyle M. Grossman, hereby declare and state as follows:

I am an active member in good standing of the State Bar of California. I am a counsel at O'Melveny & Myers LLP, counsel of record for Kaiser Foundation Health Plan; Kaiser Foundation Health Plan of Colorado; The Permanente Medical Group; Southern California Permanente Medical Group; and Colorado Permanente Medical Group (collectively, "Defendants"). I submit this declaration in support of Defendants' Motion to Dismiss United States' First Amended Complaint-in-Intervention. This declaration is based upon my personal knowledge and, if called as a witness, I could and would testify to the matters set forth below.

1. Attached hereto as **Exhibit A** is a true and correct copy of the redline created by comparing the text of United States' Complaint-in-Intervention (Dkt. No. 110) with the text of United States' First Amended Complaint-in-Intervention (Dkt. No. 240) using the Change-Pro software program.

2. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

EXECUTED this 2nd day of February, 2023.

Kyle M. Grossman
Kyle M. Grossman

Exhibit A

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. RONDA OSINEK, Plaintiff, v. KAISER PERMANENTE, et al., Defendants~~.~~	Case No. 3:13-cv-03891-EMC UNITED STATES' ~~COMPLAINT-IN-INTERVENTION~~AMENDED COMPLAINT- IN-INTERVENTION

(captions continued on next page)

UNITED STATES OF AMERICA ex rel. NASER AREFI, AJITH KUMAR, and PRIME HEALTHCARE SERVICES, Plaintiffs, v. KAISER FOUNDATION HEALTH PLAN, INC., et al., Defendants.	Case No. 3:16-cv-01558-EMC UNITED STATES' ~~COMPLAINT-IN-INTERVENTION~~AMENDED COMPLAINT- IN-INTERVENTION

UNITED STATES OF AMERICA ex rel. MARCIA STEIN AND RODOLFO BONE, Plaintiffs, v. KAISER FOUNDATION HEALTH PLAN, INC., et al., Defendants.	Case No. 3:16-cv-05337-EMC UNITED STATES' ~~COMPLAINT-IN-INTERVENTION~~AMENDED COMPLAINT- IN-INTERVENTION

UNITED STATES OF AMERICA and STATE OF CALIFORNIA ex rel. GLORYANNE BRYANT and VICTORIA M. HERNANDEZ, Plaintiffs, v. KAISER PERMANENTE, INC., et al., Defendants.	Case No. 3:18-cv-01347-EMC UNITED STATES' ~~COMPLAINT-IN-INTERVENTION~~AMENDED COMPLAINT- IN-INTERVENTION

(captions continued on next page)

UNITED STATES OF AMERICA and STATE OF CALIFORNIA ex rel. MICHAEL BICOCCA, Plaintiff, v. PERMANENTE MEDICAL GROUP, INC., et al., Defendants.	Case No. 3:21-cv-03124-EMC UNITED STATES' ~~COMPLAINT-IN-INTERVENTION~~AMENDED COMPLAINT- IN-INTERVENTION

UNITED STATES OF AMERICA ex rel. JAMES M. TAYLOR, Plaintiff, v. KAISER PERMANENTE, INC., et al., Defendants.	Case No. 3:21-cv-03894-EMC UNITED STATES' ~~COMPLAINT-IN-INTERVENTION~~AMENDED COMPLAINT- IN-INTERVENTION

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The United States of America ("United States" or "Government") brings this action against Defendants Kaiser Foundation Health Plan, Inc., Kaiser Foundation Health Plan of Colorado, The Permanente Medical Group, Inc., Southern California Permanente Medical Group, and Colorado Permanente Medical Group, P.C. (collectively, "Kaiser" or "Defendants"), to recover treble damages and civil penalties for violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and conspiracy to violate the FCA, and damages and other relief for common law claims of payment by mistake and unjust enrichment. Having filed a notice of intervention pursuant to 31 U.S.C. § 3730(b)(4)(A), the United States alleges for its amended complaint-in-intervention ("Amended Complaint") as follows:

I. PRELIMINARY STATEMENT

1. Beginning sometime prior to 2009 and continuing through at least 2018, Kaiser engaged in a widespread coordinated scheme to unlawfully obtain payments from the Medicare Part C program, also called Medicare Advantage. ~~Kaiser obtained these payments~~The allegations in this Amended Complaint concern Kaiser's efforts to increase its Medicare revenue by systematically ~~altering patient medical records~~pressuring its physicians to add diagnoses that ~~either~~ did not ~~exist or 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,~~ appear in the original visit note. Kaiser mined Medicare Advantage patient medical files for potential additional diagnoses. Kaiser then pressed its physicians to add the diagnoses to medical records retrospectively using an addendum to make it appear as if the conditions had been addressed in some way during the patient visit when in fact they had not. Kaiser engaged in this scheme regardless of whether the conditions had any relevance to the visit and even where the medical record for the visit contradicted the existence of the conditions. Kaiser pressured physicians to create these addenda ~~were added~~often 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, much less diagnoses contradicted by the patient's medical records, 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.

2. Kaiser's scheme led directly to the widespread submission of inaccurate diagnosis codes that were false in two related and overlapping ways—both of which resulted from the scheme's failure to account for what actually occurred at the patient visit. First, Kaiser falsely submitted diagnosis codes for conditions that were unrelated to the visit—i.e., for conditions that did not require or affect patient care, treatment, or management, as required by the International Classification of Diseases ("ICD") Official Guidelines for Coding and Reporting (the "ICD Guidelines"). Second, Kaiser falsely submitted diagnosis codes for conditions that the patient did not actually have at the time of the visit, as the existence of the conditions was contradicted by the medical record. The driver of Kaiser's scheme was money: Kaiser submitted these improper diagnosis codes in order to receive a risk-adjustment payment. Indeed, Kaiser's scheme focused on diagnoses and patients for whom Kaiser could receive a risk- adjustment payment. See infra ¶¶ 126-39.

~~2~~3. As Medicare Advantage ("MA") Organizations, Kaiser's Health Plans were responsible for covering the costs of medical services for the Medicare patients enrolled in Kaiser's MA plans. Kaiser's Health Plans, in return, received monthly payments from CMS for each patient for whom Kaiser provided such coverage. 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. To make these adjustments, CMS relies on "risk adjustment" data, including medical diagnosis codes, collected from MA Organizations. This payment model creates powerful incentives for MA Organizations like Kaiser's Health Plans to exaggerate the expected healthcare costs for their enrollees by "over-reporting" diagnosis codes. See infra ¶¶ ~~20-22, 52-72.~~22-24, 54-74. Misrepresentations affecting risk- adjustment payments have a substantial financial effect on the Medicare Advantage program.

~~3~~4. Kaiser knew that, pursuant to this risk-adjustment system, the amount of payment that CMS made to Kaiser for a Medicare Advantage patient depended directly on the diagnoses that Kaiser submitted to CMS for that patient. In fact, internally, executives repeatedly stressed the importance of these risk-adjustment payments to the financial health of Kaiser, emphasizing that "risk adjustment is by far the biggest lever we have to change our revenue from Medicare. If we don't do this well, our financial health could be seriously impacted." Kaiser touted that its structure gave it a strategic advantage over other health plans in obtaining risk-adjustment revenue because Kaiser's health plans were integrated with its physician groups "under one roof" and coordinated with each other. Kaiser's risk-adjustment programs were highly successful at achieving Kaiser's goal of increasing Medicare Advantage risk-adjustment revenue. See infra ¶¶ ~~28-40, 100-20~~30-42, 105-25.

~~4. The allegations in this complaint concern one of the ways that Kaiser increased its diagnoses and therefore its risk-adjustment revenue—by systematically creating retrospective addenda to medical records of patients' visits with physicians. Kaiser would mine a Medicare Advantage patient's medical file for potential additional diagnoses, regardless of their relevance to the visit. Kaiser would then seek to have the physician add the new diagnoses to the medical record retrospectively using an addendum, as if the new diagnoses had been addressed in some way during the patient visit when in fact they had not been. The driver was money: so that Kaiser could submit these improper diagnoses to CMS for payment. Indeed, Kaiser employed these initiatives only for diagnoses and patients for whom Kaiser could receive a risk-adjustment payment. See infra ¶¶ 121-32.~~

5. During all relevant times, CMS has imposed specific standards regarding which diagnoses could be submitted for risk-adjustment payment. Among other limitations, diagnoses could be submitted only if they conformed to the ~~International Classification of Diseases ("ICD") Official Guidelines for Coding and Reporting (the "~~ICD Guidelines~~")~~. The ICD Guidelines limited reportable diagnoses to those that both existed at the time of the visit and required or affected patient care, treatment, or management at the visit. In other words, only those conditions that specifically mattered to the patient care, treatment, or management that the physician actually provided at the visit could be submitted to CMS for payment. These standards applied regardless of whether the diagnosis was reported in the original medical record of the visit or an addendum. See infra ¶¶ ~~73-87~~75-89.

6. Kaiser knew and understood these standards~~,~~ and knew that any ~~diagnoses~~diagnosis codes submitted for payment had to comply with these standards. Kaiser's own internal compliance materials stated that diagnoses submitted for payment must comply with these specific standards. Kaiser knew that it could not submit ~~diagnoses~~ for payment diagnosis codes for conditions that did not exist at the time of or were irrelevant to the visit. See infra ¶¶ ~~88-96~~90-100.

7. Kaiser nevertheless systematically violated these standards as it pursued various risk-adjustment initiatives that routinely resulted in the creation of addenda to retrospectively add diagnoses to patient medical records. These initiatives included "data mining" and "chart review," where Kaiser would utilize automated algorithms and/or human reviewers to identify new diagnoses for a patient. Such never-before-diagnosed conditions should rarely, if ever, have resulted in addenda because these diagnoses were, almost by definition, not relevant to the visit. Yet Kaiser routinely added these diagnoses to medical records using addenda and submitted them for payment, often without even telling patients about these brand-new diagnoses.

8. Kaiser also ~~employed a related~~implemented a data-mining program called "refresh," where Kaiser would routinely mine patient medical files to find old diagnoses that had not yet been diagnosed in the current service year. If a physician failed to address any of these old diagnoses at a patient visit, Kaiser provided the physician ~~would be provided~~with a list of these "missed opportunities"—i.e., opportunities for risk-adjustment payment—to create an addendum to retrospectively add these diagnoses to the medical record. ~~Kaiser's efforts focused especially on diagnoses it knew were lucrative, and Kaiser routinely ignored the requirement that every diagnosis must have required or affected~~

9. These risk-adjustment initiatives often failed to properly account for contradictory information contained in a patient's medical file, especially with respect to the medical visit at issue. The inevitable result was the widespread submission of invalid diagnosis codes where the condition did not require or affect patient care, treatment, or management at the visit ~~in order to be submitted for payment~~and, in many instances, where the very existence of the condition at the time of the visit was contradicted by the medical record. See infra ¶¶ ~~133-83~~140-200.

~~8~~10. Kaiser regularly brought these mined diagnoses to the physician's attention for addition to the patient's medical record using a tool called a "query"—which in the healthcare industry is a communication tool used to clarify documentation in the health record. Queries present significant risks for improper diagnosis coding, and there are national standards guiding and limiting the use of queries. The standards include that a query cannot be leading (i.e., cannot direct a provider to a specific diagnosis) and cannot discuss financial impact. But Kaiser routinely violated the national query standards and used queries not to clarify medical records, but instead for the purpose of pressing physicians to retrospectively add new diagnoses via addenda that had nothing to do with the visit, so that Kaiser could then seek payment from CMS for these diagnoses. Further, many times Kaiser would query physicians to add conditions whose existence at the time was contradicted by the medical record, but without even alerting the physicians to this contradictory information. See infra ¶¶ ~~185-216~~202-33.

~~9~~11. Kaiser employed numerous tactics to pressure physicians to improperly add these diagnoses across the board. In addition to improper queries, Kaiser required its physicians to

meet certain metrics related to its risk-adjustment program. Kaiser meticulously tracked and monitored these metrics across physicians, facilities, and regions. Physicians who scored high were praised and rewarded. Those who did not would often be required to meet with supervisors about their risk-adjustment performance and could face financial consequences. As each year drew to a close, some employees referred to Kaiser's rush to capture as many diagnoses as possible as the "dash for cash." Kaiser employed numerous other tactics, such as "coding parties," where it would gather physicians in a room and expect them to work through lists of diagnoses and add these diagnoses to the records of their patient visits. See infra ¶¶ ~~217–68~~234-86.

~~10~~12. Kaiser knew that its addenda practices were widespread and unlawful. Kaiser ignored numerous red flags and internal warnings that it was violating Medicare rules, including concerns raised by its own physicians that these were false claims and audits by its own compliance office identifying the issue of inappropriate addenda. As Relator Randi Osinek (a Kaiser certified medical coder) reported to several Kaiser executives in 2011: "over 50% of the physicians tell me they feel that they are being 'forced' to add diagnoses that they did not consider[], evaluate[], and/or treat. Especially since they feel their bonuses are being impacted." (Emphasis in original.) Physicians also complained of regularly being asked to add conditions that the patient did not actually have at the visit. See infra ¶¶ ~~269–331~~287-358.

~~11~~13. Through these coordinated and systematic efforts to have physicians create retrospective addenda to patient medical records with diagnoses that ~~did not exist or~~ were unrelated to the medical visit and many times were contradicted by the patient's own medical record, Kaiser improperly submitted thousands upon thousands of diagnoses to CMS as claims for payment. Based on these unlawful false claims, Kaiser improperly obtained and retained hundreds of millions of dollars in risk-adjustment payments from CMS, in violation of both the FCA and the common law. If CMS had known that Kaiser was submitting fraudulent diagnosis codes, CMS would have refused to make risk-adjustment payments based on the improper coding and/or taken other appropriate actions to ensure that Defendants did not receive or retain risk-adjustment payments to which they were not entitled, including by recouping payments through administrative processes, payment adjustments, or obtaining repayments in enforcement actions.

II. PARTIES

A. Plaintiff and Relators

~~12~~14. Plaintiff is the United States of America, suing on behalf of the Department of Health and Human Services ("HHS"), which includes its operating division, CMS. At all times relevant to this Amended Complaint, CMS administered the MA Program and made risk-adjustment payments under the MA Program. The United States filed its notice of intervention in this consolidated action on July 27, 2021. See 31 U.S.C. § 3730(b)(4)(A).

~~13~~15. Relator Randi Osinek filed an action alleging violations of the FCA on behalf of herself and the United States Government pursuant to the qui tam provisions of the FCA on August 22, 2013. See 31 U.S.C. § 3730(b). Randi Osinek is a citizen of the United States and a resident of the State of Oregon. Randi Osinek, a certified medical coder, worked for Defendant The Permanente Medical Group as a Data Quality Trainer and Audit Manager at Kaiser's San Rafael,

California facility.

~~14~~16. Relator James Taylor, M.D., filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the qui tam provisions of the FCA on October 22, 2014 in the District of Colorado. His action was transferred to the Northern District of California on May 11, 2021. Dr. Taylor is a citizen of the United States and a resident of the State of Colorado. Dr. Taylor worked for Defendant Colorado Permanente Medical Group from 1995 through 2015, most recently as the Medical Director of Revenue Cycle/Claims, where his responsibilities included revenue cycle risk adjustment programs and coding governance and compliance. Dr. Taylor also previously served as Chair of the Board of Directors of Defendant Colorado Permanente Medical Group.

~~15~~17. Relators Naser Arefi, Ajith Kumar, and Prime Healthcare Services, Inc. ("Prime") filed an action alleging violations of the FCA on behalf of themselves and the United States Government pursuant to the qui tam provisions of the FCA on September 4, 2015. Naser Arefi is a citizen of the United States and a resident of the State of California. Naser Arefi worked for Defendant The Permanente Medical Group, Inc. as a Clinical Documentation Specialist from 2011 to 2014. Ajith Kumar is a citizen of the United States and a resident of the State of California. Ajith Kumar was Vice President of Reimbursement Management at Prime. Prime owns and operates 45 acute care hospitals, including 15 in California.

~~16~~18. Relators Marcia Stein and Rodolfo Bone filed an action alleging violations of the FCA on behalf of themselves and the United States Government pursuant to the qui tam provisions of the FCA on May 16, 2016, and filed an amended complaint on November 3, 2016. Marcia Stein is a citizen of the United States and a resident of the State of California. From 1987 to 2011, Marcia Stein worked for Kaiser Foundation Hospitals as a Regional Health Information Manager. In that role, she trained physicians and other medical professionals on correct coding and documentation practices. Rodolfo Bone is a citizen of the United States and a resident of the State of California. Rodolfo Bone is a medical graduate who worked as a part-time coder for Kaiser Foundation Hospitals.

~~17~~19. Relators Gloryanne Bryant and Victoria Hernandez filed an action alleging violations of the FCA on behalf of themselves and the United States Government pursuant to the qui tam provisions of the FCA on March 1, 2018. Gloryanne Bryant is a citizen of the United States and a resident of the State of California. Prior to her retirement in 2017, Gloryanne Bryant was the National Director of the Coding Quality Group for Defendant Kaiser Foundation Health Plan. Victoria Hernandez is a citizen of the United States and a resident of the State of California. Victoria Hernandez worked for Defendant The Permanente Medical Group, Inc. from 1995 to 2015 and held various positions, including Regional Director for Auditing and Coding.

~~18~~20. Relator Michael Bicocca, M.D., filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the qui tam provisions of the FCA on February 10, 2020 in the Eastern District of California. His action was transferred to the Northern District of California on April 28, 2021. Dr. Bicocca is a citizen of the United States and a resident of the State of California. Prior to his retirement in December 2019, Dr. Bicocca was the Chief of Pain Management for three Kaiser hospitals in California and a practicing physician at Defendant The Permanente Medical Group's office in South Sacramento,

California.

B. Defendants

~~19~~21. The Defendants are part of Kaiser Permanente, an integrated health-care consortium comprised of three components: health plans ("Health Plans"); physician medical group practices (referred to as "Permanente Medical Groups"); and hospitals. This Amended Complaint concerns Kaiser's Health Plans and Permanente Medical Groups in Northern California, Southern California, and Colorado.

1. Kaiser Health Plans

~~20~~22. Defendants Kaiser Foundation Health Plan, Inc. ("the Health Plan") and its wholly owned subsidiary, Kaiser Foundation Health Plan of Colorado ("the Colorado Health Plan"), are Kaiser Health Plans that have executed contracts with CMS to be MA Organizations and provide MA plans.

~~21~~23. Defendant the Health Plan is headquartered in Oakland, California. The Health Plan has contracted with CMS to provide MA plans in California, covering Kaiser's Northern California and Southern California regions.

~~22~~24. Defendant the Colorado Health Plan is also headquartered in Oakland, California. The Colorado Health Plan has contracted with CMS to provide MA plans in Colorado, covering Kaiser's Colorado region.

2. Permanente Medical Groups

~~23~~25. Defendants The Permanente Medical Group, Inc. ("N. California Medical Group"), Southern California Permanente Medical Group, a California partnership ("S. California Medical Group"), and Colorado Permanente Medical Group, P.C. ("Colorado Medical Group") are regional Permanente Medical Groups that contract exclusively with the Health Plan (or the Colorado Health Plan in the case of the Colorado Medical Group) to provide medical services to patients who enroll in Kaiser healthcare plans, including patients who enroll in Kaiser's MA plans. Collectively, the N. California Medical Group, the S. California Medical Group, and the Colorado Medical Group provide medical services to over one million MA beneficiaries in California and Colorado.

~~24~~26. Defendant the N. California Medical Group is headquartered in Oakland, California and employs approximately 9,500 physicians. The N. California Medical Group provides medical services for Kaiser's Northern California region.

~~25~~27. Defendant the S. California Medical Group is headquartered in Pasadena, California, and employs approximately 7,800 physicians. The S. California Medical Group provides medical services for Kaiser's Southern California region.

~~26~~28. Defendant the Colorado Medical Group is headquartered in Denver, Colorado, and employs approximately 1,100 physicians. The Colorado Medical Group provides medical services for Kaiser's Colorado region.

~~27~~29. Kaiser's Permanente Medical Groups, including the N. California Medical Group, the S. California Medical Group, and the Colorado Medical Group, have a national leadership and consulting organization, the Permanente Federation LLC ("Permanente Federation"). The Permanente Federation is run by the leadership of the Permanente Medical Groups.

3. Kaiser's integrated and collaborative risk-adjustment operations

~~28~~30. Kaiser's Health Plans, Permanente Medical Groups, and hospitals publicly hold themselves out and do business collectively as an integrated healthcare provider called "Kaiser Permanente." Kaiser Permanente publicly declares that its Health Plans, Permanente Medical Groups, and hospitals are "under one roof," and that "[t]he interconnectedness and interdependence of the hospitals, health plan, and medical groups that make up Kaiser Permanente have advanced our efforts to operate seamlessly as an enterprise."

~~29~~31. Kaiser's Health Plans and Permanente Medical Groups use an integrated system for storing patient electronic medical records, KP HealthConnect. Both the Kaiser Health Plans and the Permanente Medical Groups directly access patient medical records through KP HealthConnect.

~~30~~32. The coordination touted by Kaiser extended to its efforts to increase risk-adjustment revenue from the MA Program. Kaiser's internal Medicare Risk Adjustment Manual highlighted that "[c]ollaboration is the key to the success of the Medicare Risk Adjustment program at Kaiser Permanente." Many offices and individuals from the Kaiser Health Plans and the Permanente Medical Groups were collectively involved in Kaiser's submission of risk-adjustment claims to CMS.

~~31~~33. Internal Kaiser documents and training materials discussed how "[w]e at KP have a strategic advantage to be successful under Medicare risk adjustment compared to other health plans because of our integrated structure, our partnership with the Permanente Medical Groups, and our electronic medical record, KP HealthConnect. We are better poised to know about and to manage chronic conditions better than anyone else."

~~32~~34. According to Kaiser's internal Risk Adjustment Manual, Medicare risk-adjustment work at Kaiser is "governed by several groups and has many stakeholders." The "governing parties" include the "National Medicare Leadership Team," the "National Medicare Finance Advisory Council," the Chief Financial Officer, and the Executive Director of the Permanente Federation. "[D]ue to the importance of this work to financial performance and compliance," the many "stakeholders" include: "Sales and Marketing, Regional and National Controllers, the CFOs, Permanente Medical Groups, Pricing and Actuarial, Revenue Cycle, Compliance, Government Relations, and Regional Presidents."

~~33~~35. By way of example, in 2009, the "Executive Sponsors" of the "National KP Risk Adjustment Initiative" were Kathy Lancaster (Executive Vice President and Chief Financial Officer of the Health Plan) and Jack Cochran (Executive Director of the Permanente Federation). The National Leads were Diane Morissette (National Director for Medicare Risk Adjustment, National Medicare Finance for the Health Plan) and Dr. Simon Cohn (Associate Executive Director of the Permanente Federation).

~~34~~36. Kaiser's National Medicare Finance department is housed within the Health Plan and employs dozens of individuals with expertise in cost reimbursement, risk management, finance and accounting, and systems and project management. There is also a special Risk Adjustment Team, whose analysts help interpret Medicare risk-adjustment trends and data and also perform risk-score forecasting. A dedicated part of the team focuses on "coordinating efforts across the regions, sharing successful practices among the regions, distilling information, and communicating results to leadership."

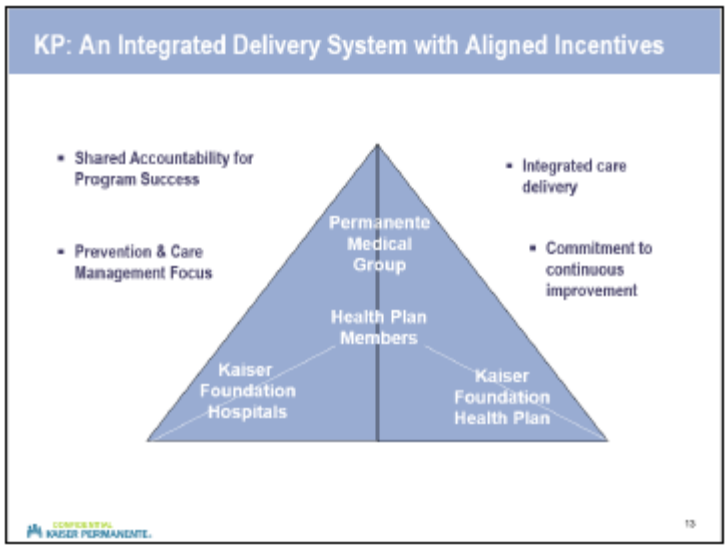
~~35~~37. The Medicare Risk Adjustment Regional Reporting Group ("Medicare Regional Reporting Group") is a "community" that coordinates how both the Kaiser Health Plans and the Permanente Medical Groups implement Medicare risk-adjustment initiatives, and includes coders, physicians, programmers, analysts, legal and compliance advisors, project managers, statisticians, forecasters, accountants, strategists, government-relations influencers, and business-line leaders from both the Kaiser Health Plans and the Permanente Medical Groups. The Medicare Regional Reporting Group is co-led by the National Director for Risk Adjustment in Kaiser's National Medicare Finance department and the Associate Executive Director of the Permanente Federation.

~~36~~38. Kaiser's National Medicare Finance department supports the semi-annual Medicare Regional Reporting Group conference that brings together Health Plan employees and Permanente Medical Group physicians from multiple regions to "increase their knowledge of Medicare risk adjustment, share best practices, and improve consistency and coordination."

~~37~~39. Kaiser's National Compliance, Ethics & Integrity Office ("National Compliance Office") is also housed within the Health Plan. Kaiser's National Compliance Office is led by the senior vice president and Chief Compliance Officer of the Health Plan. The Chief Compliance Officer reports directly to the Chief Executive Officer and the Board of Directors of Kaiser. While it is housed within the Health Plan, the National Compliance Office provided training to coders and physicians in the Permanente Medical Groups. It also conducts audits of the Permanente Medical Groups, including audits of the Permanente Medical Groups' coding of patient diagnoses.

~~38~~40. Each Kaiser region's Health Plan (e.g., Colorado) also has a Regional Compliance Officer and a regional Compliance Committee. These regional Compliance Committees oversee compliance activities, including with respect to Medicare Advantage.

~~39~~41. The following diagram from an internal Kaiser training depicts the integrated nature of Kaiser's operations:



~~40~~42. Because of the interconnected and interdependent nature of Kaiser, each of the Defendants—the Health Plan, the Colorado Health Plan, the N. California Medical Group, the S. California Medical Group, and the Colorado Medical Group—collaborated on their mutual Medicare risk-adjustment efforts.

III. JURISDICTION AND VENUE

~~41~~43. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 because the United States is the Plaintiff. In addition, the Court has subject-matter jurisdiction over the FCA claims for relief under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. § 3732(a)-(b).

~~42~~44. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because at least one of the Defendants can be found in, resides in, transacts business in, or has committed the alleged acts in this District. Moreover, all of the Defendants have extensive contacts with California. See also Fed. R. Civ. P. 4(k)(1)(C) (providing that serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant "when authorized by federal statute").

~~43~~45. Venue also lies in this District pursuant to 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because at least one of the Defendants can be found in, resides in, and transacts business in this District, a substantial part of the events or omissions giving rise to the claims occurred in this District, and/or all of the Defendants are subject to the Court's personal jurisdiction under the FCA.

~~44~~46. Intradistrict assignment to the San Francisco or Oakland Division is proper under Civil L.R. 3-2(c) because Defendants the Health Plan, the Colorado Health Plan, and the N. California Medical Group are all headquartered in Oakland and a substantial part of the events or omissions that give rise to the claims occurred therein.

IV. THE FALSE CLAIMS ACT

~~45~~47. The FCA is the primary civil remedial statute designed to deter fraud upon the United States and reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986), 1986 U.S.C.C.A.N. 5266.

~~46~~48. A defendant violates the FCA when it "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Under the FCA, a claim includes a request for money. Id. § 3729(b)(2). Further, a claim is "false or fraudulent" under the FCA if the entity or person submitting the claim was not entitled to payment.

~~47~~49. After the 2009 amendments to the FCA by the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21 (May 20, 2009), a defendant violates the FCA when it "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

~~48~~50. Conspiracy to violate Sections 3729(a)(1)(A) and (a)(1)(B) is also actionable under the FCA.

~~49~~51. Under the FCA, the terms "knowing" and "knowingly" mean that the defendant had actual knowledge of or acted in deliberate ignorance or reckless disregard of information relating to the truth or falsity of its claims for payment or its false records or statements. 31 U.S.C. § 3729(b)(1)(A). The FCA does not require proof that the defendant had specific intent to defraud the Government. Id. § 3729(b)(1)(B). The terms "knowing," "knowingly," "knowledge," "knows," and "knew," as used in this Amended Complaint, have the meaning ascribed to them by the FCA.

~~50~~52. The term "material," as used in the FCA, "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).

~~51~~53. The FCA imposes liability of treble damages plus a civil penalty for each false claim in an amount (as pertinent here) not less than $5,500 and not more than $11,000 for claims submitted prior to August 1, 2016; not less than $10,781 and not more than $21,563 for claims submitted between August 1, 2016 and February 3, 2017; and as appropriately statutorily adjusted for inflation each successive year under the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 584, 599- 601 (2015). See 28 C.F.R. § 85.5 (identifying applicable inflation adjustments on an annual basis); 31 U.S.C. § 3729(a)(1).

V. THE MEDICARE ADVANTAGE PROGRAM AND ITS RISK-ADJUSTMENT PAYMENT SYSTEM

A. Medicare Part C and risk-adjustment payments to MA Organizations

~~52~~54. Medicare is a federally operated health insurance program administered by CMS for individuals 65 and older and the disabled. See 42 U.S.C. §§ 1395c et seq. There are four parts to the Medicare Program: Part A primarily covers inpatient and institutional care; Part B primarily covers outpatient care; Part C is the Medicare Advantage Program at issue in this case; and Part D is prescription drug coverage.

~~53~~55. A Medicare beneficiary may choose what is commonly referred to as "traditional" Medicare. Under Medicare Parts A and B, the Government reimburses healthcare providers using a ~~fee-for-service~~fee- for-service system, in which providers submit claims to CMS for healthcare services actually rendered, such as a provider office visit or hospital stay. CMS then pays the providers directly for each service based on payment rates predetermined by the Government.

~~54~~56. Alternatively, under the MA Program, a Medicare beneficiary can opt out of the traditional Medicare Program (Parts A and B) and instead enroll in an MA plan managed by an MA Organization. See Subchapter XVIII of the Social Security Act, 42 U.S.C. §§ 1395w-21 to 1395w-28.

~~55~~57. MA Organizations are insurers who contract with CMS to provide healthcare plans called MA plans to people who are eligible for Medicare Part C. See 42 U.S.C. §§ 1395w-21-1395w-28. MA plans must provide Medicare beneficiaries all the services that they are entitled to receive from the traditional Medicare program, at a minimum, subject to limited exceptions. Defendants the Health Plan and the Colorado Health Plan are MA Organizations that administer Kaiser's MA plans in California and Colorado.

~~56~~58. A Medicare beneficiary who enrolls in an MA plan is considered a member of and enrollee in that plan.[1]

~~57~~59. CMS reimburses MA plans differently than traditional Medicare. Under Medicare Part C, the Government pays each MA Organization a predetermined base monthly amount for each enrollee in their MA plans. This monthly payment is known as a "per-member, per-month" payment and varies for each MA plan depending on various factors. See 42 U.S.C. § 1395w-23 (Payments to Medicare+Choice Organizations[2]); see also 42 C.F.R. Part 422 Subpart F (Submission of Bids, Premiums, and Related Information and Plan Approval); 42 C.F.R. Part 422 Subpart G (Payments to Medicare Advantage Organizations).

~~58~~60. Additionally, since 2000, Congress has required that CMS adjust the "per-member, per-month" base payment for each MA plan beneficiary to account for: (1) demographic factors such as age and gender (among others) and (2) health status. See 42 U.S.C. § 1395w-23(a)(1)(C)(i). This is known as risk adjustment. Each beneficiary's risk score acts as a multiplier that is applied to the MA plan's base rate to determine the overall monthly payment for the beneficiary. See 42 U.S.C. § 1395w- 23(a)(1)(G); see also 42 C.F.R. § 422.308(e).

~~59~~61. HHS has the authority to determine the risk-adjustment methodology. See 42 U.S.C. § 1395w-23(a)(1)(C). For Medicare Advantage, since 2004, HHS has used a model called the CMS Hierarchical Conditions Category ("CMS-HCC") model, which determines each patient's risk score by accounting for the patient's demographic factors and health status. See 42 C.F.R. §

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[1] In this Amended Complaint, the terms beneficiaries, members, enrollees, and patients are used interchangeably and mean the same thing, i.e., individuals enrolled in MA plans.

[2] Medicare+Choice was the predecessor to the Medicare Advantage Program. Any provisions, such as 42 U.S.C. § 1395w-23, that reference Medicare+Choice are "deemed a reference to 'Medicare Advantage' and 'MA.'" See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-73, § 201(b), 117 Stat. 2066, 2176 (Dec. 8, 2003) (codified at 42 U.S.C. § 1395w-21 note).

422.308(c); see also 42 U.S.C. § 1395w-23(a)(1)(C)(i).

~~60~~62. 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"). The diagnoses included in the CMS-HCC model are a subset of diagnosis codes from the International Classification of Diseases. The diagnoses in the CMS-HCC model generally include major, severe, and/or chronic medical conditions.

~~61~~63. HHS has adopted the ICD and its accompanying ICD Guidelines as the standard for medical record documentation, including the identification of diagnosis codes for health conditions. See 45 C.F.R. §§ 162.1002(a)(1), (b)(1), (c)(2), (c)(3) ("The Secretary [of HHS] adopts . . . the official ICD- 10-CM Guidelines for coding and reporting"). At all relevant times, CMS regulations have therefore required MA Organizations to "submit data that conform to" the ICD Guidelines. 42 C.F.R. § 422.310(d)(1) (requiring MAOs to submit data in conformity with "all relevant national standards"); see also CMS, Medicare Managed Care Manual, Chapter 7, Exhibit 30 (Rev. 57, Aug. 13, 2004); CMS, Medicare Managed Care Manual, Chapter 7 § 40 (Rev. 118, Sept. 19, 2014). Section 422.310(d)(1) provides a benchmark to assess the accuracy of the information provided and is not limited to data format.

~~62~~64. 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. The applicable ICD diagnosis codes are set forth in the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9") through October 1, 2015, and thereafter in the International Classification of Diseases, Tenth Revision, Clinical Modification ("ICD-10"). See 45 C.F.R. § 162.1002 (listing dates for use of Medical data code sets). The particular ICD Guidelines provisions relevant to the allegations in this Amended Complaint have remained the same.[3] The Health Insurance Portability and Accountability Act ("HIPAA") and HHS regulations broadly mandate the use of the ICD, including the ICD Guidelines, across the healthcare industry.

~~63~~65. The CMS-HCC model relies upon the ICD diagnosis codes and the ICD Guidelines. The ICD diagnosis codes included in the CMS-HCC model are grouped into categories of clinically related medical diagnoses that comprise the HCCs (i.e., the categories). For example, various cancer diagnosis codes are grouped together (e.g., colorectal and bladder cancers). The CMS-HCC model organizes related conditions into hierarchies based on disease severity and expected cost. For example, various cancer HCCs are in the same hierarchy, with the HCC associated with metastatic cancer diagnosis codes as the most severe. With rare exception, the CMS-HCC model only provides for risk-adjustment payments based upon active condition ICD diagnosis codes, not historical ones. Thus, for example, a patient with active cancer is coded differently than a patient with a history of cancer, and the model only pays based upon an active cancer diagnosis code. If a patient is diagnosed with conditions (diagnosis codes) that correspond to more than one HCC in a hierarchy, only the most severe HCC is kept and any lower-ranking HCCs are

[3] Because the relevant guidelines have remained the same, the Amended Complaint will not reference any particular version of the ICD Guidelines. All ICD Guidelines for the relevant years are available at https://www.cdc.gov/nchs/icd/icd9cm.htm and https://www.cdc.gov/nchs/icd/icd10cm.htm.

dropped.

~~64~~66. For a given payment year, an MA plan beneficiary might have zero HCCs or might have one or more HCCs, depending on whether the beneficiary had any diagnoses from the service year that correspond to an HCC. Some examples of HCC codes are diabetes with chronic complications (HCC 18), protein-calorie malnutrition (HCC 21), congestive heart failure (HCC 80), and vascular disease (HCC 108).[4]

~~65~~67. Each HCC is assigned a coefficient. CMS calculates a beneficiary's risk score by adding the coefficients associated with each of the beneficiary's applicable demographic characteristics (such as age and gender) and the applicable HCCs, if any, that apply to the beneficiary.[5] A risk score of 1.0 reflects the average expected Medicare-incurred expenses. A risk score of 0.75 reflects expected costs for a particular beneficiary that are 25% less than the estimated average costs for enrollees in the MA plan, and a risk score of 1.25 reflects expected costs that are 25% greater than the estimated average costs for enrollees in the MA plan.

~~66~~68. CMS uses these risk scores to adjust the base monthly payment for each MA plan beneficiary. As noted, each patient's risk score is based upon diagnosis codes submitted from medical visits in the ~~"~~service year.~~"~~ CMS uses those service-year calculations to determine the monthly payments to the MA organizations in the following year (the "payment year"). Each MA plan beneficiary's risk score is calculated each year.

~~67~~69. To understand the operation of the CMS-HCC model, imagine a hypothetical patient whose "demographic" characteristics—i.e., age, sex, and institutional and disability statuses—were assigned a coefficient of 0.60. If this patient had no diagnosed diseases, an MA plan would be paid 60% of its base rate (which is keyed to the average beneficiary) for covering this patient. If the imagined patient had one diagnosis in the service year that mapped to an HCC, the CMS-HCC model would add the risk-adjustment coefficient for that HCC. For example, if that HCC had a risk-adjustment coefficient of 0.30, the patient would then have a risk score of 0.90, and the MA plan would be paid 90% of its base rate in the payment year for covering this patient. If this patient had a second diagnosis that mapped to another HCC, CMS would add the risk adjustment coefficient for that HCC as well. So if that second HCC had a risk adjustment coefficient of 0.20, the patient would then have a risk score of 1.10, and the MA plan would be paid 110% of its base rate in the payment year for covering this patient. If we assume the base payment amount for the patient was $10,000, the first diagnosis would cause CMS to pay out $3,000 more in risk adjustment payments, and the second diagnosis would cause CMS to pay out an additional $2,000 in risk adjustment payments.[6]

~~68~~70. The CMS-HCC model relies upon MA Organizations and authorized physicians to correctly document and submit ICD diagnosis codes for their patients pursuant to the ICD

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[4] CMS has adjusted the CMS-HCC model over time, utilizing different versions. The numerical examples of HCC codes cited in this paragraph are from the Version 22 model.

[5] CMS makes several further adjustments to the risk score before reaching a final calculation. See CMS, Medicare Managed Care Manual, Chapter 7 § 100 (Rev. 114, June 7, 2013). These adjustments are not relevant to the allegations in the Amended Complaint.

[6] As noted above, CMS makes several technical adjustments to the risk score not relevant to the allegations in the Complaint. For purposes of this example, all adjustments are incorporated within the hypothetical coefficients.

Guidelines. When a Medicare Advantage insurer reports to CMS a relevant diagnosis for a covered patient, that reported diagnosis directly increases the amount that CMS pays the insurer for providing coverage. A higher risk score translates into higher payments by CMS to the MA Organization. Thus, the ~~risk-adjusting~~risk-adjusting diagnosis codes that correspond to HCCs directly impact how much money CMS pays an MA Organization. The CMS-HCC model does not predict any costs associated with a patient simply having a condition or having been diagnosed with a condition in the past. Rather, as explained above, the CMS-HCC model predicts expected costs based upon particular ICD diagnoses coded in conformance with the ICD Guidelines in the service year.

~~69~~71. CMS, through its regulations and guidance, has made clear to MA Organizations and healthcare providers, including physicians, that it relies on the risk-adjusting diagnosis codes to determine and make accurate payments for each patient enrolled in the MA Program. "Accurate risk- adjusted payments rely on the diagnosis coding derived from the member's medical record." See, e.g., 42 C.F.R. § 422.504(l); CMS, 2013 National Technical Assistance Risk Adjustment 101 Participant Guide 13 (2013).

~~70~~72. During the relevant time period, MA Organizations submitted risk-adjustment data, including diagnosis codes, through two electronic systems administered by CMS: the Risk Adjustment Processing System ("RAPS") and the Encounter Data Processing System ("EDPS"). Up to 2014, CMS calculated risk-adjustment payments based solely on data submitted through RAPS. Starting in 2015, CMS has calculated risk-adjustment payments using a combination of data submitted through RAPS and EDPS.

~~71~~73. Each RAPS and EDPS submission by an MA Organization is a claim for payment because the reported diagnosis codes factor directly into CMS's risk-adjustment calculations and into the resulting payments made by CMS to the MA Organization.

~~72~~74. MA Organizations can delete or "redact" ~~diagnoses~~diagnosis codes from both the RAPS and EDPS databases to remove erroneous, invalid, unsupported, or otherwise improper diagnosis codes previously submitted to CMS. After a diagnosis code is deleted or redacted, CMS's electronic-processing system recalculates the payment.

B. Standards governing risk-adjustment payments

~~73~~75. CMS has the authority to issue rules to implement and regulate Medicare Part C. See 42 U.S.C. § 1395w-26(b). CMS has promulgated regulations governing the Medicare Advantage Program, including numerous regulations imposing obligations and responsibilities on MA Organizations. 42 C.F.R. Part 422.

~~74~~76. Further, in order to participate in the MA Program, MA Organizations such as Kaiser's Health Plans must enter into and execute a written contract with CMS for the MA plans they operate. 42 U.S.C. § 1395w-27(a); 42 C.F.R. Part 422, Subpart K. Pursuant to 42 C.F.R. § 422.505, these contracts are renewed annually unless CMS or the MA Organization provides a notice of intention not to renew. As relevant here, the Health Plan and the Colorado Health Plan executed such contracts with CMS for the MA plans they operated.

~~75~~77. These contracts impose numerous obligations. Among others, the contracts require an

MA Organization to operate its MA plans in compliance with the requirements of the contract, applicable federal law and regulations, and CMS's policies, including CMS's Medicare Managed Care Manual. Furthermore, the MA Organization must certify the accuracy, completeness, and truthfulness of the data it submits to CMS. 42 C.F.R. § 422.504(l).

~~76~~78. Entities—like physician groups—enter into agreements with MA Organizations to provide health care services to MA plan beneficiaries. These entities are called first tier and downstream entities. See, e.g., 42 C.F.R. § 422.500 ("First tier entity means any party that enters into an acceptable written arrangement with an MA Organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual."); id. ("Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA Organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services."); see also, e.g., 42 C.F.R. § 422.504(i) (listing some of the obligations).

~~77~~79. First tier and downstream entities—such as the Permanente Medical Groups—must, among other things, agree in their contracts with the MA Organization to terms that commit them to comply with the MA Organization's contractual obligations to CMS, 42 C.F.R. § 422.504(i)(3)(iii), and agree to "comply with all applicable Medicare laws, regulations, and CMS instructions," id. § 422.504(i)(4)(v). Furthermore, if the entity generates data relating to an MA Organization's claims for payment, it must certify the accuracy, completeness, and truthfulness of that data. Id. § 422.504(l)(3). The Defendant Permanente Medical Groups have each executed contracts agreeing to these and other obligations related to the MA Program.

~~78~~80. CMS imposes, and Kaiser Health Plans have contractually agreed to, numerous obligations with respect to diagnosis codes submitted to obtain risk-adjustment payments. As most relevant to this Amended Complaint:

~~79~~81. First, given the material impact of diagnoses in calculating the Government's payments, MA Organizations must ensure that diagnosis codes submitted for risk-adjustment payments are accurate, complete, and truthful. MA Organizations must attest to the validity of their risk-adjustment data, including diagnoses, in a Risk Adjustment Attestation submitted to CMS each year. Specifically, the chief executive officer, chief financial officer, or an individual delegated with authority to sign on behalf of one of these officers and who reports directly to such officer, must certify that the risk- adjustment data that the MA Organization submitted to CMS is accurate, complete, and truthful. See 42 C.F.R. § 422.504(l); CMS, Medicare Managed Care Manual, Chapter 11 § 130 (Rev. 79, Feb. 17, 2006). In its contracts with CMS, Kaiser (like other MA Organizations) agreed that: "[a]s a condition for receiving a monthly payment under paragraph B of this article, and 42 CFR Part 422 Subpart G," it must attest to "the accuracy, completeness and truthfulness of the data identified on these attachments." CMS's regulations further specify that the MA Organization's submission of its such attestations regarding "the accuracy, completeness, and truthfulness" of this data is "a condition for receiving a monthly payment" from CMS. 42 C.F.R. § 422.504(l).

~~80~~82. Second, diagnosis codes submitted for risk-adjustment payments are valid only if they are documented in the medical record as a result of a face-to-face visit between a patient and

physician.[7] See, e.g., CMS, Medicare Managed Care Manual, Chapter 7 § 40 (Rev. 118, Sept. 19, 2014) ("All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit."); CMS, Medicare Managed Manual, Chapter 7 § 111.3 (Rev. 57, Aug. 13, 2004) ("Physician risk adjustment data is defined as diagnoses that are noted as a result of a face-to-face visit by a patient to a physician (as defined above) for medical services.").

~~81~~83. Third, diagnosis codes submitted for risk-adjustment payments must be in conformance with the ICD, including the ICD Guidelines. 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."); CMS, Medicare Managed Care Manual, Chapter 7 § 40 (Rev. 118, Sept. 19, 2014) ("The diagnosis must be coded according to International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting."); CMS, Medicare Managed Care Manual, Chapter 7 § 40 (Rev. 114, June 7, 2013); CMS, Medicare Managed Manual, Chapter 7, Exhibit 30 (Rev. 57, Aug. 13, 2004); 42 C.F.R. § 422.504(h)(2) (requiring MA Organizations to comply with HIPAA simplification rules at 45 C.F.R. part 162, which includes the adoption of the ICD and ICD Guidelines as the national standard); ICD Guidelines, Preamble ("These guidelines are a set of rules that have been developed to accompany and complement the official conventions and instructions provided within the ICD-10-CM itself. Adherence to these guidelines when assigning ICD-10-CM diagnosis codes is required under [HIPAA]."). The Medicare Managed Care Manual makes explicit the importance of complying with the ICD Guidelines. Indeed, CMS has long declared the risk-adjustment "guiding principle" requires that all diagnosis codes submitted for payment must be coded according to the ICD Guidelines.

~~82~~84. The ICD Guidelines impose numerous requirements and limitations on what diagnoses may be coded in a particular visit and in a particular setting. Those Guidelines differ with respect to when diagnoses can be coded for non-outpatient and outpatient visits. Compare ICD Guidelines §§ II, III (non-outpatient guidelines), with § IV (outpatient guidelines). This Amended Complaint concerns outpatient visits, which are covered by Section IV of the ICD Guidelines.

~~83~~85. For an outpatient visit (sometimes referred to as an encounter), the ICD Guidelines only permit the coding of documented conditions that both exist at the visit and that "require or affect patient care treatment or management." ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K.[8] In other words, it is not enough that a condition merely exists; the condition must have specifically mattered to patient care, treatment, or management.

~~84~~86. The ICD Guidelines state that "[c]hronic diseases treated on an ongoing basis may be

[7] The Medicare Managed Care Manual provides a table of Acceptable Physician Specialty Types. See CMS, Medicare Managed Care Manual, Chapter 7 Table 19 (Rev. 118, Sept. 19, 2014). The type of physician is not at issue in this Amended Complaint; this Amended Complaint will therefore refer simply to "physician."

[8] The ICD Guideline provisions discussed in this Amended Complaint are identical in all relevant editions of the ICD-9 and ICD-10 Guidelines; the subsection letter changed because one subsection not relevant to the Amended Complaint was removed for the ICD-10.

coded and reported as many times as the patient received treatment and care for the condition(s).” ICD- 10 Guidelines § IV.I; ICD-9 Guidelines § IV.J. As CMS explained in a 2013 Participant Guide: “For a chronic condition to be accepted for risk adjustment, the patient must have a face-to-face visit each year with a provider/physician who assesses and documents that condition.” CMS, 2013 National Technical Assistance Risk Adjustment 101 Participant Guide 17 (2013).

~~85~~87. For example, even if an MA organization knows that a patient was previously diagnosed ~~in a prior year~~ with a chronic condition that tends not to go away, the MA organization may not submit ~~the diagnosis~~ for payment ~~for~~ the ~~current~~diagnosis code in a particular service year unless the physician has a face-to-face visit with the patient in ~~the current year~~that service year, the chronic condition existed at that patient visit, and the chronic condition required or affected care, management, or treatment during that patient visit.

~~86~~88. The ICD Guidelines further provide that if a patient does not have a medical condition at the time of a visit, it may not be coded. Moreover, uncertain conditions—such as probable, suspected, questionable, working diagnoses, etc.—may not be coded. See ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I. ~~Prior~~Historical conditions may be coded only with special ICD “history codes” if the ~~prior~~patient has a history of a condition ~~has an impact on~~that impacts current care or treatment. See ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K.

~~87~~89. In sum, the diagnosis codes that MA Organizations submit to CMS for risk-adjustment purposes must be:

a. established by a qualified physician;

b. based on a face-to-face medical visit between the patient and physician;

c. documented in the medical record; and

d. coded in compliance with the ICD Guidelines, including the limitation that the condition must have required or affected patient care, treatment, or management for the visit.

VI. KAISER KNEW THE CMS STANDARD FOR SUBMISSION OF RISK-ADJUSTMENT DIAGNOSES

~~88~~90. Kaiser knew that diagnoses submitted to CMS for risk-adjustment purposes must be: (a) established by a qualified physician; (b) based on a face-to-face medical visit between the patient and physician; (c) documented in the medical record; and (d) coded in compliance with the ICD Guidelines, including the limitation that the condition must have required or affected patient care, treatment, or management for the visit.

~~89~~91. Kaiser’s own internal documents recognized the need to comply with the ICD Guidelines, including the requirements in an outpatient visit that a condition may not be reported unless it both existed at the time of the visit and required or affected patient care, treatment, or management. As far back as 2008, Kaiser issued a “Program Advisory” (the “2008 Risk Adjustment Program Advisory”) to all its regions that 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 designated points of contact for the 2008 Risk Adjustment Program Advisory were: Dr. Simon Cohn (Associate Executive Director for the Permanente Federation); Gina Reese (Senior Counsel for Kaiser Foundation Hospitals and Health Plans); and Janet Franklin (at the time, a Practice Leader, Coding Compliance, with the National Compliance Office).

~~90~~92. The 2008 Risk Adjustment Program Advisory demonstrates that Kaiser knew the CMS standard for submission of risk-adjustment diagnoses. Specifically, it stated that:

a. "Diagnoses submitted as physician risk adjustment data must be recorded by a 'physician'";

b. "[R]isk adjustment data must be obtained as the result of a face-to-face visit by the physician . . . with the patient" (emphasis in original);

c. "For the outpatient or physician office visit note, it is acceptable to submit risk adjustment data for diagnoses documented in the history, physical or assessment portion of the medical record that is directly associated with the date of the face- to-face encounter with the patient"; and

d. "Documentation Must Comply with ICD-9-CM Coding Guidelines" and "[t]here must be an implicit or express indication that the physician considered, addressed or evaluated the coded diagnosis during the patient encounter. . . . [I]f the physician does not actually consider the condition during the visit, then the physician should not document the diagnosis in the medical record for that visit and that diagnosis should not be submitted to CMS as risk adjustment data." (Emphasis in original.)

~~91~~93. A 2010 Medicare Regional Reporting Group presentation to all Defendants stated that the physician must have considered, addressed, or evaluated the condition during the patient visit. "Each encounter must be evaluated separately and the condition's impact to care must be evident. This is in keeping with Coding Clinic and as iterated [sic] by CMS in their participant guide." The presentation then cited the specific provision in the ICD Guidelines requiring that the condition must require or affect patient care, treatment, or management in order to be coded.

~~92~~94. A 2014 Medicare Regional Reporting Group presentation reiterated these requirements: "Documentation must comply with the ICD-9-CM Coding Guidelines." To be coded, the condition must be "[e]valuat[ed], treat[ed] or affect care," must be the "result of face-to-face encounter" with an acceptable physician, and "must have occurred in the applicable year."

~~93~~95. In 2015, Kaiser issued an updated version of the Program Advisory (the "2015 Risk Adjustment Program Advisory"), with similar guidance. As with the 2008 Risk Adjustment Program Advisory, the 2015 Risk Adjustment Program Advisory was "intended to provide guidance about the documentation necessary to support the diagnoses reported by physicians and diagnoses codes submitted by Kaiser Foundation Health Plans to [CMS] for physician encounter risk adjustment data." The designated points of contact for the 2015 Risk Adjustment Program Advisory were: Dr. Simon Cohn; Paula Ohliger (Senior Counsel for the Health Plan); and Janet Franklin (at that time, a Compliance Manager for Risk Adjustment with the National Compliance Office).

~~94~~96. Specifically, the 2015 Risk Adjustment Program Advisory states that "CMS requires that diagnoses submitted for risk adjustment be" made:

a. By "a physician deemed acceptable for risk adjustment";

b. "[A]s a result of a face-to-face encounter";

c. "[D]ocumented in the medical record"; and

d. "Documentation Must Comply with ICD-9-CM Coding Guidelines. . . . Generally, physicians should document all conditions that coexist at the time of the encounter/visit, and require or affect the physician's care, treatment or management of the patient. [I]f the physician does not actually consider the condition during the encounter or the diagnosis did not impact that encounter then the physician should not document the diagnosis in the medical record for the visit and that diagnosis should not be submitted to CMS as risk adjustment data." (Emphasis in original.)

97. Kaiser reiterated this guidance to its internal coding auditors again in December 2017: "As noted previously however, if the physician does not actually consider the condition during the encounter or the diagnosis did not impact that encounter then the physician should not document the diagnosis in the medical record for the visit and that diagnosis should not be submitted as risk adjustment data to CMS."

~~95~~98. Various employees, including those from the National Compliance Office, confirmed Kaiser's awareness of these requirements. As Janet Franklin testified, "in order to submit a diagnosis that impacted reimbursement, you had to meet the coding rules that showed that it impacted—that there was monitoring, evaluation, assessment, treatment, or some kind of impact to the encounter that day."

99. Further, Kaiser's Program Advisories recognized that condition must coexist at the time of the visit in order to be coded and reported and that history codes needed to be used for historical conditions.

~~96~~100. Internal Kaiser training documents also stressed the importance of the compliance "Golden Rule" regarding coding for patient diagnoses: "'If it's not documented by the physician, it didn't happen.' In compliance and in coding, there is no deviation from this principle. We can't code it if it isn't documented, and we can't bill for it."

VII. KAISER KNOWINGLY SUBMITTED OR CAUSED TO BE SUBMITTED FRAUDULENT DIAGNOSIS CODES

~~97~~101. ~~Despite its obligations to the contrary, Kaiser knowingly submitted or caused to be submitted diagnoses that had no relevance to the patient visit and sometimes did not exist at all and sought~~Kaiser operated a widespread coordinated scheme to wrongfully obtain risk-adjustment payments ~~based on such fraudulent diagnoses~~. Kaiser knew that it could submit only those diagnoses that existed at the time of and required or affected care, treatment, or management for a patient visit. Yet Kaiser knowingly submitted or caused to be submitted thousands upon thousands of diagnoses that it knew had nothing to do with those visits and were

not addressed or considered in any way at the patient visits. Indeed, information in patient medical records many times demonstrated that the patient did not even have the condition Kaiser prompted the physician to add at the time of the relevant visit.

~~98~~102. Kaiser generated such diagnoses through the use of medical record addenda—changes to the medical record after the patient visit, often months or even a year or more after the visit—to add unrelated diagnoses identified through one of Kaiser's risk-adjustment programs. Kaiser mined patient records for anything that might support a risk-adjusting diagnosis and then had the physician retrospectively create an addendum to the medical record to make it appear as if the diagnosis was part of the original patient visit, regardless of ~~whether it actually was~~what actually occurred during the visit and without taking into account contradictory information in the medical record of the visit.

103. Through these programs, Kaiser fraudulently added hundreds of thousands of false diagnoses to the medical records of unrelated patient visits. All of these diagnoses violated the ICD Guidelines requirement that a diagnosis "require or affect patient care, treatment, or management" at a patient visit. And many times, contradictory information in patient medical records indicated the patient did not even have the condition at the time of the visit.

~~99~~104. Defendants all knew that the purpose of these programs was to add diagnoses that the Health Plan and the Colorado Health Plan could submit to CMS to falsely claim entitlement to hundreds of millions of dollars in additional risk-adjustment payments, which the Health Plans then shared with the Permanente Medical Groups. Indeed, the Defendants routinely tracked these programs in great detail to identify the diagnoses added, money earned, and return on investment. Meanwhile, Permanente Medical Group physicians often did not tell their patients that they supposedly had the diagnoses for which the Kaiser Health Plans claimed payment.

A. Kaiser recognized the importance of Medicare revenue and implemented national initiatives to increase patient risk scores.

~~100~~105. Kaiser recognized and emphasized internally that Medicare Advantage, and in particular risk-adjustment payments from diagnoses, were (and are) critical to Kaiser's business. Internal Kaiser documents stressed repeatedly how "Medicare is important to KP," how "Medicare is KP's largest single payor," and how Medicare is a "[s]ignificant contributor to operating income." Kaiser's internal analyses reflected that although Medicare accounted for roughly 10% of Kaiser's members, Medicare accounted for more than 30% of Kaiser's total revenue. And risk-adjustment payments (i.e., CMS payments based upon risk-adjustment diagnoses) accounted for more than half of all of Kaiser's Medicare revenue.

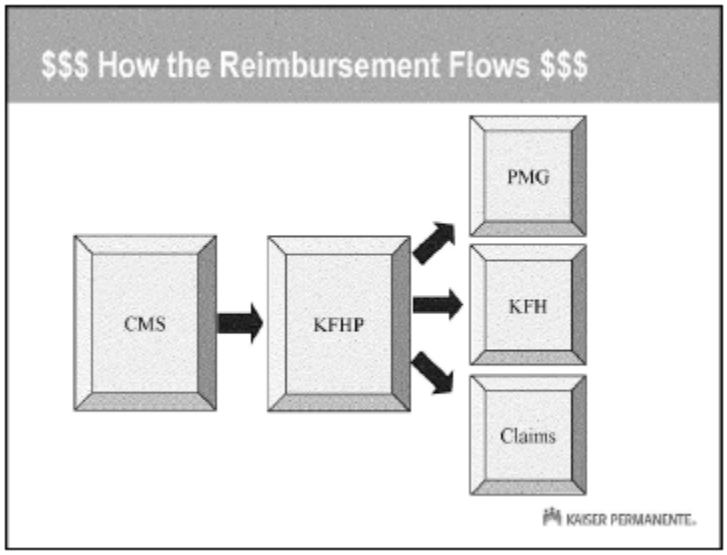
~~101~~106. In his speaker notes for a National Compliance Office summit meeting, Dr. Simon Cohn (Associate Executive Director of the Permanente Federation) explained: "So why are we talking to you about this [Medicare Risk Adjustment] again? … because of KP[']s critical dependencies on Medicare Revenue—risk adjusted revenue—which is almost 1/3 of program revenue and the only thing we are currently making a margin on—the more you know about this the better."

~~102~~107. As Diane Morissette (National Director for Medicare Risk Adjustment, National

Medicare Finance for the Health Plan) explained to the Medicare Regional Reporting Group, including representatives from all of the Defendants, in 2010: "Why a focus on risk adjustment . . . that's enough to warrant its own 2-day meeting? Because risk adjustment is by far the biggest lever we have to change our revenue from Medicare. If we don't do this well, our financial health as a company could be seriously impacted."

~~103~~108. Revenue from the Medicare Advantage program was shared among the Kaiser entities. As one set of internal Kaiser training materials put it, "Many management consultants will advise people to 'follow the money', so let's do that here. In Medicare Advantage, Medicare or 'CMS' pays Kaiser Foundation Health Plan to cover Medicare covered benefits for our Medicare Advantage members. Our Health Plan, in turn, pays the Permanente Medical Groups, Kaiser Foundation Hospitals, and various external providers through claims to care for our members."

~~104~~109. The same Kaiser internal training depicted the flow of money in the following way:



~~105~~110. Recognizing the importance of risk adjustment as a revenue driver, Kaiser's National Medicare Leadership Team, National KP Risk Adjustment Initiative, National Medicare Finance department, and the Medicare Regional Reporting Group were all key players involved in risk- adjustment activities at Kaiser. Kaiser's National Medicare Finance department assigned one or more persons from its ranks to lead each region's risk-adjustment efforts. National Medicare Finance's region leads collaborated with the regional Permanente Medical Groups to ensure coordination, identify and analyze potential opportunities to increase risk-adjustment revenues, and share information across regions. If particular regions had successful initiatives that increased their risk scores, Kaiser's National Medicare Finance department would work with other regions to duplicate those efforts. The Medicare Regional Reporting Group shared information across all Kaiser entities and regions regarding risk adjustment, including so that successful initiatives could be shared and duplicated.

~~106~~111. Internally, Kaiser touted that it had a "strategic advantage" in Medicare risk

adjustment because of its integrated structure. This structure enabled Kaiser to coordinate its efforts between each of its entities and across regions. The National KP Risk Adjustment Initiative and the various working groups it spawned, as well as Kaiser's National Medicare Finance department, ensured this high level of coordination.

~~107~~112. Key to Kaiser's ability to coordinate risk-adjustment activities among the Kaiser Health Plans and the Permanente Medical Groups was the fact the Kaiser Health Plans and the Permanente Medical Groups actively monitored and shared risk-adjustment data, including diagnosis documentation.

~~108~~113. Kaiser's National Medicare Finance department tracked numerous metrics. Risk scores were compared across regions, trended over time, tracked against forecasts, and compared to benchmarks. Volumes of diagnoses were tracked and compared across time, regions, and against expected thresholds. The number of diagnoses per visit, visits per member, HCCs per member, HCC frequencies, and number of un-refreshed diagnoses were all tracked within Kaiser's National Medicare Finance department.

~~109~~114. A variety of reports on all of these metrics were distributed to individuals throughout the Kaiser Health Plans and Permanente Medical Groups involved with Medicare risk adjustment, as well as posted to the internal "KP Medicare Risk Adjustment Website," the purpose of which was to "provide one central location as a resource to staff across the regions who are working on Medicare Risk Adjustment."

~~110~~115. In addition to the various risk-adjustment reports, the KP Risk Adjustment Website contained presentations from Medicare Regional Reporting Group conferences, training materials, compliance policies, and National Compliance Office work plans.

~~111~~116. As Kaiser's internal Risk Adjustment Manual further explains: "[a]ccuracy and completeness of diagnosis documentation, coding and data submission is tracked monthly by reviewing a full suite of reports that are produced by [Management Information & Analysis], reviewed by National Medicare Finance and the Permanente Federation and consolidated into a monthly summary of reports. In addition, as soon as new monthly risk score results are available, a Medicare Risk Adjustment flash report is distributed to CFOs, Medicare Risk Adjustment regional leads, National Medicare Finance managers and other key stakeholders."

~~112~~117. An additional function of Kaiser's National Medicare Finance department was to work with each region to develop a "risk adjustment improvement plan." The plans covered seven areas relating to "completeness and accuracy of documentation, coding and data submission." These plans "are developed early in the year and are evaluated quarterly. Gaps that are identified are worked through to resolution with the Region and successful practices that are identified are highlighted and shared with other Regions."

~~113~~118. In addition to monthly meetings, the Medicare Regional Reporting Group held semi- annual conferences to ensure that key leaders and staff involved in Medicare risk adjustment were updated with the latest information from CMS, reviewed risk score trends and accuracy rates, and learned new tools to allow them to work more efficiently and effectively. The Medicare Regional Reporting Group conferences were also an important opportunity to share

successful practices, such as "[n]ew and promising regional initiatives to improve completeness and/or accuracy of risk adjustment data."

~~114~~119. In addition, the "KP Risk Adjustment Data Leads" for all regions and representatives from the national risk-adjustment reporting team meet weekly to "share new risk adjustment information, discuss and resolve data submission issues, and share successful practices." "Data Leads often adopt each others' initiatives, especially as KP regions move toward common sources for risk adjustment data. Best practices and lessons learned are discussed, with a focus on moving toward common national practices to the greatest extent possible."

~~115~~120. Kaiser made clear that it expected results and would hold employees accountable for achieving them. In a 2006 Medicare Regional Reporting Group presentation regarding Improving Diagnosis Capture for Medicare Risk-Adjusted Payment, Diane Morissette and Dr. Simon Cohn stated that there was leadership focus on this issue at both the Health Plan and the Permanente Medical Groups, and that leadership in those organizations "holds direct reports accountable for results."

~~116~~121. Kaiser identified that the risk score is "one of the primary drivers of overall revenue and is a key driver for organizational performance." Kaiser knew that if it could increase the average risk scores of its patients, even by a small amount, it could receive a significant increase in revenue. As an internal Kaiser training emphasized: "If a risk score increases from, say, 1.10 to 1.11, this is considered a point. It might not sound like much of a change, but that point is worth over $28 Million dollars to a Region like Northern California and over $62 Million dollars if the overall average risk score for the whole KP program increases by a point." Kaiser calculated the value of each point every year. By 2015, Kaiser calculated that the value of each point was more than $80 million.

~~117~~122. A key component of Kaiser's risk-adjustment programs involved setting risk-score targets for the average risk score for all of Kaiser's patients. The Health Plan, through the National Medicare Finance department, set the annual risk-score target for each region, specifically instructing each region what the average risk scores for its members should be. Generally, these targets would take the historical score from the region and add on points for the following year. Each region was expected to work with Kaiser's National Medicare Finance department to develop a plan, including the specific initiatives it would undertake, to meet the risk-score target. These regional initiatives were discussed regularly with Kaiser's National Medicare Finance department, who shared successful initiatives with other regions. Often, regions would present these initiatives at Kaiser's Medicare Regional Reporting Group meetings so that other regions could duplicate their efforts.

~~118~~123. Kaiser set increasingly higher risk-score targets every year. As previously noted, the average risk score for Medicare beneficiaries under the CMS-HCC model is 1.0. But Kaiser set increasingly higher targets well above this 1.0 average. Kaiser's National Medicare Finance department increased these risk-score targets over time despite concerns from physicians that it created "a culture of 'meet the target at any cost.'"

~~119~~124. Kaiser worked to conceal this financial motive, especially documents that could

be disclosed in litigation. For example, in 2011, Karen Graham (Managing Director of the N. California Medical Group's Encounter Information Operations ("EIO") office) wrote to other members of the N. California Medical Group's management that "[i]n the past we've steered away from publicizing the dollar value of diagnoses, particularly in any printed / discoverable format." She reminded them that "[y]ou've heard Dr [David] Bliss put on his 'money grubbing' hat and comment in this fashion."

~~120~~125. Kaiser's risk-adjustment program was highly successful with respect to its goal of increasing Medicare revenue and increasing risk scores. When CMS began using the CMS-HCC model in 2004, most Kaiser regions had average patient risk scores of around 0.90, with some regions slightly above and some slightly below. Kaiser's 2004 risk score, slightly below 1.0, was consistent with research showing that Medicare Advantage beneficiaries are on average healthier, have lower medical spending, and use fewer medical services than traditional Medicare beneficiaries.[9] However, by 2014, after spending substantial resources on these risk-adjustment initiatives, Kaiser's average risk score increased to 1.16, with the California and Colorado regions meeting or exceeding this score. Put differently, Kaiser's risk-score initiatives enabled it to make its patient population appear sicker, allowing Kaiser to achieve a roughly 30% increase in Medicare revenue per patient than it would have received based on its 2004 average risk score. This risk-score increase translated into billions of dollars of additional Medicare revenue to Kaiser.

B. Kaiser mined patient medical records to add lucrative risk-adjustment diagnoses via addenda to achieve risk-score targets.

~~121~~126. In order to meet the ever-increasing risk-score targets set by Kaiser's National Medicare Finance Department, each region was expected to develop and implement initiatives to increase their average patient risk score. It was not sufficient for Permanente Medical Group physicians to simply have visits with their patients and identify those conditions relevant to the visits. Instead, the Defendant Kaiser Health Plans and Permanente Medical Groups created and implemented numerous initiatives aimed at raising patient risk scores.

~~122~~127. Kaiser made systematic efforts in the California and Colorado regions to increase risk scores by adding lucrative risk-adjustment diagnoses after a patient visit, even where the condition had nothing to do with the visit and, in many instances, even where the patient's medical record contradicted that the condition existed at the time. Kaiser—through the Kaiser Health Plans and the regional Permanente Medical Groups—used automated algorithms and human reviewers to mine its patients' medical files for potential additional diagnoses.

~~123~~128. After identifying potential diagnoses, Kaiser then had its physicians retrospectively add these diagnoses to the patients' medical records using addenda, as if the new

[9] See, e.g., Kaiser Family Foundation, Do People Who Sign Up for Medicare Advantage Plans Have Lower Medicare Spending? (May 2019), available at https://files.kff.org/attachment/Issue-Brief- Do-People-Who-Sign-Up-for-Medicare-Advantage-Plans-Have-Lower-Medicare-Spending (last visited Oct. 25, 2021); Jason Brown et al., How Does Risk Selection Respond to Risk Adjustment? Evidence from the Medicare Advantage Program, 104 Am. Econ. Rev. 3335 (2014); UnitedHealthcare Ins. Co. v. Becerra, 9 F.4th 868, 876 (D.C. Cir. 2021) (referencing studies finding "that Medicare Advantage insurers in fact have tended to attract healthier-than-average beneficiaries").

diagnoses were addressed in some way during the patient visits when, in fact, they were not, and many times without regard to whether they were contradicted by the medical record of the visit.

~~124~~129. An "addendum" is a part of a patient's medical record that is a note drafted by a physician that amends a previous note made by that same physician. In other words, an addendum is an addition to a patient's medical record made after the visit but linked to the record of that visit. Generally, a medical-record addendum is a means by which medical-record entries can be updated, corrected, or supplemented. An addendum can be used to clarify or correct a medical record that contains conflicting or insufficient information.

~~125~~130. Under CMS rules and guidance, as well as industry practice, addenda have legitimate uses. CMS recognizes the use of an addendum where it is related to a service that was provided during the visit. See CMS, Medicare Program Integrity Manual, Chapter 3 § 3.3.2.5(A); CMS, 2008 Risk Adjustment Data Technical Assistance Participant Guide § 6.4.2. An addendum must clearly delineate any amendment, including the date and author of the amendment, from the original content of the medical record, which must be preserved without deletion. CMS, Medicare Program Integrity Manual, Chapter 3 § 3.3.2.5(A).

~~126~~131. Kaiser, however, did not use addenda simply to timely clarify or correct medical records. ~~Some~~Many of the diagnoses that Kaiser added via addenda ~~did not even exist, and many more did~~were not current conditions and were contradicted by the patient's medical record. More broadly, Kaiser used addenda to make it appear as if the diagnoses were actually relevant to the visit when, in fact, they did not require or affect patient care, treatment, or management at the patient visit as required by the ICD Guidelines. Often, these addenda were added months or even a year or more after the visit so that Kaiser could obtain risk-adjustment payments for the newly added diagnoses.

~~127~~132. Broadly speaking, Kaiser pushed several types of initiatives to add diagnoses via addenda. These included "data mining" and "chart review," where Kaiser would utilize automated algorithms and/or human reviewers to identify brand-new diagnoses. Such never-before-diagnosed conditions should rarely, if ever, result in addenda because these diagnoses were, almost by definition, not relevant to the visit. Yet Kaiser routinely created addenda to medical records with these diagnoses and submitted them for payment, often without even telling the patient about these brand-new diagnoses.

~~128~~133. Kaiser also employed a related nationwide data-mining program called "refresh," where Kaiser would mine patient medical files to find old diagnoses that had not been diagnosed in the current service year.

134. Following a patient visit, if a physician failed to address any of these unrefreshed diagnoses, the physician would receive a list of these "missed-opportunity" diagnoses—i.e., opportunities for ~~risk-adjustment~~risk-adjustment payment. Because Kaiser had numerous different initiatives, physicians would often receive lengthy lists of both data-mined diagnoses and missed-opportunity diagnoses. Kaiser generated these lists without accounting for contradictory information in the medical record of the visit.

~~129~~135. Kaiser typically brought these new mined diagnoses to the physician's attention

through a query. As commonly defined in the healthcare industry, a "query" is any communication tool or process used to clarify documentation in the health record for accurate code assignment. This would encompass any communication to a physician, after the physician had a visit with a patient, relating to modifying, adding, or deleting any diagnosis in the patient's medical record for the visit. Queries can take any form; they can be written or oral.

~~130~~136. There are standards, discussed in more detail in paragraphs ~~185-216~~202-233, guiding and limiting the use of queries, including that a query cannot lead or be presumptive (i.e., cannot direct a provider to a specific diagnosis) and that a query cannot discuss the financial impact of a change to the patient's record. In general, queries are supposed to be limited to clarifying the medical record, for example to resolve conflicting information in the medical record. But Kaiser routinely violated the standards that apply to queries, and used queries not to clarify a medical record, but instead to add new diagnoses via addenda that had nothing to do with the record or the original patient visit, so that Kaiser could then seek higher payments from CMS.

137. As noted above with respect to the lists sent to physicians, Kaiser's risk-adjustment initiatives often suffered from an additional significant defect in failing to properly account for contradictory information in a patient's medical file, especially with respect to the patient visit at issue. Consequently, even if the medical record indicated the condition was historical or otherwise resolved, or documented clinical indicators that contradicted the current existence of the condition, Kaiser would often still query the physician after a visit to create an addendum to add the diagnosis. To make matters worse, Kaiser would often send queries that did not even alert its physician to the contradictory information in the medical record. The inevitable result was the widespread submission of invalid diagnosis codes for conditions that did not require or affect patient care, treatment, or management and whose very existence many times was contradicted by the patient's medical record.

~~131~~138. As an illustration of how this process worked, consider hypothetical Permanente Medical Group physician Dr. Smith. Through Kaiser's refresh process, Kaiser identifies diagnoses for each of Dr. Smith's MA patients prior to the visits. If Dr. Smith ~~were to~~does not re-diagnose all of these diagnoses at the visits for all of her patients, Kaiser would send Dr. Smith queries following those patient visits prompting her to add the remaining "missed opportunity" diagnoses after-the-fact through addenda. Then, Kaiser would mine the medical records for Dr. Smith's ~~patients~~ MA patients using electronic algorithms or human reviewers to identify potential new diagnoses for conditions that had never previously been identified for Dr. Smith's MA patients. After these potential new diagnoses were identified, Kaiser would begin sending Dr. Smith queries prompting her to also create addenda to add these new diagnoses for all of her patients. In this way, Dr. Smith would receive a continual stream of queries throughout the year prompting her to add her "missed-opportunity" and data-mining or ~~chart- review~~chart-review diagnoses, the overwhelming majority of which did not matter to her visits with her patients and many times would not even reflect actual current conditions at the time of the visits.

~~132~~139. As detailed below, each region employed similar although slightly different techniques.

1. Data mining generates new risk-adjustment diagnoses.

~~133~~140. Kaiser's "data mining" programs focused on identifying brand-new diagnoses, that is, diagnoses relating to conditions that no physician had ever diagnosed the patient as having. The programs identified these diagnoses using various algorithms that mined the patient's electronic medical records for key words, lab results, medications, clinical indicators, and other items that Kaiser believed might be suggestive of potential diagnoses that would increase risk-adjustment payments.

141. These programs and their algorithms, however, often failed to properly account for inconsistent information, especially in the medical record for the visit at issue. For example, if a patient previously had a high body mass index ("BMI"), Kaiser's programs many times would identify obesity-related diagnoses for the patient notwithstanding that the patient had lost weight (and thus had a lower BMI) by the time of the visit at issue. This same issue persisted for numerous other clinical indicators. Kaiser's algorithms often would likewise fail to properly account for other contradictory information, such as physicians identifying in the medical records that conditions were resolved, inactive, or did not exist.

142. These programs were further flawed because Kaiser would often generate after-visit queries based on previously run algorithms that relied upon outdated information (i.e., they did not take into account later information, such as what occurred at the visit). Kaiser would generally not confirm before querying physicians to ensure that newer contradictory information had not arisen after the algorithm was run. For example, a data-mining algorithm may be run at the beginning of the year and identify a potential diagnosis based on information from a visit in the prior year. If the patient visit occurred after the algorithm was run, Kaiser would then generate queries related to the data-mined diagnosis without regard to what occurred at the visit. As a result, even if the clinical indicators at the time of the visit showed that the condition did not exist, Kaiser would often still query the physician for the data-mined condition and would not alert the physician to the contradictory information. Internally, Kaiser identified these data lag issues as a threat and weakness of their data-mining and refresh programs.

~~134. As~~143. These flaws, however, did not deter Kaiser from using these programs because, as Kaiser made clear in internal training materials, "[d]ata mining is used to improve reimbursement," i.e., to increase payments from CMS.

~~135~~144. In keeping with that aim, Kaiser focused only on diagnoses that would impact HCCs and increase risk scores. For example, when two Northern California auditors, Steven Simos and Ellen Lingar, discussed data mining for another medical condition that was associated with development of a cancer with a high mortality rate but that would not have resulted in increased payments to Kaiser, the response from Danielle Sheetenhelm (Clinical Review Manager), was that "our strategy is to only explore data mining suggestions for conditions that are in the CMS MA model or ACA model."[10]

~~136~~145. Similarly, Kaiser focused only on those patients for whom Kaiser could receive a ~~risk-adjustment~~risk-adjustment payment. For example, Kaiser provided medical care to some traditional (fee-for-service) Medicare beneficiaries. Kaiser did not apply its data-mining

[10] When the Affordable Care Act ("ACA") was implemented in 2014, it provided for additional risk-adjustment payments from the Government for ACA patients.

algorithms to these traditional Medicare patients and instead applied them only to Medicare Advantage patients for whom Kaiser could receive additional payments from CMS.

~~137~~146. Kaiser organized a large Risk Adjustment Data Mining Workgroup to collect, analyze, and disseminate information throughout Kaiser on data-mining initiatives, including effective algorithms and return on investment. This working group was comprised of representatives from the Kaiser Health Plans, including each regional health plan, as well as representatives from each regional Permanente Medical Group. Every region was represented, both from the Kaiser Health Plans and the Permanente Medical Groups. The working group was sponsored by an executive from Kaiser's National Medicare Finance department (Diane Morissette) and the Associate Executive Medical Director from the Permanente Federation (Dr. Simon Cohn). The chairs included Ken Nelson (the Health Plan's Director of Risk Adjustment Analytics) and Relator Dr. James Taylor (Director of Coding for the Colorado Medical Group). The working group grew over time to nearly 40 members across Kaiser's regions and entities.

~~138~~147. Kaiser's National Medicare Finance department also organized a smaller predecessor group called the HCC Data Mining Workgroup. That workgroup had similar information sharing goals, with representatives from each of the regions.

~~139~~148. The Risk Adjustment Data Mining Workgroup met approximately monthly and ensured that information regarding data mining was widely dispersed across Kaiser. Each region presented at the meetings regarding its data-mining activities and results. Topics included data-mining initiatives, tracking initiatives, algorithm-improvement ideas, and addenda to medical records. The workgroup's activities were further presented to a broader audience within Kaiser, including presentations to the Medicare Regional Reporting Group.

~~140~~149. Kaiser's data-mining programs covered an extensive range of potential diagnoses. The Health Plan ran algorithms nationally for all MA patients and distributed the results to each region. In addition, individual regions developed their own algorithms and initiatives, which they regularly shared at workgroup meetings. For example, in 2014, the N. California Medical Group developed data-mining algorithms covering over 30 risk-adjusting diagnoses, which it shared with the workgroup so that these algorithms and initiatives could be duplicated in other regions.

~~141~~150. Many of these diagnosis-specific algorithms coincided with regional initiatives. For example, the N. California Medical Group created an initiative in 2012 to focus on four "key conditions": protein calorie malnutrition, diabetes with neurological manifestations, aortic atherosclerosis, and chronic kidney disease. Each of these diagnoses matched up with a data-mining algorithm run in the region. Kaiser expected each facility in the region to hit a specified prevalence rate for each condition. And Kaiser instructed the facilities that forty percent of their monetary performance allocation would depend on how well they captured these four conditions (the remaining sixty percent was based on how well they "refreshed" diagnoses, discussed in the next section). Each facility was required to develop work plans for how it would meet the diagnosis capture rate. For example, one facility stated that it would make data mining a parameter for physicians when receiving their mid-year and year-end "CMS Performance incentive."

~~142~~151. Other data-mining algorithms focused on particular patients. For example, at the

urging of Kaiser's National Medicare Finance department, Kaiser encouraged the regions to run algorithms to address and review any MA patients who did not have any diagnoses resulting in a risk-adjustment payment.

~~143~~152. Another version of data mining, called Natural Language Processing, was developed by the Southern California region and led by Dr. Paul Minardi (the S. California Medical Group's Medical Director of Operations). Natural Language Processing involved sophisticated algorithms that purported to better read the natural language of medical records to identify potential undiagnosed diagnoses. Kaiser ultimately expanded the use of Natural Language Processing algorithms to every region across the country.

~~144~~153. Generally, once the algorithm results were released, it was up to each region to determine how to turn those results into risk-adjustment payments. For the most part, this task fell to the Permanente Medical Groups, but in some cases the Health Plan communicated directly with Permanente Medical Group physicians about potential diagnoses identified via algorithm.

~~145~~154. In the Colorado region, the Colorado Health Plan and the Colorado Medical Group jointly developed data-mining algorithms to support various risk-adjustment initiatives. Auditors from the Colorado Health Plan would then use the results to send a template Medicare Query directly to the physicians with the suspected diagnosis to ~~addend~~add to the medical record via an addendum.

~~146~~155. Initiatives were sometimes sparked by the prospect of reduced revenue from Medicare based on existing diagnoses. For example, when CMS made changes to the CMS-HCC model related to the diagnosis of hypoxia (a below-normal level of oxygen), the Colorado Health Plan identified patients on oxygen in an effort to generate other diagnoses that would result in risk-adjustment payment. Health plan auditors queried the patients' physicians to create addenda adding suspected diagnoses of (1) acute and/or chronic respiratory failure and (2) obesity hypoventilation syndrome to patient medical records. The auditors sent these queries even if the patients already had diagnoses, such as hypoxia, that would serve as a basis for the oxygen. The query—which was drafted in conjunction with Dr. Teresa Welsh (the Colorado Medical Group Director of Coding)—instructed physicians that hypoxia (and several other common diagnoses for which patients may receive oxygen) ~~was~~were insufficient for reimbursement ~~and identified acute respiratory failure as an appropriate alternative diagnosis~~.

~~147. Colorado used this initiative~~156. The query had several additional flaws. The query informed physicians that acute respiratory failure was an appropriate alternative diagnosis for hypoxia even though Dr. ~~Teresa~~ Welsh, the query's author, acknowledged to the Kaiser Risk Adjustment Data Mining Workgroup that it was not clear that patients with hypoxia could be categorized as having acute respiratory failure.

157. Moreover, the query identified obesity hypoventilation syndrome as a suspected diagnosis for all patients on oxygen. But as its name suggests, obesity hypoventilation syndrome exists only in obese patients. In the CMS-HCC model, it maps to the morbid-obesity HCC. However, Kaiser sent this query to physicians even when patients were not obese and therefore could not have this condition, and Kaiser did not inform the physician that this contradictory information existed in the patient's medical record.

~~148~~158. In general, queries to the physicians were generated in two circumstances: (1) when data- mined diagnoses were identified through algorithms run after a patient visit had already occurred; or (2) if the data-mined diagnosis was previously released to the physician but not diagnosed at a visit. The queries themselves often violated numerous query standards, as further detailed below.

~~149~~159. In some regions, in particular Northern California, a physician could not simply reject a data-mined diagnosis and end the issue. Instead, the physician was required to draft a justification for the decision—referred to internally as a "stop prompt" (i.e., a request for the organization to stop prompting the diagnosis)—which was required to be reviewed and approved by other employees in the organization. These stop prompts are discussed in greater detail later in the ~~complaint~~Amended Complaint.

~~150~~160. The Kaiser regions developed various tracking mechanisms so that they could monitor the success of their data-mining initiatives. These tracking mechanisms were regularly discussed and shared across Kaiser regions and entities, including through the Risk Adjustment Data Mining Workgroups. Some of these tracking mechanisms specifically tracked how many addenda were generated and how much risk-adjustment compensation would be received. Similarly, details about data-mining programs were reported in the risk-adjustment improvement plans that were provided to the Kaiser Health Plans. In other cases, for example in Northern California, special computer programs were utilized that routinely notified physicians of their metrics relating to addressing data-mined diagnoses, and physicians were instructed that they were expected to meet certain targets. The N. California Medical Group monitored these metrics for physicians and facilities.

2. "Refresh" and "missed-opportunities" are more data-mining programs that generate risk-adjustment diagnoses.

~~151~~161. Another category of Kaiser's data-mining efforts focused on capturing diagnoses that had been made in a prior year. Kaiser referred to this program as "refresh" and to conditions that needed to be captured as "unrefreshed diagnoses." Kaiser created algorithms that mined patients' electronic medical records for any diagnoses that had been made in any setting during the past several (typically three) years. As previously noted, however, the algorithms that identified these historical diagnoses many times failed to properly account for contradictory information in the medical record. Consequently, even if a medical record was inconsistent with the condition—for example, if the medical record indicated the condition was historical or otherwise resolved, or the clinical indicators for the visit contradicted the actual existence of the condition—Kaiser would many times not remove the diagnosis from the refresh program.

162. As detailed below, Kaiser meticulously monitored and tracked these diagnoses, and if a physician failed to re-diagnose these conditions at a patient visit, Kaiser would systematically pressure the physician to add the diagnoses via addenda, as it did with its other data-mining efforts.

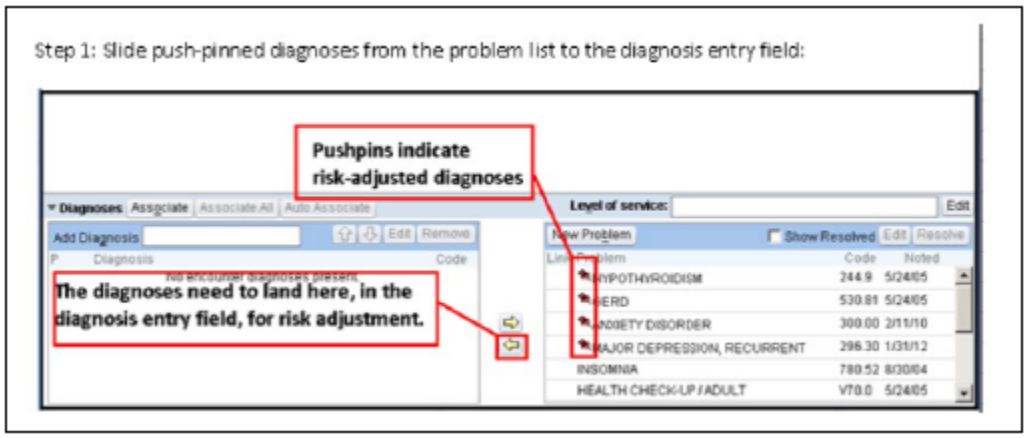
~~152~~163. As with the data-mining programs, the refresh program was focused on obtaining risk- adjustment payments. The program only identified "unrefreshed diagnoses" for which Kaiser could obtain a risk-adjustment payment. Kaiser excluded any diagnosis that did not

correspond to an HCC and would not result in an increased payment. Similarly, only patients for whom Kaiser could obtain a risk-adjustment payment were included. In fact, as risk-adjustment payments became available through other programs, such as the Affordable Care Act, Kaiser honed its algorithms to ensure that physicians had to refresh only the specific risk-adjusted diagnoses covered by the patient's specific program (e.g., ACA).

~~153~~164. Refresh was a nationwide Kaiser program, with small adaptations in each region. At a Medicare Regional Reporting Group meeting in October 2006, Dr. Simon Cohn (Associate Executive Director of the Permanente Federation), Sue Gertz (Vice President, Medicare at the Health Plan), and Diane Morissette (National Director for Medicare Risk Adjustment, National Medicare Finance for the Health Plan) jointly presented on improving diagnosis capture for Medicare risk-adjusted payments. A key aspect of the presentation concerned unrefreshed diagnoses, which the presentation noted Kaiser tracked and was estimated to be a $400 million opportunity for Kaiser in 2006 alone. Kaiser instructed each region to reduce unrefreshed diagnoses by two-thirds in 2006 and by two-thirds again in 2007.

~~154~~165. Kaiser's National Medicare Finance department identified and monitored unrefreshed diagnoses on a regular basis and shared results with each region, some of which also ran their own algorithms to identify and monitor unrefreshed diagnoses. Each region was required to discuss their refresh program annually with Kaiser's National Medicare Finance department as part of their risk- adjustment improvement plans. Refresh was also regularly discussed amongst the regions and Kaiser entities as part of the Medicare Regional Reporting Group and the Risk Adjustment Data Mining Workgroup.

~~155~~166. Much of the refresh program related to capturing diagnoses during the patient visit. Kaiser expended enormous efforts throughout its regions to ensure that a physician could easily find any refreshable diagnosis at the visit. For example, physicians would generally be given a list of refreshable diagnoses prior to each patient visit either in paper or electronic format. Further, Kaiser utilized "pushpins" in its electronic health record to flag these diagnoses. If a physician reviewed a patient's problem list during a visit, the risk-adjusted diagnoses were specifically flagged with a "pushpin." All a physician had to do was press one button to "slide" any risk-adjusted diagnoses to the medical record for the visit. In fact, this process was so easy that some within Kaiser expressed concern that physicians were adding old diagnoses that were incorrect or no longer existed. As one internal Kaiser presentation explained, "pushpins indicate risk-adjusted diagnoses" and those "diagnoses need to land here, in the diagnosis entry field, for risk adjustment":



~~156~~167. To make things even easier for physicians, Kaiser also developed a tool within the electronic health record called a chronic-disease widget or chronic-disease grid. This tool automatically populated a patient's medical record for the visit with these conditions, and physicians merely needed to add a status update for the conditions.

~~157~~168. In short, Kaiser physicians were presented with numerous lists and tools that made it easy for them to identify and add refreshable diagnoses to a visit record at the time of the visit. These tools also made it all the more inappropriate for Kaiser to query physicians after a visit to add "missed opportunity" diagnoses for which there was no indication in the medical record that the diagnoses had any impact on patient, care, treatment, or management at the visit.

~~158~~169. In many circumstances, Kaiser physicians did not actually consider or address all of a patient's prior diagnoses at a visit. For example, if a patient presented with an acute medical condition, the physician might spend the visit addressing that specific acute condition. Yet, Kaiser engaged in systematic efforts to have physicians add unrefreshed diagnoses via addenda that had nothing to do with the visit so that Kaiser could obtain additional risk-adjustment payments.

~~159~~170. When a physician did not "refresh" (i.e., re-diagnose) at the patient visit all of the diagnoses identified by Kaiser through the refresh program, Kaiser would begin efforts to have the physician retrospectively add these diagnoses to the medical records for the visit via addenda. These "missed" refresh diagnoses had different names in different regions. For example, they were labeled "missed opportunities" in the Northern California region or "not fully refreshed" in the Colorado region. For purposes of this ~~complaint~~Amended Complaint, these diagnoses will be referred to as "missed-opportunity" diagnoses, and the allegations here concern Kaiser's systematic and improper addition of these ~~missed-opportunity~~missed- opportunity diagnoses via addenda when Kaiser knew that these diagnoses were not allowed to be coded under the ICD Guidelines.

~~160~~171. Similar to data mining, once Kaiser identified a missed-opportunity diagnosis, it began sending the physician queries to add the diagnosis to a visit record. In most instances, the queries were generated by the Permanente Medical Groups. As further detailed below, these queries routinely violated national standards. Often, these queries came in the form of lists (often stretching multiple pages) labeled missed-opportunity reports or sheets, unaddressed diagnosis

reports, refresh lists, and not-fully-refreshed reports. These lists compiled the unrefreshed diagnoses for a physician's patients. Many of these lists came with specific instructions as to how the physician could create an addendum to the record of the visit, including with suggested language to be included in the addendum. As explained in more detail below, these instructions routinely ignored the ICD Guideline requirement that the diagnoses needed to have mattered to the visit, and instead provided contrary instructions to physicians.

~~161~~172. If a physician did not address a condition on the list—e.g., by creating an addendum to add the diagnosis to a visit—the physician would continue to receive additional queries for the diagnosis. Depending on the facility, the physician might receive the list on a weekly to monthly basis. In some cases, these lists also included potential new diagnoses identified from data-mining initiatives. If a physician did not respond to the queries, the physician would often receive follow-ups from Permanente Medical Group employees, either in person or by email.

~~162~~173. In some instances, physicians had to obtain permission in order to delete a diagnosis on a refresh list, similar to the process for data mining. For example, the Northern California region created a process whereby a physician who believed that a diagnosis identified through the refresh program was invalid had to submit a stop-prompt request in order to not assign the diagnosis. Other Kaiser employees would then review the request to determine if the stop was appropriate before it could be removed.

174. Through these queries, Kaiser often failed to alert physicians to information that directly contradicted the existence of the condition, leading to the addition of many inaccurate diagnoses via addenda, and the resulting submission of inaccurate diagnosis codes to CMS for risk-adjustment payments.

175. For example, in one instance, a patient was seen by Bradley Reynolds, an orthopedic physician assistant ("PA") for a physical exam for left knee pain. The visit had nothing to do with malnutrition, with no documented clinical indicators for malnutrition. The patient was documented to be obese at the visit. As a result of Kaiser's flawed refresh program, the PA addended the diagnosis of malnutrition to the orthopedic visit record. Kaiser further failed to alert the PA that it had also prompted the patient's primary care physician to refresh malnutrition, but that physician documented that the patient did not have malnutrition. The Health Plan submitted the diagnosis code for malnutrition and received a risk-adjustment payment based upon this submission. The Health Plan was not entitled to this risk-adjustment payment because the patient did not have malnutrition, as the primary care physician documented, and the condition did not require or affect patient care, treatment, or management during the visit.

176. In another instance, a patient was seen by Dr. Donald Perez, a head and neck surgeon, for a throat issue. The visit again had nothing to do with malnutrition, and the patient was documented to be obese and "well nourished" at the visit. Kaiser failed to alert the physician that the patient's medical record was inconsistent with malnutrition, both because she was documented to be "well nourished" at the visit and her most immediate prior test results were inconsistent with malnutrition. As a result of Kaiser's flawed refresh program, Dr. Perez addended malnutrition to the visit record. The Health Plan then submitted the diagnosis code for

malnutrition and received a risk-adjustment payment based upon this submission. The Health Plan was not entitled to this risk-adjustment payment because the patient did not have malnutrition, and the condition did not require or affect patient care, treatment, or management during the visit.

177. Similarly, Kaiser physicians who were requested to add diagnoses through addenda many times would comply with Kaiser's request by creating addenda documenting that the patient had a history of the condition. The ICD Guidelines provide that a historical condition may be coded with a specific historical condition code. As previously noted, with rare exception not applicable here, the CMS-HCC model only provides for risk-adjustment payments based on active condition diagnosis codes, not historical codes. However, instead of using historical condition codes, as required by the ICD Guidelines, Kaiser would submit an active condition code with the condition, even though the physicians documented the condition as historical. This regularly occurred with respect to conditions that may be temporary or resolve over time with treatment, such as cancers, stroke, irregular heart rhythms, blood disorders, malnutrition, obesity-related conditions, and numerous others.

178. Kaiser knew that it had ongoing issues submitting active condition diagnosis codes when the condition was historical. Internal documents indicate that Kaiser was aware that its risk-adjustment initiatives were generating inaccurate diagnoses, including identifying, for example, that refresh reports would ask for a diagnosis to be refreshed even though it was only captured as a history of the condition.

179. Other internal documents identified this as a key problem area for cancer and stroke in particular. Yet, Kaiser failed to ensure that conditions documented as historical in addenda created through these programs would not be submitted as active, existing condition diagnosis codes. As a result, Kaiser frequently submitted active, existing condition diagnosis codes to CMS to receive risk- adjustment payments even when the physician documented the condition as historical in the addendum.

~~163~~180. Kaiser closely tracked ~~these~~ missed-opportunity diagnoses and expected physicians and facilities to meet targets for refreshing diagnoses. For example, as part of its mandatory risk-adjustment improvement plan (shared with Kaiser's National Medicare Finance department), the N. California Medical Group set a goal that its physicians would "refresh" 99% of diagnoses identified by Kaiser. In fact, by 2012, the Northern California region had achieved a 99.2% "refresh" rate of all diagnoses identified through the program. The region relied so heavily on the refresh program that Karen Graham (Managing Director for EIO) described it to colleagues as the region's "bread & butter." Other regions had similar results.

~~164~~181. These increasingly high targets caused physicians to improperly addend diagnoses to meet Kaiser's metric expectations. Kaiser provided recognition and awards, such as bottles of champagne, to high achievers. That included physicians who were able to "refresh" 100% of diagnoses for all patients, an achievement that would seem virtually impossible if the ICD Guidelines were being properly followed.

~~165~~182. All of Kaiser's efforts, including those described in more detail below, created pressure on physicians to refresh missed-opportunity diagnoses contrary to ICD Guidelines.

These efforts accelerated toward the end of each year when physicians were expected to meet their year-end targets, and when the Kaiser regions were focused on meeting their increasingly high risk-score targets for the year. Missed-opportunity diagnoses were routinely added to visits that happened much earlier in the year without regard to whether the diagnoses had any relevance to the visit or were properly coded under the ICD Guidelines. This end-of-year rush in activity was referred to by some Kaiser employees as the "dash for cash."

3. Chart review is another program to generate risk-adjustment diagnoses.

~~166~~183. The Colorado region created another program, the "chart review" program, to generate more Medicare revenue. As one Colorado training slide explained, "Medicare Queries: Why Now?," and provided the answer, because "Diagnoses = Revenue."

~~167~~184. Similar to data mining, the chart-review program focused on identifying brand-new diagnoses after a patient visit occurred to increase Medicare risk-adjustment payments to Kaiser. After a visit, physicians received a "Medicare Query" to add new diagnoses to the medical record for the visit, even though the diagnoses played no role in the visit. Indeed, "the goal [of the program] is to identify diagnoses that have never yet been made by a physician . . . ." Such a goal was inconsistent with the ICD Guidelines, which permit coding of only those diagnoses that ~~require or affect~~both existed at the visit and required or affected patient care, treatment, or management for a visit. Instead, Kaiser submitted thousands of improper diagnoses added via addenda for tens of millions of dollars in risk-adjustment payments.

~~168~~185. The Colorado Medicare Group and the Colorado Health Plan jointly ran and funded this chart review program. Key players included: Dr. Teresa Welsh (the Colorado Medical Group Director of Coding); Jeremy Walsleben (the Colorado Health Plan's Senior Manager of Risk Adjustment); and Maegen Leake (the Colorado Health Plan's Senior Risk Adjustment Operations Consultant). In addition, auditors from the Colorado Health Plan sent Medicare Queries to physicians for various HCC conditions.

~~169~~186. With funding from the Colorado Health Plan, the Colorado Medical Group paid chart- review physicians to review the medical records of Colorado Health Plan beneficiaries for conditions on "the Review Grid to find additional diagnoses that you will query for." (Emphasis in original.) In 2014, the "review grid" covered more than 50 risk-adjusting diagnoses.

~~170~~187. The reviewers were instructed to identify only potential new diagnoses. The reviewers were further instructed that if they identified a new diagnosis that was in the same category (i.e., that corresponded to the same HCC) as another diagnosis that was already made, the reviewers should not send a query to the physician. Under the CMS-HCC model, an MA Organization can only receive a risk-adjustment payment once per HCC, so if a patient has two conditions that correspond to the same HCC, the HCC risk factor is counted only once. Accordingly, because this potential new diagnosis would not yield additional revenue to Kaiser, the chart reviewers were told not to send a query.

~~171~~188. All of the conditions on the Review Grid were lined up with Medicare HCCs, even listing the HCC number. When CMS changed the CMS-HCC model, the Colorado chart-review program updated its Review Grid to remove conditions that no longer corresponded to

HCCs and to add new conditions that corresponded to new HCCs.

~~172~~189. As Dr. Teresa Welsh (who led the program) explained, it was necessary to pay chart- review physicians to conduct the chart review because most physicians found it too time consuming or technologically demanding.

~~173~~190. The chart reviews were conducted after patient visits. Even though the chart reviewers were identifying conditions that had never been previously diagnosed, and the physicians were unaware of them during their patient visits, chart reviewers were instructed to send "Medicare Queries" to physicians every time they identified a potential new diagnosis.

~~174~~191. A typical example would involve a patient whose visit was entirely unrelated to the queried condition. Following the visit, the physician would be queried to add a suspected diagnosis, such atherosclerosis of the aorta (hardening of the walls of the aorta), based on a historical radiology report from years prior. The medical record would contain no indication that the physician was aware of this historical report at the patient visit, let alone that the physician considered or addressed the condition at the patient visit. Often, the addendum would just include the diagnosis or would copy portions of the query into the medical record. The medical record would likewise contain no indication that the physician even contacted the patient about the brand-new diagnosis.

~~175~~192. The chart review program violated the ICD Guidelines because it involved the systematic creation of addenda for conditions that were entirely unrelated to the visit. Because the explicit purpose of the program was to identify "new" diagnoses that had never been made by a physician, a physician queried to add a chart-review diagnosis could not have been previously aware of the condition, and certainly could not have considered, evaluated, or treated the condition at the visit. The ICD Guidelines therefore prohibited the coding of such conditions, yet Kaiser submitted thousands of such diagnoses for tens of millions of dollars in risk-adjustment payments.

~~176~~193. Money was the clear driver of the program. Kaiser did not conduct these chart reviews for patients for whom they could not receive risk-adjustment payments, nor for conditions for which they could not receive such payment. Moreover, physicians were told not to spend any significant time addressing the suspected new diagnoses. Dr. Teresa Welsh wrote to clinician supervisors that physicians should not "spend more than 1 minute a query" because responding to queries was "like doing a refill request" and that she could do "two a minute." When discussing the Medicare Queries, Kaiser physicians repeatedly discussed that each added diagnosis was worth approximately $3,000 to Kaiser.

~~177~~194. Physicians at the Colorado Medical Group were required to respond to queries. The Colorado Medical Group and the Colorado Health Plan tracked which physicians had open queries. When physicians had significant open queries, their clinical chiefs would be asked to address the problem with the physicians. If a physician was deleting too many queries (i.e., not adding the suspected diagnoses to the medical record), Dr. Teresa Welsh might address the issue with the physician. If that did not work, sometimes Dr. Welsh would have a meeting with them. Dr. Welsh even suggested that physicians with open queries could be placed on a performance improvement plan.

~~178~~195. To further pressure physicians to respond to queries, the Colorado Medical Group and the Colorado Health Plan created a physician incentive program, to pay physicians to respond to queries. Jeremy Walsleben managed the program and determined which Colorado Medical Group physicians would be eligible for the incentive and the amount of the payment. As one of the Colorado Medical Group's chief clinicians, Dr. Jennifer Ziouras, stated in support of the incentive payment: "we are just trying to get paid for the work that we are doing, esp[ecially] when we have to go back and addend things [because] they were not on our radar (atherosclerosis of the aorta, obesity equivalent, etc)."

~~179~~196. The Colorado Medical Group and the Colorado Health Plan meticulously tracked the results of the chart-review and query program. The reviewer instructions stated that Kaiser would track both queries and addenda to identify which diagnoses were captured. In fact, Kaiser tracked all chart reviewers, all physicians, and all Kaiser facilities to determine the results of the chart reviews.

~~180~~197. Through a regularly updated dashboard, the Colorado Medical Group and the Colorado Health Plan tracked every physician and facility for how many diagnoses they added via addenda and how much revenue they generated through those addenda. The Colorado Health Plan generated spreadsheets that were shared with the Colorado Medical Group tracking any open Medicare queries and which queries led to addenda.

~~181~~198. The Colorado Medical Group and the Colorado Health Plan likewise tracked the overall number of queries, addenda, revenue generated, and return on investment for the program. For example, the Colorado Health Plan calculated as part of an internal financial analysis that, in 2014, the chart- review program generated 10,900 queries, leading to 9,432 addenda and $17.4 million in risk- adjustment revenue. Similarly, in 2013, the Colorado Health Plan calculated that the chart-review program resulted in 11,388 HCCs added through addenda, generating $24.9 million in risk-adjustment revenue. Calculations for other query programs involving data mining showed that they generated thousands of queries and addenda, resulting in millions of dollars in risk-adjustment revenue. These reports were widely circulated, including to Kaiser's National Medicare Finance department.

~~182~~199. The Colorado Medical Group and the Colorado Health Plan even tracked all chart reviewers to identify which reviewers were generating sufficient revenue. Reviewers were placed in quadrants based on speed and effectiveness at getting diagnoses added to medical records.

~~183~~200. The Colorado Health Plan provided weekly reports to Dr. Teresa Welsh to monitor the progress of the program. At times, if she thought the number of queries generated was too small, Dr. Welsh suggested placing more resources into querying physicians to ensure that the Colorado Health Plan and the Colorado Medical Group would hit the risk score targets set by the National Medicare Finance department.

C. Kaiser pressured physicians to add diagnoses via addenda.

~~184~~201. After refresh, data-mining, or chart-review processes identified potential diagnoses, the next step in Kaiser's scheme was to pressure physicians to generate addenda to add these diagnoses retrospectively to the records of their past visits with their patients. As

described below, Kaiser applied this pressure ~~even when the diagnosis in question did not require or affect patient care, treatment, or management at the patient visit being amended~~without regard to what actually occurred at the visits.

1. Inappropriate queries pressured physicians to create addenda.

~~185~~202. One mechanism through which Kaiser applied pressure to physicians was through inappropriate queries to physicians.

~~186~~203. Kaiser's queries came in various forms. Sometimes, an auditor or other Kaiser employee would send a direct "staff message" (essentially an email within Kaiser's electronic health record) to a physician, requesting that the physician review and add a specific diagnosis from one of Kaiser's risk- adjustment initiatives to a patient visit. Other times, the queries came in the form of lists of multiple diagnoses for various patients. These lists often compiled unaddressed diagnoses from various risk- adjustment initiatives, routinely listing CMS as the payor so that it was clear to the physician why they were being asked to consider the addendum. Depending on the facility, physicians would generally receive such lists on a weekly to monthly basis. If the physician did not address the diagnoses on the list, the list would keep growing.

~~187~~204. As these programs became more sophisticated, some Kaiser regions developed electronic tools so that physicians could access these lists via computer. For example, the N. California Medical Group instructed physicians to use a particular electronic report that was available on their desktop "as your default page [to] look for addendum and capture opportunities after the visit (Missed Dxs [diagnoses])." (Emphasis in original.)

~~188~~205. Still other times, the queries came orally. For example, data-quality trainers or other similar Kaiser employees would meet with physicians in person to work on their lists of diagnoses.

~~189~~206. Several regions, including both California regions, would have group coding sessions where data-quality trainers, and other similar Kaiser employees, would meet with physicians while the physicians coded their refresh lists. At these sessions, physicians would be expected to sit together, perhaps at lunch or after work with food and beverages provided by Kaiser, and work through their lists of specified diagnoses to add to patient visits. These sessions were sometimes called "coding parties" or "refresh parties."

~~190~~207. Kaiser's various query practices violated national standards relating to queries.

~~191~~208. The American Health Information Management Association ("AHIMA") is an organization that sets national coding standards and provides standards for proper query language. Kaiser has incorporated the AHIMA standards into its own policy documents and training materials.

~~192~~209. As far back as 2006, Kaiser issued a Program Advisory (the "Addenda Program Advisory") to all its regions that was "intended to clarify under what circumstances addenda to the medical record will be considered acceptable as support for risk adjustment data submitted to [CMS]." The designated points of contact for the Addenda Program Advisory were: Dr. Simon Cohn (Associate Executive Director for the Permanente Federation); Gina Reese (Senior

Counsel for Kaiser Foundation Hospitals and Health Plans); and Janet Franklin (at the time, a Practice Leader, Coding Compliance, with the National Compliance Office).

~~193~~210. There are some specific rules for queries set forth in the AHIMA standards and Kaiser's Program Advisory. First, the standards set by AHIMA and adopted by Kaiser make clear that queries cannot be leading; in other words, they cannot suggest a particular diagnosis. In general, queries should be written as open-ended or multiple-choice questions, so that they do not sound presumptive, directing, or prodding to the physician.

~~194~~211. AHIMA's 2008 practice brief, "Managing an Effective Query Process," provides that "Queries that appear to lead the provider to document a particular response could result in allegations of inappropriate upcoding. The query format should not sound presumptive, directing, prodding, probing, or as though the provider is being led to make an assumption." AHIMA's 2013 practice brief, "Guidelines for Achieving a Compliant Query Practice," which replaced the 2008 practice brief, provides that "[a] leading query is one that is not supported by the clinical elements in the health record and/or directs a provider to a specific diagnosis or procedure."

~~195~~212. Kaiser's Addenda Program Advisory specifically cited the 2001 AHIMA practice brief (which was superseded by the 2008 version) for the requirement that queries be "open-ended" and avoid "leading" physicians to a particular diagnosis. As the Addenda Program Advisory explained, "physician queries must be carefully drafted such that undue pressure is not placed on the physician to code the diagnoses in the manner indicated on the query and/or otherwise interfere with physician decision- making." It further stated that "[q]ueries that appear to lead the physician to provide a particular response could lead to allegations of inappropriate upcoding." It also stated that queries such as "'Please enter the following diagnoses in the record' (followed by a list of diagnoses and codes[])" were not appropriate. Similarly, relying on the 2008 AHIMA practice brief, a 2011 Northern California training instructed that "[t]he query format should not sound presumptive, directing, prodding, probing, or as though the provider is being led to make an assumption."

~~196~~213. Second, queries cannot mention money; they are not allowed to include any discussion of the financial impact of altering a patient's medical record.

~~197~~214. AHIMA's 2008 practice brief states that "the query should never indicate that a particular response would favorably or unfavorably affect reimbursement or quality reporting." And AHIMA's 2013 practice brief states simply that a query "should not indicate the impact on reimbursement." Kaiser's Addenda Program Advisory similarly stated that queries "should not indicate the financial impact of the response . . . ." And a 2014 training given by Nancy Andersen (then a Senior Compliance Manager with Kaiser's National Compliance Office) provided the same guidance.

~~198~~215. Third, because a query is intended merely to clarify the medical record, queries cannot introduce new information not previously documented in the medical record.

~~199~~216. AHIMA's 2008 practice brief states that "[t]he introduction of new information not previously documented in the medical record is inappropriate in a provider query." The 2008

practice brief then gives an example of an inappropriate query where a physician is given information about a diagnosis and clinical information from an emergency room record from the prior week. The practice brief states that this is inappropriate to query the physician because the diagnosis and information (from the emergency room) was not documented by the physician in the medical record of the current visit. In compliance trainings, Kaiser similarly repeatedly instructed that a query "should not introduce new information not otherwise contained in the medical record." These trainings emphasized that a query is permissible only "to the extent it provides clarification" of the medical record.

~~200~~217. In practice, however, the queries Kaiser sent to physicians frequently ran afoul of the standards set by AHIMA and Kaiser's Addenda Program Advisory.

~~201~~218. For example, a 2012 query sent by Priscilla Schor (an auditor in Southern California) was leading. It told the physician, Dr. Grace Jean Fu, regarding her patient: "You saw this patient on 7/3/12. Based on a chest x-ray dated 7/3/12 this patient has Atherosclerosis of Aorta. Please create an addendum to ADD the diagnosis to your 'diagnosis order entry' box." Dr. Fu created an addendum to her patient's medical record to add the diagnosis of aortic atherosclerosis after receiving the query.

~~202~~219. A query sent by Data Quality Trainer Shannon Henson in Northern California in 2013 was also leading. It informed the physician, Dr. Sri Madhavi Cholleti, regarding her patient, that "[a]fter review it was found that the diagnosis, AORTIC ATHEROSCLEROSIS, is supported by Imaging Report dated 10/15/12. Please addend your visit note dated 01/04/13 to include this diagnosis. If you do not agree, please provide me with your reason so I may forward to Dr Awsare for review." Dr. Cholleti created an addendum to her patient's medical record add the diagnosis of aortic atherosclerosis after receiving the query.

~~203~~220. A query sent in 2014 in Northern California by Dr. Amy Hung was similarly direct about the desired outcome. It told the physician, Dr. Luu Phuc Nguyen, regarding his patient, simply: "Could you please addendum 'thrombocytopenia' to your visit …?" Thrombocytopenia is a condition where a patient has a low blood platelet count. Dr. Nguyen had seen the patient nine months earlier for leg pain and cramping. Dr. Nguyen created an addendum to his patient's medical record ~~add~~stating the ~~diagnosis~~patient "has hx [history] of thrombocytopenia~~ after receiving the query.~~." The Health Plan then submitted the diagnosis code for the active condition of thrombocytopenia and received a risk-adjustment payment based upon this submission. The Health Plan was not entitled to this risk-adjustment payment because the physician documented that the patient had a history of thrombocytopenia, not the active condition, and the condition did not require or affect patient care, treatment, or management during the visit.

~~204~~221. A 2012 query in Southern California from Compliance Auditor Rey D. Creencia inappropriately mentioned money. It asked that the physician, Dr. Gallit Slonimsky Luftman, add a new diagnosis, aortic atherosclerosis, to her patient's last visit, explaining that "[t]he Medicare Unrefreshed Risk project requires that we report a diagnosis at least once a year to be reimbursed for treatment for the patient for the entire year." Dr. Luftman created an addendum to her patient's medical record add the diagnosis of aortic atherosclerosis after receiving the query.

~~205~~222. Queries often were both leading and mentioned money. For example, a 2013 query in Northern California from Data Quality Trainer Shahida Dossa to a physician, Dr. George T. Chuang, regarding his patient, stated "[f]or reimbursement of risk adjusted diagnoses all chronic dxs [diagnoses] must be captured at face to face visit. … Please amend DOS: 9/10/13 with Major Depression in full remission."

~~206~~223. Often these queries, including many of the examples above, introduced new information and diagnoses not documented in the medical record and instead mined from elsewhere.

~~207~~224. If physicians did not immediately respond to queries, they often received the query multiple times or from multiple people. For example, N. California Medical Group physician Dr. Irene Soojung O'Farrell, saw a patient in September 2012. During that visit, she chose a specific diagnosis for that patient of "failure to thrive." On November 11, 2012 (about two months after the visit), Dr. O'Farrell received a query from Data Quality Trainer Kerri Guerrero that stated: "Please review your note listed above and consider if it would be appropriate to report a label for cachexia. Thank you. . . ." Cachexia is a complex metabolic syndrome associated with underlying illness (such as cancer or HIV) and characterized by loss of muscle and physical wasting~~, weight loss and muscle atrophy~~.

~~208~~225. Just one week later, Dr. O'Farrell had not responded to the query. On November 19, 2012, the Data Quality Trainer forwarded the initial query to Dr. Steven Olson (Regional Physician Director, Clinical Documentation and Coding) with the message "For your review. No response as of 11/19/12." On November 21, 2012, Dr. Olson sent Dr. O'Farrell a second query regarding adding cachexia for M.D.: "Hi Irene, Would you feel comfortable addending your note of 9/18/2012 and adding a dx of cachexia? We get significant additional resources to care for our members disease burden from appropriately coding that diagnosis. You had mentioned that she was losing weight-failure to thrive. She has indeed been losing weight so undoubtedly meets the criteria for cachexia. Please contact me if you would like to discuss or need help. I would ask you to addend your last visit note, and add the encounter dx [diagnosis] of cachexia if you feel that is appropriate. Also, adding it to the problem list will make it easier to code in the future. Thanks, Steve O." Two days later, Dr. O'Farrell created an addendum to add the diagnosis of cachexia.

~~209~~226. Internal communications reveal that the rationale for using this type of language in queries, contrary to AHIMA guidance and Kaiser policy and training, was that if Kaiser did not "'tell' the physicians directly to capture a diagnosis (i.e., not use leading language) then the refresh rates will go down as result. Presumably because the physicians will . . . not feel like it is required to add the diagnosis." The flaws in the queries for cachexia were not unique to that diagnosis and extended to numerous other diagnoses that similarly generated additional risk-adjustment payments.

~~210~~227. As discussed above, in Colorado, Kaiser had previously data-mined and queried physicians to add hypoxia for patients receiving oxygen, specifically flagging the increased reimbursement potential. However, CMS later removed hypoxia as a condition from the CMS-HCC model. In response, the Colorado Health Plan and the Colorado Medical Group queried physicians to addend medical records for different diagnoses (acute and/or chronic respiratory

failure and obesity hypoventilation syndrome) that would generate more revenue for Kaiser: "Please note that the following common diagnoses are insufficient for appropriate reimbursement for patients who need oxygen: hypoxia, sleep apnea, obesity, COPD. Please continue to use these if clinically appropriate in addition to adding one or more of the above suspected diagnoses [acute and/or chronic respiratory failure and obesity hypoventilation syndrome]."

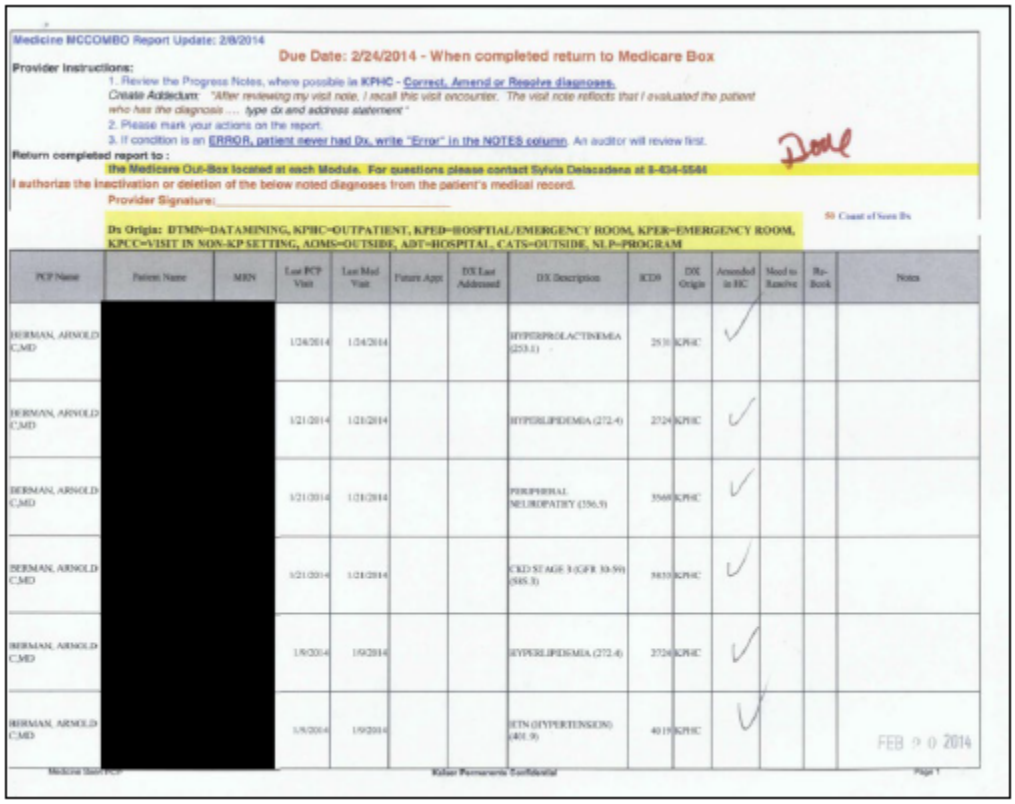
~~211. These Medicare~~228. Kaiser's queries led to numerous false claims, with physicians simply adding the diagnoses Kaiser ~~instructed them to add. In at least one instance~~pressured them to add, including many times even if the medical record of the visit contradicted the existence of the condition. For example, after receiving a query like the one described above from Medicare Risk Auditor Denice Hogan, Colorado Medical Group physician Dr. Patrick Martin 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). This type of error occurred many times and was the inevitable results of Kaiser's flawed programs, given the way that the diagnoses were generated and the pressure on physicians to add them.

~~212~~229. In October 2013, Nancy Andersen (then a Senior Compliance Manager with the National Compliance Office) specifically warned Dr. Teresa Welsh (the Colorado Medical Group Director of Coding) that the Medicare Query template that the Colorado region was using might be viewed as leading by CMS. Nancy Andersen even provided a copy of the standards and requirements that must be followed for compliant queries. Her warnings were ignored, and the Colorado Medical Group and the Colorado Health Plan continued to use the improper queries to generate thousands upon thousands of addenda.

~~213~~230. Kaiser's queries to physicians also often omitted any reminder to the physician that the diagnosis in question must have been considered, evaluated, or treated at the prior patient visit in order to be included in addenda. Instead, the language in Kaiser's queries often indicated that physicians could add a condition to a prior visit record regardless of whether the diagnosis was based on or evaluated at that visit, so long as they could confirm after the fact at the time they completed the addenda that "the patient has the listed condition."

~~214~~231. For example, in queries called "GSAA Data Mining Reports," which contained lists of conditions (identified through data mining) that went to many physicians, the form instructions directed the physician to "determine whether or not the patient has the listed condition," and if so "addend the chart note and add the [diagnosis]."

~~215~~232. Below is an example of the first page of a two-page 2014 "Medicine MCCOMBO Report" report that went to N. California Medical Group physician Dr. Arnold Berman. The "Provider Instructions" tell Dr. Berman to "Create Addendum" and provided the language he should use: "After reviewing my visit note, I recall this visit encounter. The visit note reflects that I evaluated the patient who has the diagnosis . . . ." The report has a "Due Date" and instructs that when the physician completes it, it should be "return[ed] to Medicare Box." This page of the report asks Dr. Berman to add six different diagnoses for three different patients. Dr. Berman added all six diagnoses:



Medicine MCCOMBO Report Update: 2/8/2014

Due Date: 2/24/2014 - When completed return to Medicare Box

Provider Instructions:

1. Review the Progress Notes, where possible in KPHC - Correct, Amend or Resolve diagnoses.

Create Addendum: "After reviewing my visit note, I recall this visit encounter. The visit note reflects that I evaluated the patient who has the diagnosis .... type dx and address statement."

2. Please mark your actions on the report.

3. If condition is an ERROR, patient never had Dx, write "Error" in the NOTES column. An auditor will review first.

Done

Return completed report to :

the Medicare Out-Box located at each Module. For questions please contact Sylvia Delacadena at 8-434-5544

I authorize the inactivation or deletion of the below noted diagnoses from the patient's medical record.

Provider Signature:_____

Dx Origin: BTMN=DATAMINING, KPHC=OUTPATIENT, KPED=HOSPITAL/EMERGENCY ROOM, KPER=EMERGENCY ROOM, KPCC=VISIT IN NON-KP SETTING, AOMS=OUTSIDE, ADT=HOSPITAL, CATS=OUTSIDE, NLP=PROGRAM

PCP Name	Patient Name	MRN	Last PCP Visit	Last Med Visit	Future Appt	DX Last Addressed	DX Description	ICD9	DX Origin	Amended in HC	Need to Resolve	Re-Book	Notes
HERMAN, ARNOLD C,MD	[redacted]		1/24/2014	1/24/2014			HYPERPROLACTINEMIA (253.1)	253.1	KPHC	✓			
HERMAN, ARNOLD C,MD			1/21/2014	1/21/2014			HYPERLIPIDEMIA (272.4)	272.4	KPHC	✓			
HERMAN, ARNOLD C,MD			1/21/2014	1/21/2014			PERIPHERAL NEUROPATHY (356.9)	356.9	KPHC	✓			
HERMAN, ARNOLD C,MD			1/21/2014	1/21/2014			CKD STAGE 3 (GFR 30-59) (585.3)	585.3	KPHC	✓			
HERMAN, ARNOLD C,MD			1/9/2014	1/9/2014			HYPERLIPIDEMIA (272.4)	272.4	KPHC	✓			
HERMAN, ARNOLD C,MD			1/9/2014	1/9/2014			HTN (HYPERTENSION) (401.9)	401.9	KPHC	✓			

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~~216~~233. For queries where physicians were being asked to addend older visits—often a year or more after the visit—Kaiser included misleading language in many queries to assure physicians that the addenda were allowed: "Medicare allows physicians to clarify the medical record by making an addendum without any time limitations. Diagnoses that were present at the time of the visit may be clarified by entering the diagnosis in an addendum." This information was false and misleading, because it omitted the requirement, included in the ICD Guidelines and Kaiser's own policies, that only diagnoses that required or affected patient care treatment or management at the patient visit could be added to the patient's medical record.

2. Kaiser used "SmartPhrases" to make it easy for physicians to create addenda even when the condition did not require or affect patient care, treatment, or management.

~~217~~234. Another mechanism Kaiser employed to ensure that physicians could easily add diagnoses via addenda was the use of "SmartPhrases." SmartPhrases are a tool within Kaiser's electronic-health-record system that, upon entry of a single phrase, automatically imported ~~pre-formatted~~pre-formatted language into a patient's medical record.

~~218~~235. Kaiser created multiple SmartPhrases that physicians were trained to use when creating addenda. The input language varied over time and across regions, but the following examples are representative.

~~219~~236. Entry of ".DXOMITTED" would generate the following language in the patient record: "After review of my note for this visit encounter, I recall this encounter and am addending this note to state that this patient has diagnosis of "

~~220~~237. Entry of ".FOL" would generate the following language in the patient record: "I have confirmed with the patient and/or the medical record the presence of the above diagnoses, and the diagnoses are followed or will be followed by his or her PCP or appropriate specialist."

~~221~~238. Entry of ".STABLE" would generate the following language in the patient record: "Diagnoses recorded for this visit were addressed and are stable, unless otherwise indicated in this note."

~~222~~239. The queries physicians received would often instruct the physician to use a specific SmartPhrase when they created the addendum.

~~223~~240. For example, a 2012 Missed Opportunity Report for a physician, Dr. Stewart Wong, instructed him for his patient to "Please consider to capture [sic] Aortic Atherosclerosis based on CXR on 08/0[sic]/11: Aortic atherosclerosis," with a "reminder" to "include .fol in your encounter."

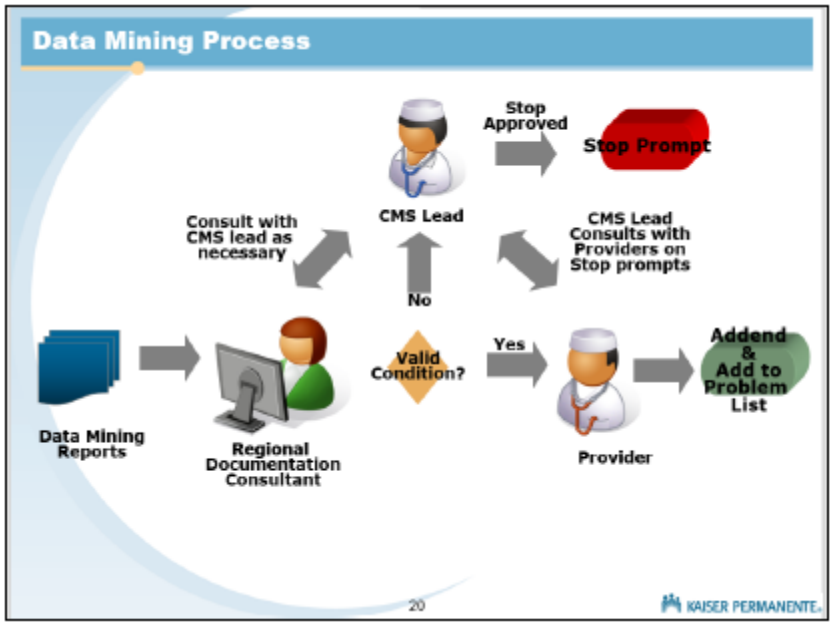
~~224~~241. A 2015 query to a physician, Dr. Jan Kwong, regarding her patient, stated: "Capture AA on visit dated 6/16/15; LINK: XR which showed evidence of condition ordered on this date; If agree, addend with smartphrase .DXADDITIONAL and address dx. Add to PL as well."

~~225~~242. Another 2015 query to a physician, Dr. Wendy Yang, regarding her patient, stated: "Capture SEVERE OBESITY WITH BMI OF on visit dated 4/27/15; LINK: BMI listed as 36.21 and DM2 comorobidty [sic]. If agree, addend with smartphrase .DXOMITTED and address DX."

3. Kaiser pressured physicians by requiring them to justify refusals to add diagnoses.

~~226~~243. In addition to drafting queries and creating SmartPhrases in a manner that maximized positive responses, Kaiser forced physicians who declined to add diagnoses to justify their decision in burdensome ways.

~~227~~244. As previously noted, in the Northern California region, the N. California Medical Group implemented the "stop prompt" process. The following diagram from an internal Kaiser training depicts how the stop prompt process generally worked:



~~228~~245. After receiving a query to add a data-mining diagnosis, the easiest route a physician could take was to add the data-mining diagnosis to the patient's record (using an addendum). This would generally lead to no further review from Kaiser, even where the condition was unrelated to the visit, the existence of the condition was contradicted by the medical record for the visit, and/or the physician documented in the addenda that the patient had only a history of the condition. Instead, Kaiser would simply submit for payment a diagnosis code representing the active condition without further review.

~~229~~246. If the physician disagreed, however, the physician had to initiate a "stop prompt" and justify their decision in writing, often through multiple review levels, including to a supervising physician known as the "CMS Lead."

~~230~~247. Internal communications show that this process was onerous. Dr. Pearl Wu, the Documentation and Coding Lead for Redwood City, noted that a refusal by a physician to add a diagnosis went through "stringent" review, starting with collecting all of the stop prompts, having those stop prompts undergo a "second pass" by the "Trainer," "and then final review by me as Physician Lead of all stop prompts to ensure accuracy."

~~231~~248. Beginning around 2012, stop prompts received even more review in Northern California; the Clinical Review Team within N. California Medical Group's EIO office provided a second-level review after the physician-lead review.

~~232~~249. In other words, through the stop-prompt process, if a physician added a diagnosis, the process ended; if a physician refused to add a diagnosis for a patient, the physician had to justify their decision to other Kaiser employees, none of whom had actually seen the patient.

~~233~~250. As Karen Graham (Managing Director for EIO) explained when one facility wanted to cease reviewing all prompts: "The concern is that if physicians know the stops are not being reviewed, they are less likely to go to the trouble to capture the dx [diagnosis]." Kaiser

wanted to make it easy for physicians to add diagnoses and hard to say no, and this tactic led directly to the addition of diagnoses unrelated to the visit, including diagnoses for conditions whose existence was contradicted by the medical record of the visit.

4. Kaiser used financial incentives and other metrics to pressure Permanente Medical Group physicians to create addenda.

~~234~~251. As previously discussed, consistent with the financial focus of the risk-score goals, Kaiser placed both positive and negative financial pressures on physicians (and the facilities where they worked) to add addenda to patient-visit records.

~~235~~252. One form of pressure involved calling out facilities with low "refresh rates" and emphasizing that the failure to add diagnoses would cost money for Kaiser, the facilities, and the physicians themselves.

~~236~~253. For example, in November 2010, when a facility in Northern California was in the "bottom third . . . of refresh performance," Mike Geranio (the Medical Office Controller) noted that the facility had not yet "received a call for a meeting nor any pressure," and then requested that Dr. Robert Klein (a N. California Medical Group Associate Executive Director) call their physician lead, Dr. Paul Rose, to say that they had "$4 million and 2,000 diagnos[es] at risk. Please send me your action plan every Friday or let[']s meet for 15 minutes until the end of the year." (Emphasis added.)

~~237~~254. In June 2012, when a Kaiser facility in Northern California was not sufficiently "address[ing]" a specific initiative to create addenda, Joel Weiner (the Director of the Business Intelligence Team for the N. California Medical Group) spoke with their CMS Project Manager, Jeremy Lawrence, and discussed that creating the addenda was "so important, easy to do and worth about $800K." (Emphasis added.) Karen Graham responded, "excellent – referencing money seems to speak to some of the [CMS Project Managers]."

~~238~~255. In January 2014, Dr. Teresa Welsh (the Medical Director of Coding for the Colorado Medical Group) cited "a few physicians who apparently didn't work their refresh lists to completion. . . . Each of these diagnoses adds about $2500 to our bottom line." (Emphasis added.) Reflective of how focused Kaiser was on getting this money, she offered to "drive around and sit with people personally if that is what it takes, usually it just takes the chief telling them to do it. In past years, I recall doctors were placed on a work improvement plan if they didn't complete this work. I will let you operations guys decide if that is what it takes." The pressure with respect to such lists did not differentiate amongst the diagnoses on the lists—it was applied across the board.

~~239~~256. In addition to calling out "underperforming" physicians and facilities, Kaiser explicitly linked physician bonuses and financial incentives to responses to data-mining diagnoses. For example, in one facility, Kaiser offered a "Bonus/Premium when addressing >90% of datamining diagnoses" as well as a "Bonus worth 30% of annual payout at 98% performance" with an "Additional premium of 2.5% for each 0.5% above 98%."

~~240~~257. As noted above, as part of its mandatory risk-adjustment improvement plan (shared with Kaiser's National Medicare Finance department), the N. California Medical Group

set a goal that its physicians would "refresh" 99% of diagnoses identified by Kaiser. Each physician's and facility's progress in reaching this goal was monitored and tracked throughout each year.

~~241~~258. The Colorado Medical Group paid physicians a stipend in 2013 to respond to all pending queries by the end of the year. The Colorado Medical Group noted that its spending of $350,000 on paying reviewers and stipends to doctors resulted in $24 million to Kaiser over just five months.

~~242~~259. The Colorado Medical Group considered the program so successful that it sought to pay thousands of dollars more in stipends to doctors in 2014. "We will post a table with the anticipated pay out by doc on the website and the average pay out so they understand the dollars being much more than last year."

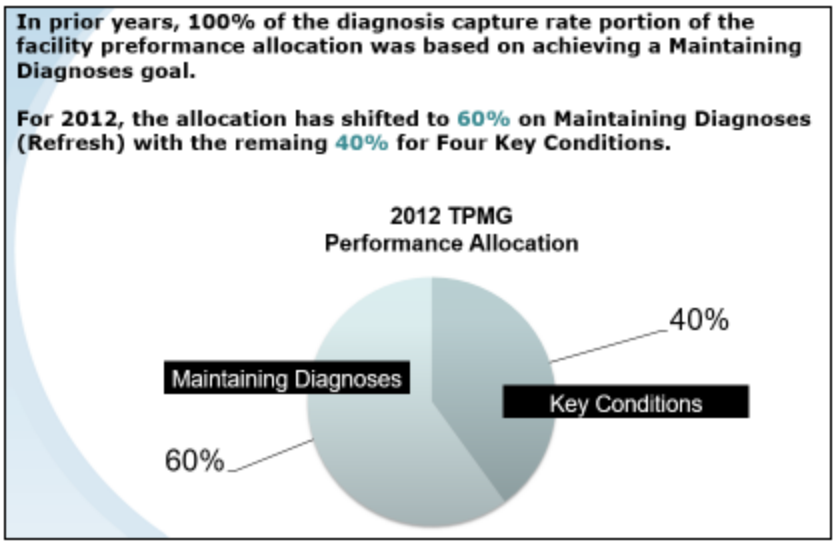
~~243~~260. Along these same lines, managers were required to hold documentation and "coding parties" (where physicians were expected to work on their "missed opportunity" and data-mining lists), which were described as supporting "healthy competition" and providing "performance tracking by provider and department."

D. How Kaiser targeted the diagnosis aortic atherosclerosis to increase risk-adjustment payments: "$40M is no chump change."

~~244~~261. Beginning around 2010 or 2011, one diagnosis targeted throughout all of Kaiser's regions was atherosclerosis of the aorta ("AA"), which was emphasized to have a "high rate of reimbursement." Atherosclerosis is the hardening of the artery walls, in this case of the aorta.

~~245~~262. The N. California Medical Group pursued a multi-pronged strategy to code AA for "revenue capture" purposes. The process involved three basic steps: First, radiologists were instructed to document the presence of any calcium in the aorta in a radiology impression, regardless of significance, and describe it as AA. Kaiser tracked how well each radiologist performed and compared their performance. Radiologists were also informed that the purpose was financial. Second, the data- mining team would mine patient medical records by searching for the key words the radiologists had been instructed to document in the radiology reports. Third, based on that data mining, physicians would then be queried to diagnose AA, often by creating addenda to the medical records of prior patient visits. Physicians (and their facilities) were tracked in their performance for coding AA and received incentives and awards for coding AA.

~~246~~263. The N. California Medical Group identified AA as one of four key conditions and instructed facilities that beginning in 2012, 40% of their monetary performance allocation would be based on how well they coded these conditions, with the remaining 60% based upon their refresh performance. Facilities were told what prevalence rates they were expected to hit for AA and the other key conditions and were required to develop work plans to meet these rates. A 2012 internal training described this financial allocation:



~~247~~264. The reason for this initiative was money. In response to MA plans receiving substantially more money per beneficiary than the costs for a traditional Medicare beneficiary, Congress amended the Medicare Advantage statute, and CMS altered the CMS-HCC model in an attempt to bring MA reimbursement in line with traditional Medicare. In light of these changes, Kaiser was intent on making much of this revenue back by increasing its coding of lucrative conditions such as AA. As that same 2012 internal training explained: "[G]iven the changing CMS climate regarding Medicare legislation and potential changes to the reimbursement models, it is no longer viable for us to continue to focus only on the Maintaining Diagnoses goal." Hence, the new focus on coding the four key lucrative conditions.

~~248~~265. Northern California repeatedly stressed the financial benefit of coding AA. For example, one presentation by Dr. Robert Klein (a N. California Medical Group Associate Executive Director) and Dr. David Bliss (the N. California Medical Group Regional Director of Documentation and Coding) to each facility's Documentation and Coding Lead highlighted that each AA diagnosis was worth an additional $2,800 to Kaiser, and that one medical center earned an additional $150,000 in revenue for one month by focusing on coding AA.

~~249~~266. Following up on that presentation, on August 19, 2011, Dr. David Bliss sent an email to the N. California Medical Group Coding Leads. Dr. Bliss wrote that "With the Natural Language Processor, we have identified patients over the past two years with evidence of Aortic Atherosclerosis in the Radiology Report. . . . These have been pre-screened and are being sent to you to consider capturing the diagnosis of [AA]."

~~250~~267. The N. California Medical Group physicians responded with concerns about diagnosing more patients with AA. At the time, every patient diagnosed with AA was entered into Kaiser's PHASE program. "PHASE," which stands for "Preventing Heart Attacks and Strokes Everyday," required physicians to perform additional monitoring of patients diagnosed with cardiovascular disease.

~~251~~268. Given the large volume of patients Kaiser was directing be diagnosed with AA (and thus enrolled in PHASE), physicians were worried that this initiative would require the

physicians to do more follow-up with these patients. As Karen Graham (the Managing Director for EIO) testified, "[t]here was concern about adding it [AA] to the PHASE program because it would create significant increase in workload of follow-up with the patients."

~~252~~269. In response, Dr. David Bliss and Dr. Robert Klein offered a solution that addressed workload concerns without sacrificing Kaiser's bottom line: in mid-September 2011, they eliminated the requirement that patients diagnosed with AA automatically be enrolled in PHASE. This allowed Kaiser to capture the revenue associated with additional AA diagnoses (which at the time was estimated at $40 million for the Northern California Region alone) without requiring physicians to provide care, treatment, or management associated with the condition.

~~253~~270. Following this change, the N. California Medical Group continued to pressure physicians to capture more AA diagnoses. As Dr. James Chang (another Associate Executive Director at the N. California Medical Group) wrote in late September 2011 to the Northern California Chiefs of Radiology, copying Dr. David Bliss and Anne Cadwell (the Managing Director of the N. California Medical Group): "We are missing a $40M opportunity. In the current reality of contracting revenue stream, this would become devastating to us." Referring to physicians who had captured fewer AA diagnoses, Dr. Chang wrote, "What are our steps to improve? How can we tweak the environment or create habits to take us to 100%? Can we find out from the bright spots on how they do it? How do we rally the herd?" Dr. Chang concluded, "Everybody join in the discussion. $40M is no chump change."

~~254~~271. Many physicians were concerned that for many patients AA was clinically irrelevant. One physician, Dr. Matthew James Sena, observed that "Aortic atherosclerosis is nearly ubiquitous in patients this age. It is not a clinically relevant diagnosis and doesn't require treatment. Isolated CXR [chest x-ray] interpretations are not grounds for clinical diagnosis in this case. . . . [I]t's clinically inconsequential in almost all cases."

~~255~~272. Yet another Kaiser physician, Dr. Jill Dunton (a CMS Lead Physician), noted the disconnect between Kaiser's pressure on physicians to code the diagnosis and the clinical basis for doing so, noting that a Kaiser cardiologist said: "When people are seeing fraud cases reported in the paper, people want very much to feel that they are not putting themselves at risk. Presenting requests to code AA when there is there may not be [sic] a clinical implication or action needed that are clearly dictated by region is causing increasing discomfort." (Emphasis added.) Dr. Dunton made her report to: Anne Cadwell, Dr. Donald Dyson (an Associate Executive Director for the N. California Medical Group), and Dr. David Bliss.

~~256~~273. Another Kaiser employee tasked with pushing the AA initiative, Lisa Woll (a N. California Medical Group Area Chief of Coding and Documentation), went so far as to say that "[n]o one believes it is a real diagnosis" and bemoaned that since "it is non-compliant to tell people to code for money, we need to really sort out a way to package this." Her complaint was forwarded to Anne Cadwell, Karen Graham, Joel Weiner (the Director of the Business Intelligence Team for the N. California Medical Group), and Dr. David Bliss.

274. In 2015 a physician complained about being prompted more than once to add AA for a patient who did not have AA. Even when it was clear to Kaiser managers that the data-mining

program was erroneously identifying patients who did not have AA, they did not want to fix the program for fear of losing money.

~~257~~275. Notwithstanding these and other physician complaints, Kaiser continued to press physicians to add AA.

~~258~~276. In 2013, the N. California Medical Group, including through its Revenue Cycle office, instructed physicians in an internal training that AA was an "always code" condition and that physicians must "NOT put AA as [an] incidental finding or state [AA] is 'not clinically significant.'" Both instructions contradicted the ICD Guidelines. For outpatient encounters, as explained previously, the ICD Guidelines only permit coding those conditions that require or affect patient care, treatment, or management at a patient visit. There is no such thing as a condition that is always coded. Accordingly, incidental findings or diagnoses that are not clinically significant may not be coded.

~~259~~277. The results of this Northern California initiative were dramatic. In 2009 and 2010, before the initiative, Northern California physicians added AA via addenda 44 and 67 times, respectively. Once the initiative was fully implemented, Northern California physicians added AA via addenda approximately 10,500 times in 2012 and 11,500 times in each of 2013 and 2014.

~~260~~278. Based on the addenda data produced by Kaiser, AA diagnoses accounted for 22% of all diagnoses added by Kaiser physicians via addenda in Northern California, Southern California, and Colorado. In some years in Northern California and Southern California, AA accounted for as much as 30-40% of all addenda diagnoses. Each AA diagnosis was generally worth roughly between $2,500 and $3,000 per patient in additional risk-adjustment payment. As a result of this high rate of reimbursement, AA accounted for an even higher percentage of the risk-adjustment revenue generated from addenda.

~~261~~279. As described above, Kaiser knew, as set out in its Program Advisories, that a condition must have required or affected patient care, treatment, or management at a patient visit to be coded and submitted to CMS, and that if the physician did not actually consider the condition during the visit, the diagnosis could not be submitted to CMS.

~~262~~280. Janet Franklin (at the time, a Compliance Manager with Kaiser's National Compliance Office) acknowledged internally that aortic atherosclerosis could "be reported only if that treating physician documents that it is more than just an incidental finding and it is relevant to the face-to-face encounter that he or she had with the patient." And in an internal policy memorandum titled "Coding Aortic Atherosclerosis," Nancy Andersen (then the Regional Director of Hospital Coding) wrote that, absent evidence of AA being treated or evaluated at the visit, AA "is considered an incidental finding and the physician should not be queried about it nor should it be coded." (Emphasis in original.)

~~263~~281. Among the Physician Documentation and Coding Group, a group of physician coding leaders throughout Kaiser regions, there was complete agreement that adding AA without a physician's having addressed the condition at the patient visit was improper. According to a written summary of the meeting by Dr. Teresa Welsh (the Medical Director of Coding for the Colorado Medical Group), "[n]obody was in support of having the doctor add a diagnosis such as

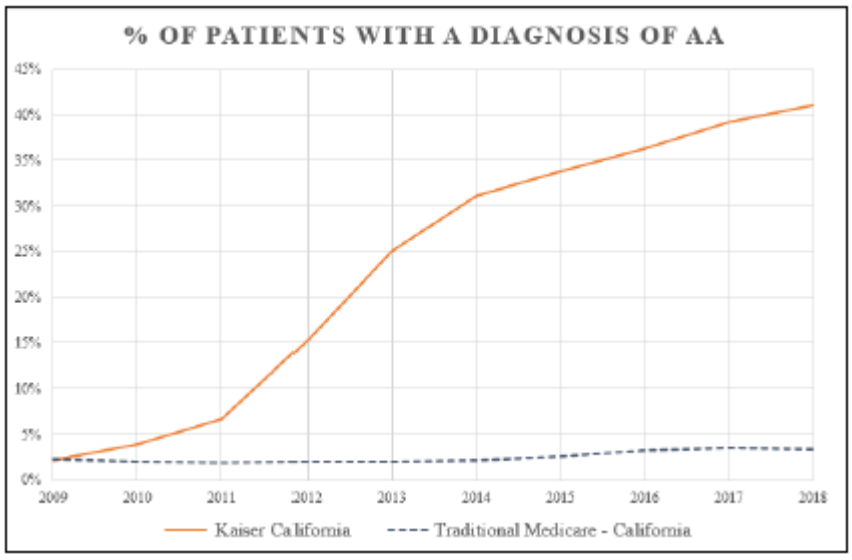
atherosclerosis of the aorta . . . in an addendum unless they had specifically addressed it within the visit note at the time of service -or- unless the doctor specifically indicates that they recall that they addressed it at the time of the visit."

~~264~~282. Nevertheless, the N. California Medical Group used queries to pressure physicians to add AA diagnoses in addenda and made no mention of these requirements when sending queries to its physicians. Rather, Kaiser's queries indicated an AA diagnosis could be added to a visit record based only on the appearance of the condition in a radiology report—while at the same time it was pressuring radiologists to note the condition in as many reports as possible.

~~265~~283. Kaiser compliance officials stated that the AA diagnoses that Kaiser was pressuring physicians to add frequently did not comply with coding requirements. Janet Franklin characterized the N. California Medical Group's practice of adding AA diagnoses as "coding for dollars" and confirmed that AA diagnosis codes should not be submitted to CMS unless AA was related to the reason that the patient was having the diagnosis test and AA's clinical significance or relevance to the patient visit was documented.

~~266~~284. The AA diagnoses that Kaiser was pressuring physicians to add via addenda to medical records of prior patient visits frequently had not required or affected patient care, treatment, or management at those visits, as required by ICD guidelines.

~~267~~285. The success of Kaiser's pressure campaign is reflected in the skyrocketing usage of the AA diagnosis in California. Prior to Kaiser's initiative, Kaiser physicians diagnosed around 2% of their MA patients in California with AA. This was approximately equivalent to the rate of AA diagnoses found in the traditional Medicare patient population in California. By 2018, Kaiser physicians diagnosed over 40% of their Medicare Advantage patients in California with AA, a more than 1000% increase. These additional AA diagnoses resulted in Kaiser receiving more than $500 million in increased Medicare Advantage revenue in California alone. The following chart depicts the percent of Kaiser's MA patients in California with AA compared to the traditional Medicare population:



~~268~~286. As discussed further below, a targeted addenda audit conducted by the N. California Medical Group revealed that, of AA diagnoses added through addenda, only 21% were "accurate," meaning that there was a close to 80% error rate for the AA diagnosis.

E. Kaiser knew that its practices resulted in the addition of improper diagnoses to patient medical records.

~~269~~287. Throughout the time period in question, Kaiser received (and ignored) numerous warnings and red flags that its practices surrounding addenda were leading to diagnoses that ran afoul of CMS rules.

1. Kaiser knew that its use of addenda to add risk-adjustment diagnoses did not comply with CMS rules for submission of diagnoses for risk-adjustment payment.

~~270~~288. Kaiser knew that when it requested that physicians add conditions to the record of a prior patient visit, it needed to follow the ICD Guidelines, including the requirement that the condition must have both existed and required or affected patient care, treatment, or management at the visit.

~~271~~289. For example, Kaiser's Addenda Program Advisory, which was "intended to clarify under what circumstances addenda to the medical record will be considered acceptable as support for risk adjustment data submitted to [CMS]," provides that that "the practitioner must clearly indicate that the information contained in the addendum related to the evaluation and/or treatment rendered during the previous patient encounter." (Emphasis added). It further states that addenda are acceptable where the diagnosis was "actually made, considered, evaluated, and/or treated during [the] encounter," but the physician "failed to document that information in the note." Relatedly, it provides that addenda are not acceptable when "there is no documentation in the previous note that indicates that the diagnosis in the addendum was actually considered/treated/evaluated during the prior visit," or when "the information documented in the note does not pertain to the previous patient encounter but, instead, is new information obtained at a later date or as the result of a later visit[.]" In such cases, as Kaiser recognized in its Addenda Program Advisory, "any diagnoses documented in the addenda may not be submitted to CMS as risk adjustment data."

~~272~~290. Kaiser recognized in its Addenda Program Advisory that "since these addenda will be used as support for the submission of risk adjustment data where the practitioner did not clearly document the diagnoses in the original documentation, it is essential that this use of addenda be closely monitored and audited for appropriateness" and that "[i]naccurate or false information submitted in support of claims for payment to federal health care programs may result in liability under the Federal False Claims or False Statement statutes." (Emphasis in original.)

~~273~~291. Kaiser's training was consistent with its Addenda Program Advisory. For example, a 2011 Northern California training highlighted that in order to include a diagnosis in the record of a patient visit, "[t]here must be evidence that the diagnosis(es) may exist in the documentation of the original encounter." (Emphasis in original.) The same training instructed

that an addendum may not be used "[w]hen the original encounter note does not indicate that the diagnosis was considered, treated, or evaluated." (Emphasis in original.) Similarly, a 2015 Northern California training instructed that a reason to perform an addendum was when "[y]ou have documentation to support that you considered, evaluated, and/or treated a diagnosis, but failed to capture it …."

~~274~~292. In the 2015 Risk Adjustment Program Advisory, Kaiser included an Attachment that is about "Addenda to the Medical Record," and provides that an addendum may be appropriate if "the physician recalls the encounter and agrees that he or she did consider, evaluate, and/or treat the diagnosis during the encounter."

~~275~~293. A 2016 training on the Fundamentals of Clinical Documentation and Reporting instructed that an addendum could be done "[t]o clearly document that the provider considered, evaluated or treated each listed diagnosis."

2. Kaiser pushed for addenda regardless of how much time had passed since the patient visit, especially at the end of the year.

~~276~~294. Despite recognizing that a physician's memory of a specific patient visit was likely to fade over time, Kaiser pushed ~~for addenda~~the physicians to create addenda for the purpose of documenting diagnoses that generated an additional risk-adjustment payment, regardless of how much time had passed since the actual patient visit. This became most apparent at year-end when Kaiser had to get diagnoses submitted in order to get paid by CMS.

~~277~~295. In the Addenda Program Advisory, Kaiser recognized that "in general, practitioners are less likely to accurately recall specific details regarding patient encounters the more that has passed since the encounter." In the addendum attachment to the 2015 Risk Adjustment Program Advisory, Kaiser reiterated this concept, noting that whether an addendum was reasonable would depend in part on the "time between the applicable encounter and the drafting of the addendum," and "[a]s this time increases, the reasonableness and appropriateness of the addendum to serve as support for a diagnosis submitted as risk adjustment data decreases." The addendum attachment to the 2015 Risk Adjustment Program Advisory continues to give "under 90 days" as an example of what CMS has stated about what a "timely" addendum would be.

~~278~~296. Kaiser employees shared this understanding. For example, Nancy Andersen (a Senior Compliance Manager with the National Compliance Office) testified that she could not identify "any situations" in which it would be appropriate to add a diagnosis "more than sixty days after an encounter."

~~279~~297. Similarly, Janet Franklin (a Compliance Manager with the National Compliance Office) testified that only on "rare" occasions would it be appropriate to add a diagnosis "greater than 30 to 60 days after the original patient encounter."

~~280~~298. In practice, however, Kaiser ignored these requirements and sought to ensure that physicians added lucrative risk-adjusting conditions to the records of their patient visits—oftentimes many months after the original visit, and regardless of whether these conditions were actually considered or addressed by the physician during the patient visits in question.

~~281~~299. The extent of Kaiser's push to add diagnoses even months after the fact is borne out through addenda data produced by Kaiser.

~~282~~300. These data show a significant number of addenda done a very long time after the visit. For example, from service years 2009 to 2018, Kaiser added over 150,000 diagnoses via addenda more than 90 days after a patient visit in California and Colorado, accounting for over 30% of diagnoses added via addenda. Over 12% of diagnoses added via addenda were more than 180 days after the patient visit. More than 6,000 diagnoses were added over a year after the patient visit.

~~283~~301. These data also show that the time lag between patient visits and the creation of addenda was particularly pronounced at the end of each year, when Kaiser sought to meet annual financial targets. Kaiser physicians added far more diagnoses via addenda at the end of the year than at the beginning of the year, especially with respect to addenda created more than 90 days after the visit.

~~284~~302. For example, for service years 2009 to 2018, Kaiser physicians added nearly three times as many diagnoses via addenda during the month of December than they did during the month of January. But the differences are even more pronounced when looking at diagnoses made through addenda more than 90 days after the visit. In January, only 13% of addenda diagnoses were more than 90 days after the visit; by December, that number jumped to over 50%. Put differently, Kaiser physicians added roughly eleven times as many diagnoses through addenda more than 90 days after the visit in December than they did in January.

~~285~~303. Conversely, Kaiser's data show that, for service years 2009 to 2018, Kaiser physicians added more than five times as many diagnoses through addenda to medical visits that took place in January than they did to medical visits that took place in December. This pattern is even more pronounced for diagnoses made through addenda more than 90 days after the visit: Kaiser physicians added nearly thirteen times as many of these diagnoses through addenda to January medical visits than they did through addenda to December medical visits.

~~286~~304. Similar patterns exist across each of the three Kaiser regions at issue (Northern California, Southern California, and Colorado) and across time periods. Likewise, similar patterns exist when comparing Kaiser addenda activity in the first quarter of the year versus the last quarter of the year.

~~287~~305. This was not happenstance. Kaiser physicians were not especially forgetful during their January medical visits, nor did their memories suddenly improve in December. Rather, this was the result of Kaiser's end-of-year activities, sometimes referred to as the "dash for cash." Year-end pressure from Kaiser for physicians to meet metrics so that Kaiser could achieve risk score targets for the given service year caused physicians to add diagnoses to medical records for older visits from earlier in the year, routinely without regard for the ICD Guidelines and CMS requirements ~~or whether the newly added diagnoses actually required or affected care, treatment, or management during those visits~~. Kaiser knew this was occurring, knew it was improper, yet still submitted these diagnoses for payment.

~~288~~306. Kaiser would not have been able to submit the thousands upon thousands of risk-

adjusting diagnosis codes that it added through addenda for payment by CMS if it had complied with ICD Guidelines and other CMS requirements. Instead, Kaiser systematically disregarded these requirements to boost its bottom line and used addenda to add diagnoses retrospectively to past patient visits, because, as Dr. Teresa Welsh (the Colorado Medical Group Director of Coding) explained, she could do "two a minute." As Dr. Welsh similarly discussed in January 2014—when by definition it was impossible for physicians to have visits with their patients for the 2013 service year any longer—in her view physicians "can still make addendums on 2013 dates of service for 2 more months if needed. . . . Each of these diagnoses adds about $2500 to our bottom line. I can drive around and sit with people personally if that is what it takes, usually it just takes the chief telling them to do it." (Emphasis added.)

3. Kaiser physicians put Kaiser on further notice of fraudulent diagnoses.

~~289~~307. Physicians provided further notice that Kaiser's addenda ~~practice was~~practices were leading to fraudulent diagnoses unrelated to the patient visit and sometimes contradicted by the medical record.

~~290~~308. For example, in 2011 Relator Randi Osinek (a Kaiser certified medical coder) reported to several executives, including Karen Graham (the Managing Director for EIO), that "over 50% of the physicians tell me they feel that they are being 'forced' to add diagnoses that they did not considered, evaluated, and/or treat. Especially since they feel their bonuses are being impacted." (Emphasis in original.)

309. A 2015 N. California Medical Group internal analysis of stop prompts noted physicians pointing out that patients did not have the diagnoses Kaiser was prompting the physicians to add. A physician prompted to add stable angina reported as follows: "Has never had stable angina, now or ever. Burping and taking nitroglycerin does not= angina." Similarly, physicians asked to diagnose patients with diabetic chronic kidney disease noted that the patient was not diabetic. One physician complained, "This has definitely been raised before, as I remember this. Her nephrologist is very clear her renal disease is not caused by her DM. Can we fix this so it does not come back every year, as this may be the third time?" Another physician asked to diagnose ostomy pointed out the patient never had an ostomy.

310. Other physicians similarly complained that they were regularly being asked to add conditions that did not exist at the visit. One physician informed Danielle Sheetenhelm, a Kaiser Clinical Review Manager who had been involved with these programs for many years, that almost all of the cancer diagnoses he was being prompted to add had been cured. As recently as January 2020, another physician complained to Sheetenhelm that she was being repeatedly prompted to diagnose diabetes for patients who did not have the condition. Sheetenhelm acknowledged the ongoing problem and blamed it on Kaiser's data-mining prompting process and that data mining was picking up inaccurate information from the medical record.

311. Physicians pressured to add diagnoses for conditions that patients did not have at the visit complained that Kaiser was asking them to participate in fraud. Physicians complained that Kaiser managers returned stop prompts and continued to pressure physicians to make diagnoses even though the diagnoses were clearly wrong. "It appears we have set up the system so that when our 'data mining' identifies a potential problem and we go to the trouble to let them know

that the data mining was wrong and that the diagnosis never existed or no longer exists that is not sufficient."

~~291~~312. Pushback regarding AA diagnoses was particularly forceful. A Documentation and Coding Project Manager, Kathleen DePuydt, reported to Dr. David Bliss (the Regional Director of Documentation and Coding for the N. California Medical Group): "One physician told me that all people over 90 have this condition but he is not necessarily treating it. He wants to know if [he] has to code this on all patients over this age? The [Family Medical Services] physicians are really pushing back with this condition and DO NOT want to code it."

~~292~~313. Along the same lines, Dr. David Conant (a Chief of Medicine) noted "While we are making efforts to capture the coding to support our bottom line, I am hearing considerable concern about how we should be handling these patients." (Emphasis added.)

~~293~~314. Similar pushback occurred when Kaiser pressured physicians to diagnose patients with cachexia. The flaws detailed below in the cachexia initiative were emblematic of the flaws in Kaiser's other risk-adjustment addenda efforts: it was conducted without regard to whether the diagnosis was considered at the visit or the existence of the condition was contradicted by the medical record of the visit.

~~294~~315. As part of a 2009 training, the N. California Medical Group identified cachexia as one of a few diagnoses that would help them "Find $100 million dollars in NCal." And in 2012, cachexia was identified as one of "4 Key Conditions" for revenue purposes.

~~295~~316. As part of its focus on cachexia, the N. California Medical Group created a data-mining algorithm to identify potential cachexia diagnoses. The Northern California region created an initiative around cachexia because cachexia is based on clinical judgment rather than clinical indicators, and they wanted physicians to diagnose cachexia in patients ~~that~~who did not meet clinical indicators for malnutrition. In March 2011, the results of the data-mining algorithm were sent to physicians with queries for them to addend their patient medical records to add cachexia diagnoses.

~~296~~317. As previously noted, cachexia is not simply low body weight, yet physicians were routinely being sent queries that prompted them to add the cachexia diagnoses for patients who were merely thin.

~~297~~318. 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 and Dr. David Bliss in 2011 that the prompting would result in "inappropriate assignment of this diagnosis."

~~298~~319. 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."

~~299~~320. 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."

~~300~~321. The cachexia initiative demonstrates the extreme distorting effect from these programs: 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. Moreover, as described below, it became clear from audits that many of these diagnoses were invalid, because the patient did not even have cachexia, let alone that the physician considered or addressed the condition at the visit.

~~301~~322. And in February 2015, following a meeting of the Physician Documentation and Coding Group, Dr. Teresa Welsh reported back to her colleagues at the Colorado Medical Group and the Colorado Health Plan her concerns that "most of our addendums would not be considered acceptable," because they would not meet the requirement that "diagnoses should only be added as an addendum if they were actually evaluated, treated, or considered at the time of the visit."

323. Although some physicians pushed back against Kaiser's query practices and placed Kaiser on notice the practices were improper, Kaiser knew that other physicians were not catching or calling out such issues. Internally, Kaiser recognized that many times physicians were not properly reviewing diagnoses for which Kaiser queried and knew that this practice was leading to the repeated submission of incorrect diagnoses. For example, one internal document identified as a weakness of the program that "[s]ome clinicians refresh the diagnoses without proper and detailed review of the medical record, and as a result incorrect diagnoses keep being reported." Kaiser knew that physicians would sometimes simply agree to all diagnoses on these query lists, something Kaiser employees internally labeled as a red flag. Kaiser also knew that physicians were adding diagnoses without regard to whether they required or affect patient care, treatment, or management. Kaiser knew that these issues were especially problematic at the end of the year "dash for cash." Despite this recognition, Kaiser continued its practices. As a result, Kaiser improperly submitted for payment hundreds of thousands of fraudulent diagnosis codes where the condition had nothing to do with the visit in question and many times where the condition itself was contradicted by information in the patient's medical record.

4. Kaiser's internal audits put Kaiser on further notice of fraudulent diagnoses.

~~302~~324. CMS regulations require MA Organizations to "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. § 422.503(b)(4)(vi). The regulations specify that this compliance program "must, at a minimum, include [certain] core requirements," including: (1) to establish and implement "an effective system for routine monitoring and identification of compliance risks," which "should include internal monitoring and audits and, as appropriate, external audits," to evaluate the MA Organization's "compliance with CMS requirements and the overall effectiveness of the compliance program"; and (2) to establish and implement "procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements." Id. § 422.503(b)(4)(vi)(~~E) (~~G).

~~303~~325. In the event that an MA Organization uncovers "evidence of misconduct related

to payment," the regulations require the MA Organization to "conduct a timely, reasonable inquiry into that conduct" and to undertake "appropriate corrective action," including "repayment of overpayments" and "disciplinary actions" in response. Id. § 422.503(b)(4)(vi)(G). The regulations also provide that the MA Organization "should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee." Id.

~~304~~326. A variety of internal audits provided further notice that Kaiser's addenda and query practices were resulting in false claims to CMS.

~~305~~327. Two teams within the National Compliance Office were directly involved in audit functions. The Government Audit & Reimbursement Team "[e]nsures timely, accurate and consistent responses to federal regulator inquiries and audits by providing operational support to national departments and functions." It also "[e]nsures organizational compliance with rules and requirements associated with payments and reimbursement from government entities." The National Compliance and Audit Team "[p]erforms compliance audits on high-risk areas and coordinates with governance, internal audit, and investigative functions to ensure that compliance validation is performed."

~~306~~328. The Government Audit & Reimbursement Team conducted annual audits of each region, called "probe" audits. These audits were "documentation and coding review[s]" done "in order to determine the validity of each targeted hierarchical categorical condition category (HCC) under Part C." They were designed to "[e]nsure accurate risk adjustment data submission and payment integrity."

~~307~~329. In the Northern California region specifically, the service year 2012 probe audit conducted by Kaiser's National Compliance Office identified a "trend" of "inappropriate use of addendums where the original documentation received by [the National Compliance Office] did not support the use of addenda."

~~308~~330. The report further noted that "in each case, there was no documentation in the original note to support the use of the addenda process as required by coding and documentation guidelines and as noted" in the Program Advisory.

~~309~~331. The report was submitted by Janet Franklin (at the time, a Compliance Manager with the National Compliance Office), and distributed to the Health Plan and the N. California Medical Group.

~~310~~332. The service year 2013 probe audit conducted by Kaiser's National Compliance Office of the Northern California region specifically identified an "issue" with the coding of AA.

~~311~~333. Janet Franklin again submitted the report, and it was distributed to the Health Plan and the N. California Medical Group.

~~312~~334. As a result of this National Compliance Office audit, EIO conducted a targeted addenda audit in 2015. The scope of this audit was large: over 27,000 records where various diagnoses, including AA, had been captured by an addendum. During the audit, the reviewers were tasked with determining whether each addendum was compliant.

~~313~~335. Over 17,000 of the addendum diagnoses in the audit were AA. Of the AA diagnoses, only 21% were "accurate," meaning that there was a close to 80% error rate for the AA diagnoses. And across all diagnoses, there was approximately a 75% error rate.

~~314~~336. And the audit went further; it identified the reasons for the errors, including ones it described as "not eligible for remediation." For AA, nearly half of the errors, or approximately 6,700 addenda, were ones the audit determined could not be fixed. These included the following errors: "addenda doc not compliant, but AA Smart Phrase used"; "Addendum made greater than 1 month later"; "Dx not addressed"; "Dx not in encounter"; and "No link in encounter."

337. While this audit did not expressly categorize diagnoses where the medical record contradicted the existence of the condition, auditors nevertheless identified significant evidence that Kaiser physicians were regularly making such errors, including in particular adding morbid-obesity diagnoses when the patient had a BMI at the time of the visit that was inconsistent with the diagnosis. These errors were placed within the "No link in encounter" category.

338. Notwithstanding the approximately 75% error rate in the 2015 audit, Kaiser did not stop its addenda practices. EIO conducted another targeted addenda audit in 2016, which showed an overall error rate of around 60%. In addition to many other errors, this audit identified hundreds of instances in Northern California alone where Kaiser physicians added diagnoses via addenda where the existence of the condition was contradicted by information in the encounter note.

~~315~~339. The Health Plan, including the National Compliance Office, knew the results of the ~~2015~~ EIO addendum audit. Because AA was identified as a "program-wide" issue, in 2017 the National Compliance Office ultimately created a corrective action plan for AA that covered all regions nationwide.

~~316~~340. In the Southern California region specifically, the service year 2011 probe audit conducted by the National Compliance Office identified an "addendum issue" as one of the classification of errors, and described the errors as there being "no justification in [the] original note to support an addendum."

~~317~~341. Janet Franklin again submitted the report, and it was distributed to the Health Plan and the S. California Medical Group.

~~318~~342. In response to the National Compliance Office probe audits alleged above, the Health Plan redacted the specific diagnoses that were identified in those audits as errors. But Kaiser knew that it made thousands upon thousands of similar improper diagnoses via addenda that it submitted for payment, but it did not redact or delete those diagnoses, and indeed continued to submit them year after year.

~~319~~343. As part of the discussion that took place between the S. California Medical Group and the National Compliance Office, in July 2012, Janet Franklin wrote to Pat Lontka (the Managing Director of Business Systems of the S. California Medical Group) and others about one addendum for AA—added more than five months after the patient visit despite "no documentation in the original note to support [it]." In calling that delay into question, Janet Franklin quoted portions of Kaiser's own policies that suggested reliance on memory to such a degree is unreliable and inappropriate.

~~320~~344. But Pat Lontka "strongly objected" and criticized the National Compliance Office's conclusion as "troubling." And Dr. Paul Minardi (S. California Medical Group Medical Director of Operations) bristled at the notion that "they ([National Compliance Office]) are second guessing the credibility/judgment of the treating physician." He also dismissed the criticism as seeking "perfection not progress," and complained that S. California Medical Group physicians should not be subject to the "whims of an [National Compliance Office] auditor."

345. Kaiser was aware that it was repeatedly improperly submitting for payment diagnosis codes for active conditions when the patients had only a history of the condition at the visits. NCO audits consistently showed that Kaiser's California and Colorado regions erroneously submitted active condition diagnosis codes to CMS for payment when the medical records indicated that the patient had only a history of the condition.

346. A 2012 root cause analysis of six HCC audits reported that physicians were documenting conditions as current at the visit after the condition had been resolved. The same analysis also found that physicians were using stock phrases such as "stable" to describe conditions whose purported presence was contradicted elsewhere in the patient's medical record

347. As previously noted, a 2015 N. California Medical Group internal analysis of stop prompts identified that Kaiser's programs were prompting physicians to add diagnoses for conditions that patients never had or did not have at the time.

~~321~~348. Another example of an internal audit that put Kaiser on notice of its problematic addenda practice arises in the context of the cachexia program. As part of the audit, the Clinical Review Team (within EIO) 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." In other words, when the physicians were creating addenda based on the query, those addenda were not accurate.

~~322~~349. Despite this knowledge, the N. California Medical Group did not modify its cachexia data-mining algorithm or stop-prompt program for several years.

~~323~~350. The Health Plan, including Kaiser's National Medicare Finance department and the National Compliance Office, knew about the N. California Medical Group's cachexia data-mining algorithm and stop-prompt analysis.

~~324~~351. In the Colorado region specifically, the National Compliance Office had concerns about the leading queries being used by the Colorado Medical Group beginning in 2013.

~~325~~352. In 2013, Dr. Teresa Welsh (the Colorado Medical Group Director of Coding) presented Colorado's chart review and query program to other Kaiser regions at a semi-annual meeting of the Medicare Regional Reporting Group.

~~326~~353. After seeing the presentation, Nancy Andersen (then a Senior Compliance Manager with the National Compliance Office) told Dr. Teresa Welsh, "I do have a couple of concerns regarding the query language used and how it may be viewed by CMS and the OIG [the HHS Office of Inspector General]." She continued that the language "'this patient has a suspected diagnosis' introduces a diagnosis or suspected diagnosis not previously mentioned by

the provider and from a compliance perspective may be interpreted as 'leading.'" She further attached information on how to craft a compliant query, with suggestions how to alter the query.

~~327~~354. The Colorado Medical Group did not change its query language at that time. In the service year 2013 probe audit conducted by the National Compliance Office, the findings noted that "[t]he audit process surfaced questions about the use of queries. The questions will be further analyzed outside of this report."

~~328~~355. Kaiser ultimately determined that it had to redact all diagnoses associated with the Colorado region's chart review and leading query program, deleting over 10,000 addenda diagnoses that it had previously submitted to CMS for payment.

~~329~~356. One example of such a diagnosis is with Patient #11. Dr. Janisse Rears (a Colorado Medical Group physician) saw Patient #11 on October 17, 2013, for a physical examination.

a. The visit note identifies a number of active diagnoses, including hypercholesterolemia, hypertension, diabetes, arthritis of the right knee, and severe obesity, as well as number of other diagnoses listed on the problem list.

b. The visit note makes no mention of emphysema.

c. On October 23, 2013, Dr. Rears received a query from Dr. Jennifer Hronkin, as part of the Colorado chart review program described in paragraphs 166-83. As explained earlier, the chart review program involved physician reviewers going through patient files after a visit to "identify diagnoses that have never yet been made by a physician."

d. The query states in relevant part: "Suspected diagnosis= 'Emphysema' Supporting data= CT thorax 10/24/08 shows 'There is minimal emphysema.'

If you agree that this data indicates a diagnosis that should be documented, please:

1. Double click above to open the chart as an addendum.

2. Add the diagnosis to the diagnosis entry field.

3. Slide all chronic diagnoses over to the problem list.

4. Add supporting data or other documentation into the progress note "

e. On the same day she received the query, Dr. Rears created an addendum, copying language from the query: "emphysema Supporting data= CT thorax 10/24/08 shows 'There is minimal emphysema.'"

f. The CT scan referenced in the query was five years old. There was no indication in the visit note that Dr. Rears was aware of, let alone considered, this CT scan or the requested diagnosis of emphysema.

g. There in nothing in the medical record that indicates that Dr. Rears communicated the diagnosis of emphysema to Patient #11 after creating the addendum.

h. The Colorado Health Plan submitted an ICD diagnosis code for emphysema for Patient #11 for service year 2013 and received a risk-adjustment payment of

$2,813.76 for payment year 2014 based upon this submission.

i. The Colorado Health Plan was not entitled to this risk-adjustment payment because emphysema did not require or affect patient care, treatment, or management during the visit. The diagnosis of emphysema was merely added to Patient #11's medical record after Dr. Rears was prompted by a query to add the diagnosis based on five-year-old CT scan.

~~330~~357. After receiving the risk-adjustment payment, the Colorado Health Plan redacted (i.e., deleted) the diagnosis on April 29, 2015, as part of its redaction of diagnoses associated with the Colorado region's unlawful chart-review and leading-query program. These redactions reflected that Kaiser was aware that its improper query and addenda issues were material to CMS and that it was not lawfully allowed to submit these improper diagnoses to CMS for payment. Based on these redactions, CMS collected back the payments for these diagnoses through reconciliation. However, when Kaiser redacted this information, it failed to furnish the Government—either CMS, HHS-OIG, or the Department of Justice—with any information regarding its fraudulent diagnosis submissions, including its improper use of addenda and queries.

~~331~~358. Patient #11 is similar in all relevant respects to thousands upon thousands of other patients, including the specific additional ten patient examples in the allegations below. Yet Kaiser did not take steps to remediate the hundreds of thousands of improper diagnoses that Kaiser submitted for payment for these similar patients in Colorado, Northern California, or Southern California. The small number of diagnoses that Kaiser redacted were a miniscule fraction of the improper addenda diagnoses that Kaiser submitted to CMS and for which Kaiser received payment from CMS. Had Kaiser fully disclosed that its unlawful addenda practices had resulted in other fraudulent diagnoses, CMS would have taken appropriate actions to ensure that Kaiser did not receive or retain risk-adjustment payments to which it was not entitled, including by recouping payments through administrative processes, payment adjustments, or obtaining repayments in enforcement actions.

VIII. KAISER RECEIVED MONEY FROM MEDICARE BASED ON THE PRESENTATION OF FALSE CLAIMS.

~~332~~359. For service years 2009 to 2018, the Defendant Kaiser Health Plans submitted and received payment from CMS for nearly 500,000 diagnoses that were added to patient medical records using addenda. Approximately 100,000 of these diagnoses were for AA. The Defendant Kaiser Health Plans received in the range of $1 billion from CMS as a result of these addenda.

~~333~~360. For service years 2009 to 2018, over 12,500 physicians employed by the Defendant Permanente Medical Groups created addenda to patient medical records to add diagnoses for which the Defendant Kaiser Health Plans received payment from CMS. There are over 1,600 physicians that added more than 100 diagnoses via addenda during this time period.

And over two dozen physicians each added over 500 diagnoses via addenda during this time period.

~~334~~361. Kaiser's consistent pressure on physicians to add conditions to patient-visit records led to numerous diagnoses that were not based on the original visit ~~and~~, did not require or affect patient care, treatment, or management, and many times were contradicted by the medical record.

~~335~~362. During the period at issue, Kaiser knowingly submitted false and/or fraudulent diagnosis codes for tens of thousands of Medicare Advantage beneficiaries using the risk-adjustment data reporting systems provided by CMS. These false claims inflated CMS's reimbursements to the Kaiser Health Plans by hundreds of millions of dollars, representing a substantial monetary impact.

~~336~~363. The ~~specific~~representative examples, described below, are of Kaiser patients that had diagnoses added to their medical records by Defendant Permanente Medical Group physicians, often many months after the visit. As is clear from the medical record from the visit, those diagnoses did not require or affect patient care, treatment, or management for the visit, and many times the existence of the condition at the visit was contradicted by the medical record, yet the Defendant Kaiser Health Plans submitted them to CMS, and received and retained a risk-adjustment payment from CMS as a result. In these and thousands of other instances, Kaiser's misconduct had a direct and foreseeable impact on CMS. Specifically, Kaiser's misconduct not only enabled it to obtain and retain higher risk-adjustment payments from CMS, it also adversely affected the integrity and accuracy of CMS's ~~risk adjustment~~risk-adjustment payment system.

A. Patient #1

~~337~~364. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #1.

a. Dr. Sangita Shah (a N. California Medical Group physician) saw Patient #1 on March 28, 2012, for rib pain during coughing. Dr. Shah ordered a chest x-ray at the visit. There was no mention of AA in the medical record for the visit.

b. On March 28, 2012 (the same day of the visit), Dr. Shah sent Patient #1 a message after reviewing the radiologist's report of the chest x-ray: "Your xrays of the rib and lung area all looked normal. The bones are normal and show no evidence of 'lytic' or destructive lesions. I believe the pain is a neuralgia as we discussed today." Patient #1 responded thanking Dr. Shah for the assuring note.

c. Although the radiology report notes the presence of AA as an incidental finding, Dr. Sangita Shah did not mention or communicate anything about AA to Patient #1 in her message.

d. On June 21, 2012 (almost three months after the visit), Dr. Shah received a data- mining query from Data Quality Trainer Ellie Kamkar that stated: "Hello Please review imaging impression notes on 03/28/2012 and consider diagnosis of ATHEROSCLEROSIS AORTA. If agreed, please add the diagnosis of AORTIC ATHEROSCLEROSIS & amend the visit note for the DOS 03/28/12 Thank you."

e. Two weeks after receiving the query, Dr. Shah created an addendum to add the diagnosis of AA.

f. The addendum is nothing more than a listing of the diagnosis.

g. There is nothing in the medical record that indicates that Dr. Shah communicated to Patient #1 the diagnosis of AA after creating the addendum.

h. The Health Plan submitted an ICD diagnosis code for AA for Patient #1 for service 2012 and received a risk-adjustment payment of $2,780.16 for payment year 2013 based on that submission.

i. The Health Plan was not entitled to this risk-adjustment payment for AA for Patient #1 because AA did not require or affect patient care, treatment, or management during the visit. The diagnosis of AA was merely added to Patient #1's medical record—three months after Patient #1's visit—after Dr. Shah was prompted by a Kaiser data-mining query to add the diagnosis.

B. Patient #2

~~338~~365. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #2.

a. Dr. Silvester Rocque Lim (a S. California Medical Group physician) saw Patient #2 on May 30, 2012, for a blood pressure check and to review lab results. Dr. Lim's sole diagnosis for Patient #2 in the brief visit note was hypertension (high blood pressure). The note also included a discussion that the recent labs showed that Patient #2's creatine had improved with increased water intake.

b. No radiology exam was ordered at the visit.

c. On November 29, 2012 (approximately six months after the visit), Dr. Lim received a query from William Wang, of the "Coding Flying Squad," that stated:

"Hi Dr. Lim, I was working on your list of uncoded patients, and this patient was seen earlier this year. He has several uncoded diagnoses the region thinks should be picked up:

ATHEROSCLEROSIS AORTA (seen on CT 12/21/05)

EMPHYSEMA (seen on CT 12/21/05)-hasn't been clinically diagnosed yet though.

PROSTATE CANCER. . . ."

d. The CT scan referred to in the query for AA and emphysema was seven years old. There was no indication in the visit note that Dr. Lim was aware of, let alone considered, this CT scan or the requested diagnoses. There was no mention of AA or emphysema, which the query noted had never been clinically diagnosed. The medical record from the original visit further stated that Patient #2 had a history of prostate cancer (identified with a different ICD history code) and did not have active prostate cancer.

e. The same day he received the query, Dr. Lim created an addendum to add the diagnoses of AA, emphysema, and prostate cancer.

f. There is nothing in the record that indicates that Dr. Lim communicated to Patient #2 that he had AA or emphysema, or that his prior prostate cancer had returned.

g. The Health Plan submitted an ICD diagnosis code for AA, emphysema, and active prostate cancer for Patient #2 for service year 2012 and received a risk-adjustment payment of $7,282.68 for payment year 2013 based upon these submissions.

h. The Health Plan was not entitled to this risk-adjustment payment for Patient #2 because these conditions did not require or affect patient care, treatment, or management during the visit. The diagnoses were merely added to Patient #2's medical record—six months after Patient #2's visit—after Dr. Lim was prompted by a data-mining query to add the diagnoses.

C. Patient #3

~~339~~366. The Health Plan submitted a false claim and received money from CMS based on diagnoses added in addenda for Patient #3.

a. Dr. Chitra Chandran (a N. California Medical Group physician) saw Patient #3 on January 17, 2013, for shortness of breath and diagnosed Patient #3 with exacerbation of chronic obstructive pulmonary disease ("COPD"). Dr. Chandran prescribed prednisone (a steroid) and doxycycline (an antibiotic). Dr. Chandran ordered a chest x-ray to rule out pneumonia. When the results of the x-ray came back, Dr. Chandran told Patient #3 that the "x-ray did not show pneumonia," and that "he should take the antibiotics and prednisone like we discussed." There is no indication in the original visit note that Dr. Chandran considered, evaluated, or treated any other condition at this visit.

b. There is no mention of AA in the visit note.

c. On September 16, 2013 (eight months later), Dr. Chandran received a query from Data Quality Trainer Shahida Dossa, which stated: "Dear Dr. Chandran, On 1/17/13 you stated: A/P: ACUTE EXACERBATION OF COPD (primary encounter diagnosis) Note: will get CXR to r/o PNA, . . . XR CHEST, PA AND LATERAL.. Subsequently the imaging you ordered showed Positive Aortic Atherosclerosis. Therefore we would like you to amend the note for DOS: 1/17/13, and capture AA. A smart phrase you may want to use is DOT AORTICATHEROSCLEROSIS. Pls add AA to Problem List."

d. The SmartPhrase ".AORTICATHEROSCLEROSIS" was created by the N. California Medical Group. Entry of this SmartPhrase would generate the following language in the patient record: "Aortic Atherosclerosis noted on review of the radiology exam associate with chart review and this visit. Will follow longitudinally as an independent risk factor for CVD and CVA, with management per standard risk factor controls over time by PCP or appropriate specialist."

e. One day after receiving the query, Dr. Chandran created an addendum to add the diagnosis of AA using the SmartPhrase as instructed.

f. The addendum states: "After review of my note for this visit encounter, I recall this encounter and am addending this note to state that this patient has diagnosis of: ATHEROSCLEROSIS AORTA. Note: Aortic Atherosclerosis noted on review of the radiology exam associated with this visit. Will follow longitudinally as an independent risk factor for CVD and CVA, with management per standard risk factor controls over time."

g. There is nothing in the medical record that indicates that Dr. Chandran communicated to Patient #3 the diagnosis of AA after creating the addendum.

h. Dr. Chandran then later created two additional addenda, eight months and nine months after the visit, to add twelve more diagnoses to Patient #3's medical record. There is no indication in the original note or addenda that any of these 12 additional conditions required or affected patient care, treatment or management at the visit. This is confirmed by Dr. Chandran's addenda note which states: "I have confirmed with the patient and/or the medical record the presence of the above diagnoses, and the diagnoses are followed or will be followed by his or her PCP or appropriate specialist."

i. One of these diagnoses added via addendum was for severe obesity equivalent. The medical record states that Patient #3's BMI was 31 at the visit, which contradicts a diagnosis of severe obesity equivalent, which requires a BMI of at least 35.

j. The Health Plan submitted an ICD diagnosis code for AA, morbid (severe) obesity, diabetes with other specified manifestations, and colostomy status for Patient #3 for service year 2013 and received a risk-adjustment payment of $13,925.28 for payment year 2014 based upon these submissions.

k. The Health Plan was not entitled to this risk-adjustment payment for Patient #3 because the four diagnoses did not require or affect patient care, treatment, or management during the visit. The diagnosis of AA was merely added to Patient #3's medical record—eight months after Patient #3's visit—after Dr. Chandran was prompted by a leading query to add the diagnosis based on an incidental finding noted in a radiology report. The remaining diagnoses likewise did not require or affect patient care, treatment, or management during the visit. And the condition of severe obesity equivalent did not exist at the time of the visit, as indicated by the medical record.

D. Patient #4

~~340~~367. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #4.

a. Dr. Natalia Volkova (a N. California Medical Group physician) saw Patient #4 on July 17, 2013, for an ear problem. Dr. Volkova diagnosed Patient #4 with cellulitis on the ear lobe (bacterial skin infection).

b. The visit note makes no mention of any prior cardiac history or any past myocardial infarction ("MI").

c. On July 2, 2014 (almost one year later), Dr. Volkova received a query from Clinical Documentation Consultant Danilo Camacho that stated: "Dear Dr. NATALIA B VOLKOVA

MD, This message is sent on behalf of the Regional Clinical Review Team. [Patient #4] has been prescreened for possible Hx of MI. Please review the following clinical information: Pt was diagnosed with 'Old MI' in several office visits. The last one was on 10/27/08. Cardio office visit 11/10/08 stated 'prior h/o MI and subsequent 2 vessel CABG in 92'. Please consider evaluating and documenting Hx of MI at the next Visit if appropriate Please consider to add [sic] it to problem list as a reminder. This makes the diagnosis explicit to other clinicians and ensures quality of care. Thank you for considering this diagnosis and please respond with the action taken."

d. The same day of the query, Dr. Volkova created an addendum to add the diagnosis of history of myocardial infarction.

e. The entire addendum states: "HX OF MI. Status: Stable/Unchanged."

f. The Health Plan submitted an ICD diagnosis code for history of myocardial infarction for Patient #4 for service year 2013 and received a risk-adjustment payment of $328.79 for payment year 2014 based on this submission.

g. The Health Plan was not entitled to this risk-adjustment payment for Patient #4 because history of myocardial infarction did not require or affect patient care, treatment, or management during the visit. The diagnosis of history of myocardial infarction was merely added to Patient #4's medical record—one year after Patient #4's visit—after Dr. Volkova was prompted by a query regarding the diagnosis based on a different visit that took place five years prior. The added diagnosis code was completely unrelated to the visit that actually occurred for a skin infection on the ear lobe.

E. Patient #5

~~341~~368. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #5.

a. Dr. Jennifer Win-Yun Lam (a S. California Medical Group physician) saw Patient #5 on January 21, 2014, because of a right eye problem. Dr. Lam diagnosed Patient #5 with a stye on her right eyelids and prescribed an antibiotic.

b. The visit note makes no mention of any skin issues and states "skin is warm."

c. On May 15, 2014 (about four months later), Dr. Lam received a query from Compliance Auditor Belinda Covington that stated:

"Subject: Action Required: Coding Clarification Request

Dear Provider, The following diagnoses are on the 2014 Seen Not Coded

Diagnosis List. WHAT SHOULD I DO WITH THESE DIAGNOSES? Please review your progress note. If appropriate, you may complete an addendum in Health Connect to add the diagnosis and reason for the addendum. - Or - If the diagnosis is Not Active, please indicate if the diagnosis is Resolved or is Incorrect on the Problem list in KP Health Connect as per

instructions on the In-basket Addendum Process handout.

Diagnosis: 287.2 - Purpura Nos

Dx Source: CLIN

Dx. Date: 11/08/2013"

d. On September 13, 2014 (approximately eight months after the visit), Dr. Lam responded: "Addendum done."

e. On the same day, Dr. Lam created an addendum that states: "Upon further review, pt has 287.2 SENILE PURPURA -stable."

f. The Health Plan submitted an ICD diagnosis code for purpura, not otherwise specified for Patient #5 for service year 2014 and received a risk-adjustment of $679.08 for payment year 2015 based upon this submission.

g. The Health Plan was not entitled to this risk-adjustment payment for Patient #5 because purpura (skin bruising) did not require or affect patient care, treatment, or management during the visit. The diagnosis was merely added to Patient #5's medical record—eight months after Patient #5's visit—after Dr. Lam was prompted by a query regarding a historical diagnosis. The added diagnosis code was unrelated to the visit that actually occurred for a stye on the right eyelid.

F. Patient #6

~~342~~369. The Colorado Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #6.

a. Dr. Timothy Holcomb (a Colorado Medical Group physician) saw Patient #6 on May 1, 2014, for a hospital follow up. There was no mention of depression in the visit note.

b. On or around October 14, 2014 (five months after the visit), Dr. Holcomb received a "missed opportunity" query in the form of a report titled "Risk Adjustment Refresh – Patients seen by PCP and not all Chronic Diagnoses Addressed." Patient #6 was among dozens of patients on Dr. Holcomb's report, which listed "Major Depression, Recurrent" as the diagnosis for Patient #6.

c. Two days after receiving the query, Dr. Holcomb created an addendum to add the diagnosis of major depression, recurrent.

d. The addendum states "Major depression – stable at this time."

e. The Colorado Health Plan submitted an ICD diagnosis code for major depression, recurrent for Patient #6 for service year 2014 and received a risk-adjustment payment of $3,018.96 for payment year 2015 based upon this submission.

f. The Colorado Health Plan was not entitled to this risk-adjustment payment for Patient #6 because major depression did not require or affect patient care, treatment, or management during the visit. The diagnosis of major depression was merely added to Patient #6's medical record—five months after Patient #6's visit—after Dr. Holcomb was prompted by a "missed opportunity" query to add the diagnosis.

G. Patient #7

~~343~~370. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #7.

a. Dr. Amitabh Joglekar (a N. California Medical Group physician) saw Patient #7 on August 4, 2014, for a cough. Dr. Joglekar diagnosed Patient #7 with gastroesophageal reflux disease at the visit.

b. There was no mention of AA in the medical record from the original visit, and no radiology exam ordered at the visit.

c. On or around December 18, 2014 (four months after the visit), Dr. Joglekar received a data-mining query that stated: "Please review PA & LATERAL CHEST imaging impression notes on 12/10/2014 and consider diagnosis of ATHEROSCLEROSIS AORTA, if appropriate." Notably, the radiology exam referred to in the query was ordered after Patient #7's visit with Dr. Joglekar by a different physician, Dr. Ted Young.

d. Nevertheless, approximately four days after receiving the query, Dr. Joglekar created an addendum to add the diagnosis of AA and did so based on the radiology exam that occurred four months after the patient visit, and that was ordered by a different physician, Dr. Young.

e. The addendum states: "Reason new information. After review of my note for this visit, I recall this encounter and am addending this note to state that this patient has a diagnosis of Aortic atherosclerosis - seen on 12/10/14 CXR. Goal Met, continue with current plan. He is on ARB, beta blocker. Did not tolerant statins. BP controlled."

f. There is nothing in the medical record that indicates that Dr. Joglekar communicated the diagnosis of AA to Patient #7 after creating the addendum.

g. The Health Plan submitted an ICD diagnosis code for AA for Patient #7 for service year 2014 and received a risk-adjustment payment of $2,920.20 for payment year 2015 based upon this submission.

h. The Health Plan was not entitled to this risk-adjustment payment for Patient #7 because AA did not require or affect patient care, treatment, or management during the visit as the purported basis for the diagnosis did not even exist at the time. The diagnosis of AA was merely added to Patient #7's medical record— four months after Patient #7's visit—after Dr. Joglekar was prompted by a query to add the diagnosis based on an incidental finding noted in a radiology report for an x-ray that was ordered by different physician after the visit.

H. Patient #8

~~344~~371. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #8.

a. Dr. John Pakula (a N. California Medical Group physician) saw Patient #8 on August 11, 2014, for edema. There was no mention of AA in the visit note and no radiology exam ordered at the visit.

b. On or around October 11, 2014 (two months after the visit), Dr. Pakula received a data-mining query that stated: "Please review NONCONTRAST CARDIAC CT imaging impression notes on 10/01/2014 and consider diagnosis of ATHEROSCLEROSIS AORTA, if appropriate." Notably, the CT exam referred to in the query was ordered after the visit by a different physician, Dr. Terry Anderson.

c. Nevertheless, approximately one month after receiving the query, and three months after the visit, Dr. Pakula created an addendum to add the diagnosis of AA and did so based on the radiology exam that occurred two months after the patient visit, and that was ordered by a different physician, Dr. Anderson.

d. The addendum states: "After reviewing my visit note, I recall this visit encounter. The visit note an[sic]/or labs reflect that I evaluated the patient who has the diagnosis of: ATHEROSCLEROSIS OF AORTA. Note: Aortic Atherosclerosis noted on review of the radiology exam (CT for calcium score, 10/1/14 by cardiologist Dr. Anderson) subsequent to this visit. Pt on BB, statin, and ACE-i. Will follow longitudinally as an independent risk factor for CVD and CVA, with management per standard risk factor controls over time."

e. There is nothing in the medical record that indicates that Dr. Pakula communicated the diagnosis of AA to Patient #8 after creating the addendum.

f. The Health Plan submitted an ICD diagnosis code for AA for Patient #8 for service year 2014 and received a risk-adjustment payment of $2,785.80 for payment year 2015 based upon this submission.

g. The Health Plan was not entitled to this risk-adjustment payment for Patient #8 because AA did not require or affect patient care, treatment, or management during the visit as the purported basis for the diagnosis did not even exist at the time. The diagnosis of AA was merely added to Patient #8's medical record—three months after Patient #8's visit—after Dr. Pakula was prompted by a query to add the diagnosis based on an incidental finding noted in a radiology report for an CT scan that was ordered by different physician after the visit.

I. Patient #9

~~345~~372. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #9.

a. Dr. Christina Le (a N. California Medical Group physician) saw Patient #9 on August 22, 2014, for a hospital follow-up.

b. The visit note makes no mention of hypogammaglobulinemia.

c. On February 3, 2015 (almost six months later), Dr. Le received a query from Clinical Documentation Consultant Dani Castillo that stated: "Dear Doctor CHRISTINA ANH LOAN LE MD: This message is sent on behalf of the Regional Code Review Team and Dr. Alphana Shekhar (Documentation and Coding Lead). [Patient #9] has been prescreened for possible Hypogammaglobulinemia, either primary or secondary. . . . Action requested for Data Mining effort: If appropriate, please consider dx of Hypogammaglobulinemia. Please consider to add [sic] diagnosis to the problem list as you deem appropriate. This helps make the diagnosis explicitly apparent to other physicians and ensures quality of care. Thank you for considering this diagnosis, and please respond with the action taken."

d. The same day of the query, Dr. Le created an addendum to add the diagnosis of hypogammaglobinemia and responded to the query: "Addended. Thanks, cle."

e. The addendum states: "After review of my note for this visit encounter, I recall this encounter and am addending this note to state that this patient has diagnosis of: HYPOGAMMAGLOBULIN. Note: fu per heme/ofnc."

f. The Health Plan submitted an ICD diagnosis code for hypogammaglobinemia for Patient #9 for service year 2014 and received a risk-adjustment payment of $9,917.64 for payment year 2015 based upon this submission.

g. The Health Plan was not entitled to this risk-adjustment payment for Patient #9 because hypogammaglobinemia did not require or affect patient care, treatment, or management during the visit. The diagnosis of hypogammaglobulinemia was merely added to Patient #9's medical record—six months after Patient #9's visit—after Dr. Le was prompted by a query to add the diagnosis.

J. Patient #10

~~346~~373. The Health Plan submitted a false claim and received money from CMS based on a diagnosis added in an addendum for Patient #10.

a. Dr. Shih-Chin Thomas Wang (a N. California Medical Group physician) saw Patient #10 on October 23, 2014, for the flu.

b. The visit note makes no mention of cachexia or of Patient #10's nutritional status.

c. On November 6, 2014 (about two weeks later), Dr. Wang received a query from Clinical Documentation Consultant Albina Dvorkis that stated that Patient #10 "has been prescreened for possible Cachexia. Patient has met criteria: BMI <18.5 plus diagnosed with following comorbidities: HIV/AIDS, Active CA, COPD, rheumatoid Arthritis, Heart Failure, End Stage Liver Disease, End Stage Renal Disease, Chronic Kidney Disease, Tuberculosis, Alzheimer and Dementia. Please review the following clinical information: 73 yo female w/Bipolar, CKD st3. Wt loss 7.41% last 5 mon and 17.31% last 3 years. Last BMI -18.44. Please consider to evaluate for Cachexia next visit and add to diagnosis list if appropriate based on your clinical judgment. Please remember to update the problem list I would appreciate if you will respond with the action taken. Thank you."

d. Approximately two weeks later, Dr. Wang created an addendum to add the diagnosis of cachexia.

e. The addendum states "Cachexia. Note: patient has no general debility. But lost some lbs of weight. Will continue to follow."

f. By stating "no general debility," the addendum contradicts a diagnosis of

cachexia. The medical record further indicates that the patient is "well appearing" and that the weight loss is associated with the flu.

g. The Health Plan submitted an ICD diagnosis code for cachexia for Patient #10 for service year 2014 and received a risk-adjustment of $6,363.48 for payment year 2015 based upon this submission.

h. The Health Plan was not entitled to this risk-adjustment payment for Patient #10 because cachexia did not exist and did not require or affect patient care, treatment, or management during the visit. In fact, the addendum that was created to add that diagnosis to the medical record contradicts the representation that the patient had cachexia. The diagnosis of cachexia was merely added to Patient #10's medical record—one month after Patient #10's visit—after Dr. Wang was prompted by a query regarding the diagnosis.

374. These examples are representative of hundreds of thousands of diagnoses Kaiser submitted for conditions that did not require or affect patient care, treatment or management at the relevant visit.

375. Moreover, example patients 2, 3, and 10, as well as the examples from earlier in the Amended Complaint, are representative of thousands upon thousands of diagnoses that, in addition to being unrelated to the patient visit, were contradicted by the patient's medical record at the time of the visit. For each such diagnosis, (1) the physician did not document the condition or its relevance during the original visit record, (2) Kaiser's refresh or data-mining programs pressed the physicians to add these diagnoses despite contradictory information in the medical record and despite the condition not being relevant to the visit, (3) Kaiser failed to alert the physician to the contradictory information in the medical record, and (4) the physician followed Kaiser's direction to addend the diagnosis to the patient's medical record. Nor is there any evidence in these circumstances that the physician was correcting any mistaken information in the medical record.

376. These fraudulent diagnoses were not accidents, but the inevitable result of Kaiser's flawed programs to increase risk-adjustment revenue without regard to what actually occurred at the visit, including whether the condition was unrelated to the visit or whether the existence of the condition was contradicted by the medical record. Kaiser routinely queried physicians to add diagnoses unrelated to the visit and failed to ensure that it did not query physicians for conditions whose existence was contradicted by the medical record. Kaiser also failed to inform physicians of relevant, contradictory information regarding the conditions it sought to add. These failures were further compounded by Kaiser's failure to review the addenda created at its request to ensure that it was not submitting inaccurate ICD diagnosis codes, including when physicians documented conditions as historical. All of these failings, and others detailed in the Amended

Complaint, directly led to the false claims at issue here. None of these inaccurate diagnoses existed in the original patient visit record. All were generated at Kaiser's behest. Through its deeply flawed programs to systematically alter patient records, Kaiser submitted for payment hundreds of thousands of inaccurate ICD diagnosis codes for conditions added via addenda that did not require or affect patient care, treatment, or management at the visit, and whose very existence many times was contradicted by the medical record.

IX. CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

False Claims Act: Presenting or Causing to be Presented False Claims

31 U.S.C. § 3729(a)(1)(A) (formerly 31 U.S.C. § 3729(a)(1))

~~347~~377. The United States repeats and re-alleges the allegations contained in ¶¶ 1 to ~~346~~376 above as though they are fully set forth herein.

~~348~~378. Defendants violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval to CMS, resulting in their receiving inflated Medicare payments from CMS to which they were not entitled.

~~349~~379. Specifically, Defendants presented or caused to be presented false claims for risk-adjustment payments in the form of improper diagnosis codes for Defendants' Medicare patients, in violation of CMS regulations and policies, which Defendants agreed to and were obligated to comply with.

~~350~~380. If CMS had known that Defendants had presented or caused to be presented false claims based on these improper codes, CMS would have refused to make risk-adjustment payments based on the improper coding and/or taken other appropriate actions to ensure that Defendants did not receive or retain risk-adjustment payments to which they were not entitled, including by recouping payments through administrative processes, payment adjustments, or obtaining repayments in enforcement actions, and CMS has now done so via this suit that it has authorized.

~~351~~381. By reason of the false claims that Defendants knowingly presented or caused to be presented, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM FOR RELIEF

False Claims Act: Making or Using False Records or Statements

31 U.S.C. § 3729(a)(1)(B) (formerly 31 U.S.C. § 3729(a)(2))

~~352~~382. The United States repeats and re-alleges the allegations contained in ¶¶ 1 to ~~351~~381 above as though they are fully set forth herein.

~~353~~383. Defendants violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, and causing to be made or used, false records or statements material to false or fraudulent claims resulting in their receiving inflated Medicare payments from CMS to which they were not entitled.

~~354~~384. If CMS had known that Defendants had made, used, and caused to be made or used, false records or statements material to false claims based on these improper codes, CMS would have refused to make risk-adjustment payments based on the improper coding and/or taken other appropriate actions to ensure that Defendants did not receive or retain risk-adjustment payments to which they were not entitled, including by recouping payments through administrative processes, payment adjustments, or obtaining repayments in enforcement actions, and CMS has now done so via this suit that it has authorized.

~~355~~385. By reason of the false records and statements that Defendants knowingly made, used, and caused to made or used, the United States has incurred damages and therefore is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

THIRD CLAIM FOR RELIEF

Conspiracy to Violate the False Claims Act

31 U.S.C. § 3729(a)(1)(C) (formerly 31 U.S.C. § 3729(a)(3))

~~356~~386. The United States repeats and realleges the allegations contained in ¶¶ 1 to ~~355~~385 above as though they are fully set forth herein.

~~357~~387. Defendants Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Health Plan of Colorado knowingly conspired with the Permanente Medical Group, Inc., the Southern California Permanente Medical Group, and the Colorado Permanente Medical Group, P.C. to violate 31 U.S.C. §§ 3729(a)(1)(A) and (B) 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.

~~358~~388. By reason of Defendants' conspiracy, the United States has incurred damages and therefore is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

FOURTH CLAIM FOR RELIEF

Payment by Mistake

~~359~~389. The United States repeats and re-alleges the allegations contained in ¶¶ 1 to ~~358~~388 above as though they are fully set forth herein.

~~360~~390. As a consequence of Defendants' misconduct and the acts set forth above, Defendants received monies from the United States as a result of a mistaken understanding. Specifically, the United States reimbursed the Health Plan and the Colorado Health Plan, which

in turn reimbursed the N. California Medical Group, the S. California Medical Group, and the Colorado Medical Group, under the mistaken understanding of the United States that such claims were based on valid risk-adjustment diagnosis submissions. Had the United States known the truth, it would not have paid such claims and/or taken other appropriate actions to ensure that Defendants did not receive or retain risk-adjustment payments to which they were not entitled. Payment was therefore by mistake.

~~361~~391. As a result of such mistaken payments, the United States has sustained damages for which Defendants are liable in an amount to be determined at trial.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment

~~362~~392. The United States repeats and re-alleges the allegations contained in ¶¶ 1 to ~~361~~391 above as though they are fully set forth herein.

~~363~~393. As a consequence of Defendants' conduct and the acts set forth above, Defendants were unjustly enriched at the expense of the United States. In equity and good conscience such money belongs to the United States.

~~364~~394. The United States is entitled to recover such money based on Defendants' unjust enrichment in an amount to be determined at trial.

X. PRAYER FOR RELIEF

WHEREFORE, the United States requests that judgment be entered in its favor and against

Defendants as follows:

On Claims I, II, and III (False Claims Act), against all Defendants jointly and severally, for:

(i) the amount of the United States' damages, trebled as required by law; (ii) the maximum civil penalties allowed by law, (iii) the costs of this action, plus interest as provided by law, and (iv) any other relief that this Court deems appropriate.

As to Claim IV (Payment by Mistake), for: (i) an amount equal to the money paid by the United States through the Medicare Advantage program as a result of Defendants' false submissions, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate.

As to Claim V (Unjust Enrichment), for: (i) an amount equal to how much Defendants were unjustly enriched, plus interest; (ii) the costs of this action, plus interest, as provided by law; and

(iii) any other relief that this Court deems appropriate.

XI. DEMAND FOR JURY TRIAL

The United States of America hereby demands a trial by jury.

DATED: ~~October 25, 2021~~December 12, 2022 Respectfully submitted,

~~SARAH E. HARRINGTON~~
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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA ex rel. RONDA OSINEK,

Plaintiff,

v.

KAISER PERMANENTE, et al.,

Defendants.

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

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

Hearing Date: May 4, 2023
Time: 1:30 PM
Judge: Hon. Edward M. Chen
Courtroom: 5, 17th Floor

(CAPTION CONTINUED)

UNITED STATES OF AMERICA ex rel. GLORYANNE BRYANT and VICTORIA HERNANDEZ,

Plaintiff,

v.

KAISER PERMANENTE, et al.,

Defendants.

Case No. 3:18-cv-01347-EMC

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

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,

Plaintiff,

v.

KAISER PERMANENTE, et al.,

Defendants.

Case No. 3:21-cv-03894-EMC

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

Hearing Date: May 4, 2023
Time: 1:30 PM
Judge: Hon. Edward M. Chen
Courtroom: 5, 17th Floor

[PROPOSED] ORDER

With good cause shown, Defendants' Motion to Dismiss the United States' First Amended Complaint is GRANTED. The Court dismisses all claims for relief premised on the new allegations in the United States' First Amended Complaint with prejudice. The United States is not permitted to proceed on either a theory of fraud based on "contradictions" in the medical record, or a systemic scheme to diagnose clinically false diagnoses other than cachexia in Northern California.

IT IS SO ORDERED.

DATED:

_____
HONORABLE EDWARD M. CHEN
UNITED STATES DISTRICT JUDGE