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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA *ex rel.* KATHY ORMSBY,

Plaintiff,

v.

SUTTER HEALTH and PALO ALTO MEDICAL FOUNDATION,

Defendants.

Case No. 3:15-cv-01062-LB

DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS UNITED STATES' COMPLAINT-IN-INTERVENTION

Date: October 24, 2019
Time: 9:30 a.m.
Courtroom: Courtroom C, 15th Floor

Hon. Laurel Beeler

NOTICE OF MOTION AND MOTION TO DISMISS

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

PLEASE TAKE NOTICE that on October 24, 2019 at 9:30 a.m., or as soon thereafter as the parties may be heard, before the Honorable Laurel Beeler, Magistrate Judge, United States District Court for the Northern District of California, in the San Francisco Courthouse, Courtroom C, 15th Floor, 450 Golden Gate Avenue, San Francisco, CA 94102, Defendants Sutter Health and Palo Alto Medical Foundation ("Defendants") will and hereby do move this Court for an order dismissing the government's Complaint-in-Intervention (ECF No. 41). This motion is brought on grounds that: the government fails to allege false claims or unlawfully retained overpayments under Medicare Advantage's comparative standard; the government fails to allege with particularity that Defendants identified any overpayments or knowingly submitted false claims or statements; and the government fails to allege with particularity that any falsity in Defendants' certifications would have been material to the government's decision to pay.

Defendants' Motion is based on this Notice of Motion and Motion to Dismiss, the following Memorandum of Points and Authorities, all pleadings and papers in this action, and any oral argument of counsel.

Defendants seek an order pursuant to Federal Rule of Civil Procedure 12(b)(6) dismissing the government's Complaint-in-Intervention in its entirety for failure to state a claim upon which relief can be granted.

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I. INTRODUCTION

This False Claims Act case rests on an outdated conception of the Medicare Advantage program that federal courts have repeatedly rejected. The government's Complaint-in-Intervention alleges that defendants Sutter Health and Palo Alto Medical Foundation (collectively, "Defendants") submitted diagnosis codes to the Medicare Advantage program that they should have known were not adequately documented by medical charts. It contends that this inappropriately increased the government reimbursement Defendants received. But, as a series of recent judicial decisions makes clear, the government must allege more than just erroneous diagnosis codes to show that Defendants were overpaid. It must further allege—with requisite specificity under Federal Rule of Civil Procedure 9(b)—that the prevalence of unsupported diagnosis codes in Defendants' Medicare Advantage submissions exceeds the prevalence of such codes in traditional Medicare. As the U.S. District Court for the District of Columbia recently put it in striking down a 2014 regulation—the "Overpayment Rule"—that adopted the same theory the government is relying on here, the key question is whether "the error rate for a Medicare Advantage contract is greater than the [government] error rate" in traditional Medicare. *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 186 (D.D.C. 2018). The Complaint-in-Intervention does not and cannot make that essential allegation. And it fails to make other key allegations, too, regarding issues like whether Defendants *knowingly* committed any violations and whether allegedly false certifications that the government claims Defendants submitted were actually material to the government's payment decisions. Recent decisions in this Circuit have dismissed government False Claims Act charges involving the Medicare Advantage program for just such failures. *See United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-08697, 2018 WL 1363487, at *9, *11 (C.D. Cal. Feb. 2, 2018); *United States ex rel. Swoben v. Scan Health Plan*, CV 09-5013, 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017). This Court should do the same.

At root, the problem is that the government has mistakenly approached this case as though it involved the traditional Medicare program. Traditional Medicare uses a fee-for-service

model in which healthcare providers like Defendants treat patients, and the government reimburses the providers for the items or services utilized in doing so. In that program, it is well established that when a provider seeks reimbursement for an item or service that has *not* been provided, the claim is false—and the False Claims Act is available as a remedy to recover taxpayer funds. Here, the government attempts to wedge its Medicare Advantage case into the traditional Medicare framework by alleging that (1) Defendants submitted "diagnosis codes" for Medicare Advantage beneficiaries that were not properly documented; (2) Defendants should have known about the lack of proper documentation; and (3) Defendants were overpaid as a result.

But Medicare Advantage is a fundamentally different program with its own unique standards for establishing overpayments. Under Medicare Advantage, the government does not make payments for discrete items or services that have been provided to beneficiaries. Instead it makes fixed payments, which operate essentially as insurance premiums, in exchange for others taking on the cost of care. And by statute, the government is required to set those payments using a formula that maintains equivalence between (1) the risk that the government would face if the beneficiary were in the traditional Medicare program; and (2) the risk that it treats the Medicare Advantage participant as having taken on by agreeing to provide care in the government's place—a concept the Medicare statute refers to as "actuarial equivalence." 42 U.S.C. § 1395 w-23(a)(l)(C)(i). The key to determining whether the government has paid too much in Medicare Advantage, therefore, is whether that beneficiary has been made to appear riskier in the Medicare Advantage program than he or she would appear in traditional Medicare.

Because Medicare Advantage payments depend on this comparison, a Medicare Advantage participant is overpaid "when, *and only when*, the error rate for a Medicare Advantage contract is greater than the [government] error rate" in traditional Medicare. *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 186 (emphasis added). And that is no small thing: The government itself has estimated that a third of the diagnosis codes submitted in *traditional* Medicare are unsupported, and the true number could be even higher. To show that a Medicare Advantage participant has been overpaid, the government must show that the participant's

overall rate of unsupported diagnosis codes is even higher than the rate in traditional Medicare—otherwise, the assessment of its *comparative* risk remains accurate (or even understated), notwithstanding that some of its diagnosis codes may not be properly documented.

This legal rule—never mentioned in the Complaint-in-Intervention—is directly relevant in several ways. *First*, under the False Claims Act, the government must allege that Defendants either (1) submitted false claims, or (2) received overpayments that they failed to return. But the government does not properly allege either of those things, because it does not provide any basis for comparing the overall rate of unsupported diagnosis codes in Defendants' submissions to the rate of unsupported diagnosis codes in the traditional Medicare program. *Second*, the False Claims Act also requires the government to allege that Defendants committed those violations "knowingly." Again, though, the Complaint-in-Intervention offers no basis to conclude that Defendants *knew*, or were reckless for not knowing, that they had a higher prevalence of unsupported codes than did the traditional Medicare program. And while the government suggests that Defendants should have known that certain *other* submissions they made were false (specifically, annual certifications regarding the diagnosis codes they had submitted), it disregards both the objectively reasonable interpretation of those certifications and the fact that courts have repeatedly held that such certifications cannot support False Claims Act allegations because they are not material to the government's payment decisions.

For all of these reasons, the Complaint-In-Intervention should be dismissed under Federal Rule of Civil Procedure 12(b)(6).[1]

[1] Defendants are simultaneously moving to dismiss the Relator's separate complaint in a separate motion. These motions are appropriately considered together, and all of the arguments Defendants offer in this motion apply equally to the Relator's complaint.

II. BACKGROUND

A. Medicare Advantage, Risk Adjustment, And The "Actuarial Equivalence" Requirement

1. Medicare Advantage Pays Plans And Providers Under A Risk Adjustment Model Requiring "Actuarial Equivalence" Between Traditional Medicare And Medicare Advantage

Congress created Medicare Advantage (sometimes abbreviated "MA") as an alternative to traditional Medicare. *See* 42 U.S.C. § 1395w-21 et seq. Rather than paying for specific items and services, the Medicare Advantage program pays private insurance companies to take on the *risk* associated with Medicare beneficiaries. When a beneficiary enrolls in a Medicare Advantage plan, the insurer receives a fixed monthly payment from the government (often referred to as a "capitated payment"), and in exchange the insurer is responsible for paying for that beneficiary's covered healthcare costs, whatever those end up being. *See generally id.* § 1395w-23. The insurer can then enter into contracts with healthcare providers like Defendants in which the healthcare providers agree to provide covered care to the plan's beneficiaries in exchange for a portion of the fixed fees. The plan and providers then have an incentive to manage the beneficiary's care in a manner that promotes long-term health and provides better services at the same cost as traditional Medicare.

In establishing Medicare Advantage, Congress required the agency in charge of Medicare, the Centers for Medicare and Medicaid Services ("CMS"), to ensure that there is "actuarial equivalence" between the traditional fee-for-service Medicare program and the Medicare Advantage program. *See* 42 U.S.C. § 1395 w-23(a)(l)(C)(i). As CMS has admitted, this means that there must be equivalence "between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional, fee-for-service (FFS) Medicare, and the payments made to Medicare Advantage (MA) insurers for covering an individual with those same characteristics." Federal Defendants' Cross-Motion for Summary Judgment at 8, *UnitedHealthcare Ins. Co. v. Azar*, No. 16-cv-157 (D.D.C. Dec. 4, 2017), ECF No. 57-1. And by statute, CMS must use the "same methodology" to measure risk in both programs. *See* 42 U.S.C. § 1395w-23(b)(4)(D).

To ensure "actuarial equivalence" between fee-for-service and Medicare Advantage beneficiaries, CMS is required to adjust Medicare Advantage payments based on the risk that different Medicare Advantage beneficiaries present. For example, a healthy 65-year-old woman would be unlikely to require many interventions during a year, and would thus cost the fee-for-service program relatively little in direct fees; accordingly, a Medicare Advantage insurer and its contracted provider should receive lower payments for insuring and caring for her. In contrast, an 87-year-old man with diabetes and multiple sclerosis would require significant interventions during the year, which would cost the fee-for-service program more in direct fees; accordingly, a Medicare Advantage insurer and its contracted provider should receive higher payments for such a beneficiary.

CMS accomplishes this by calculating a total "risk score" for each patient. CMS begins with data that is readily available to it—the costs it incurs for the care of tens of millions of beneficiaries in the traditional fee-for-service Medicare program, as well as the information it has about their healthcare conditions. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d at 178-79 (describing this "risk adjustment" process). It then uses statistical regression to associate medical costs across the fee-for-service program with the demographic status of individual beneficiaries (such as their age and gender) and the "diagnosis codes" it collects for those beneficiaries during the claims submission process. *See id.* These diagnosis codes are numerical codes submitted by healthcare providers like Defendants that designate the conditions with which their patients have been diagnosed. Through its regression, CMS assigns every dollar spent in traditional Medicare to a traditional Medicare beneficiary's diagnosis code or demographic condition. *Id*. The regression calculates the incremental cost associated with a given diagnosis code—that is, how much more a patient with that diagnosis code is likely to cost as compared with an otherwise identical beneficiary who does not have that code. *Id*. For example, CMS has determined that a beneficiary who has a diagnosis code for "Diabetes without Complications," but is of otherwise average health and demographic status in the Medicare program, is likely to cost the traditional Medicare program approximately 11.8 percent more to care for than an otherwise identical beneficiary who does *not* have a diagnosis code for that

condition. *See* Centers for Medicare and Medicaid Services, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 67, https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2014.pdf.

Having calculated how a given diagnosis code or demographic status is likely to affect the risk of increased costs in the traditional Medicare program, CMS then uses those calculations to determine the likely risk posed by a Medicare Advantage plan's beneficiaries. CMS adds together the risk associated with each beneficiary's demographic status and diagnosis codes, arriving at a total "risk score" that CMS uses to adjust the monthly capitated payment for that patient upward or downward. *See UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 178-79 (describing this process of "risk adjustment"). Thus, a plan that enrolls beneficiaries with a higher incidence of diagnosis codes for high-cost conditions will receive larger "premiums" from the federal government to insure those beneficiaries, because it incurs more risk in agreeing to cover their care. *See id.* Similarly, a provider that treats beneficiaries with a higher incidence of such diagnosis codes will receive larger capitated payments under its contract with the plan.

2. A Percentage Of Unsupported Diagnosis Codes Must Be Factored Into Medicare Advantage Payments To Ensure Actuarial Equivalence

There is no dispute that the data sets CMS uses to calibrate this risk adjustment model and to award monthly Medicare Advantage payments are not perfect. In both traditional Medicare and Medicare Advantage, discrepancies often exist between the diagnosis codes submitted to the payer for a given patient and the conditions that are fully documented on that patient's medical chart. *See id*. at 179-80; *United Healthcare Ins. Co. v. Azar*, 316 F. Supp. 3d 339, 343 (D.D.C. 2018) ("[I]t is inevitable that Medicare experiences an error rate—that is, a proportion of diagnosis codes that are unsupported in underlying medical charts."). These discrepancies can arise from any number of things, from notation errors (simply mistyping a code in a data field), to misreading a medical chart (an employee in a doctor's office might see "diabetes" in a chart and enter the associated code, not realizing that the word was a reference to a family history of the disease rather than a diagnosed condition), to instances in which a doctor

just enters a code directly into a billing system without documenting in a chart. *See UnitedHealthcare Ins. Co.*, 316 F. Supp. 3d at 343 (discussing potential causes of unsupported codes). Regardless of their cause, these discrepancies all affect the way that CMS's risk adjustment model operates. Because CMS uses a database from traditional Medicare that contains both properly documented (or "supported") codes and improperly documented (or "unsupported") codes, the process generates predictions of incremental costs for a mix of supported and unsupported codes. *See UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 184. Those predictions would not be accurate if applied only to the smaller subset of *supported* codes. *See id.* Put differently, because CMS does not audit fee-for-service data before calculating the incremental costs associated with diagnosis codes, the incremental cost predictions it generates necessarily take into account the fact that a significant percentage of diagnosis codes will be unsupported in medical charts.

Until recently, CMS recognized that because it uses data from the fee-for-service program that contains unsupported diagnosis codes when it is determining the incremental cost to associate with a particular diagnosis, it cannot turn around and make payments in Medicare Advantage based just on *supported* diagnosis codes. *See UnitedHealthcare Ins. Co.,* 330 F. Supp. 3d at 187-88 (describing CMS's recognition of this point). Doing so would result in Medicare Advantage participants being paid in a manner that is not "actuarially equivalent," 42 U.S.C. § 1395 w-23(a)(l)(C)(i), and therefore violate the Medicare statute. To see why, imagine that the traditional Medicare program had exactly 1,000 beneficiaries and $1 million in costs. Imagine further that those beneficiaries' healthcare providers had submitted diagnosis codes reflecting 3,000 different medical conditions for the beneficiaries, of which 1,500 were properly supported in medical charts and 1,500 were unsupported. CMS would then have $1 million in costs to allocate among a total of 4,000 indicators—1,000 indicators reflecting the beneficiaries' demographic statuses, and 3,000 indicators reflecting reported medical conditions. The *average* value that CMS would assign to those indicators would necessarily be $250 (the resulting of dividing $1 million by 4,000).

Now suppose that a Medicare Advantage provider had agreed to care for an identical group of 1,000 beneficiaries, who had the same set of diagnosis codes reflecting 3,000 different conditions (with 1,500 of the conditions being supported in the medical charts and 1,500 being unsupported). Under the "actuarial equivalence" standard, CMS's payment under the Medicare Advantage program should be $1 million. *See supra* at 4. That would be the result if it paid $250 for each of the 4,000 indicators. If CMS required the provider to delete all of its unsupported codes, however, it would pay substantially less: At that point there would be only 2,500 codes (1,000 representing demographic conditions and 1,500 representing diagnoses), and if CMS still paid an average of $250 per code, its payment would be just $625,000—substantially less than CMS would expect to pay to care for an identical population in the traditional Medicare program.

3. CMS's Unexplained 2014 Overpayment Rule Requiring "Absolute" Accuracy Was Judicially Invalidated Because It Failed To Ensure Actuarial Equivalence

Recognizing this implication of building its risk adjustment program on unaudited data, CMS has historically agreed in the context of audits that Medicare Advantage participants are not "overpaid" simply because they submit unsupported codes. *See UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 180-81 (describing CMS's past treatment of this question in the context of "Risk Adjustment Data Validation" audits). Instead, CMS has acknowledged that a Medicare Advantage participant would be overpaid only if it had a rate of unsupported diagnosis codes that was higher than the comparable rate in the fee-for-service program. *See id.*

In 2012, therefore, CMS agreed to analyze the fee-for-service data and publish an "FFS Adjuster" that reflected the rate of unsupported codes in the FFS data. *See* CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* 4 (Feb. 24, 2012), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf. This adjuster, it said, was needed to "account[] for the fact that the documentation standard used in [Risk Adjustment Data Validation] audits to

determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)." *Id.* at 4-5.

But CMS changed course in 2014. That year, CMS adopted a new "Overpayment Rule," under which it announced that it planned to treat *every* unsupported code as an overpayment, regardless of whether a Medicare Advantage participant's rate of unsupported codes was less than, equal to, or greater than the rate in traditional Medicare program. 79 Fed. Reg. 29,844 (May 23, 2014). That theory—that every unsupported diagnosis code submitted in Medicare Advantage results in an overpayment, regardless of how the Medicare Advantage participant's overall rate of unsupported codes compares to the rate in the fee-for-service program—is the same theory that the government is asserting in this False Claims Act case.

After this case had been filed, but before it was unsealed, the Overpayment Rule was challenged in a suit brought under the Administrative Procedure Act. In September 2018, the U.S. District Court for District of Columbia held the Overpayment Rule, and the theory it had adopted, invalid. *See UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 173. In doing so, the court held that under the statutory mandate of actuarial equivalence, an overpayment exists "when, and only when, the error rate for a Medicare Advantage contract is greater than the CMS error rate" in traditional Medicare. *Id.* at 186. It recognized that "imposing a 100% accuracy requirement on [Medicare Advantage plans'] records, on pain of being required to return any 'overpayment,'" would lead to the "inevitable" result that CMS "will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed." *Id.* at 176, 187. And the court also held that the Overpayment Rule represented an unexplained departure from CMS's prior agreement to use an "FFS adjuster" when performing audits to compare rates of unsupported codes in fee-for-service and Medicare Advantage coding data. *Id.* at 186. By ignoring the relationship between fee-for-service and Medicare Advantage data, the Overpayment Rule violated actuarial equivalence and constituted an arbitrary and capricious departure from prior agency policy. *Id.* at 187-88. CMS could require Medicare Advantage participants to ensure that their data was comparable to data from the fee-for-service program (and require them to pay back any

overpayments that resulted if it was not), but could not treat every unsupported code in the Medicare Advantage program as invalid unless it did so in the traditional Medicare data as well.

B. The Government's Allegations

As noted, this case was filed after CMS had adopted the Overpayment Rule, but before that Rule had been invalidated. On March 6, 2015, Relator Kathy Ormsby filed an action alleging that Sutter and one of its affiliates, the Palo Alto Medical Foundation ("PAMF"), had violated the False Claims Act through their submission of, and subsequent failure to delete, diagnosis codes that were not adequately supported in patients' medical charts. *See* Relator's Original Complaint, ECF No. 1. Sutter and PAMF (collectively, "Defendants") are healthcare providers, and have contracted with Medicare Advantage insurers to provide care for certain Medicare Advantage beneficiaries, in exchange for a portion of the capitated payments the Medicare Advantage plans receive from the government.[2] Ormbsy claimed that Defendants, by submitting and failing to delete unsupported diagnosis codes, had been overpaid (and had caused the Medicare Advantage insurers to be overpaid as well).[3]

Three years later, the government filed a Complaint-in-Intervention. *See* ECF No. 41. Like Relator, it alleges that Defendants violated the False Claims Act by submitting unsupported diagnosis codes for their patients, and by failing to delete those unsupported codes after determining that they had been unsupported. The government also suggests that Defendants falsely certified to "the accuracy, completeness, and truthfulness" of their risk adjustment data in attestations that were required to reflect their "best knowledge, information, and belief." 42 C.F.R. §§ 422.504(l)(2), (l)(3). On the basis of those allegations, the Complaint-in-Intervention asserts two counts for violations of 31 U.S.C. § 3729(a)(1)(G), the so-called "reverse false claim" provision, on the theory that Defendants received and failed to return "overpayments" from CMS in connection with PAMF patients. *See* Complaint-in-Intervention ¶¶ 134-137, 138-

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[2] Sutter is a not-for-profit healthcare system headquartered in Sacramento, California, that is the sole corporate member of PAMF, which provides care at locations in Alameda, San Mateo, Santa Clara, and Santa Cruz. *See* Complaint-in-Intervention ¶¶ 14-15, ECF No. 41.

[3] Neither Ormbsy nor the government have named any of the Medicare Advantage insurers that received payment for beneficiaries treated by Sutter as defendants in this action.

141 (First and Second Claim for Relief). It also asserts two counts under Sections 3729(a)(1)(A) and (B) of the False Claims Act based on Defendants' alleged submission of unsupported diagnosis codes. *See id.* ¶¶ 142–145, 146–149 (Third and Fourth Claim for Relief, under 31 U.S.C. § 3729 (a)(1)(A) and (B)). The government also asserts common law claims for Payment by Mistake, *see id.* ¶¶ 150–152 (Fifth Claim for Relief), and unjust enrichment, *see id.* ¶¶ 153–155 (Sixth Claim for Relief).

III. ARGUMENT

This Court should dismiss the Complaint-In-Intervention because it "fails to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

In order to survive a motion to dismiss, a complaint brought under the False Claims Act must allege several crucial elements. *First*, depending on which section of the False Claims Act it is invoking, the complaint must allege a "false or fraudulent claim" for payment, a false statement "material to a false claim," or "an obligation to pay or transmit money or property to the Government" arising from the "retention of an[] overpayment." 31 U.S.C. §§ 3729(a)(1)(A), (B), (G); *id.* § 3729(b)(3). *Second*, the complaint must allege that the false submission was done "knowingly," *id.* §§ 3729(a)(1)(A), (B), or that the overpayment was "identified" and wrongfully withheld for at least 60 days, 42 U.S.C. § 1320a-7k(d)(2); *see also id.* § 1320a-7k(d)(3). And *third*, it must allege that any false statement or certification was "material" to the government's decision to pay. 31 U.S.C. §§ 3729(a)(1)(A), (B), (G). Moreover, because the False Claims Act is an anti-fraud statute, those allegations must be pleaded with "particularity" under Rule 9(b). *See Universal Health Services, Inc. v. United States ex rel. Escobar*, 136. S. Ct. 1989, 2004 n.6 (2016).

The Complaint-In-Intervention flunks those requirements in numerous respects. At the outset, it bases its allegations regarding false claims, false statements, and overpayments on the paradigm of a traditional Medicare fraud case—in which a provider submits claims for procedures that it did not actually perform. But Medicare Advantage involves a fundamentally different model, in which the key is an accurate *comparison* between Medicare Advantage beneficiaries and fee-for-service beneficiaries. As the D.D.C. held, an overpayment exists

"when, and only when, the error rate for a Medicare Advantage contract is greater than the CMS error rate" in traditional Medicare. *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 186. The Complaint-in-Intervention fails to allege that, under *that* paradigm, Defendants were overpaid or the diagnosis codes they submitted were an improper basis for payment. As a result, it fails to allege actionable false claims or overpayments. Additionally, the government fails to allege that either Defendant had any basis to *know* of any false claims or overpayments. And while it seeks to fill those holes by relying on certifications Defendants submitted regarding the accuracy of their data, the certifications were not, in fact, false—and were, in any event, immaterial to the government's decision to pay, as multiple federal courts considering nearly identical certifications in nearly identical circumstances have concluded.

A. The Government Fails To Establish Falsity Or The Existence Of An Overpayment Because It Does Not Allege That Defendants' Overall Rate Of Unsupported Codes Exceeds CMS's Overall Rate Of Unsupported Codes

The Complaint-in-Intervention's first fatal flaw is that, under Medicare Advantage's comparative standard, it does not allege false claims or unlawfully retained overpayments.[4] Its central legal premise is that unsupported diagnosis codes always and necessarily result in overpayments, such that "knowing" that a diagnosis code is unsupported by a medical record automatically gives rise to a duty to delete that code and return any payment that resulted from it. *See, e.g.*, Complaint-in-Intervention ¶ 23 ("Upon learning of a false diagnosis code resulting in an MA overpayment from CMS, the duty exists to delete or otherwise withdraw that code."). As multiple courts confronted with that precise question have concluded over the past several months, however, that premise is incorrect.

Under the Medicare statute, CMS is required to make payments under the Medicare Advantage program that are sufficient to account for the risk participants assume in agreeing to cover Medicare beneficiaries' future healthcare costs. The statute requires that CMS ensure these payments are "actuarially equivalent" to the payments CMS would expect to make in the

[4] This argument applies with equal force to allegations (1) that Defendants themselves submitted false claims or were overpaid, and (2) that Defendants caused MA plans to submit false claims or be overpaid. Moreover, the Complaint-in-Intervention's failure to allege any government overpayments also requires dismissal of the government's common law claims, all of which depend on a showing that the government overpaid Defendants.

traditional Medicare program in order to care for the same beneficiaries, 42 U.S.C. § 1395 w-23(a)(l)(C)(i), and to use the "same methodology" to calculate risk in both programs, *id.* § 1395w-23(b)(4)(D). Calculating an accurate payment amount for a given group of Medicare Advantage beneficiaries, therefore, depends on how the risk those patients present compares to the risk presented by average beneficiaries on traditional Medicare.

That statutory emphasis on *comparative* risk rather than *absolute* risk matters a great deal here. When CMS evaluates risk in the traditional fee-for-service program for purposes of performing this comparison, its methodology treats supported and unsupported diagnosis codes identically. As the D.D.C. put it, "[i]t is critical to appreciate that CMS does not claim that it audits traditional Medicare patient records; to the contrary, it accepts their diagnosis codes as given." *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 184. And CMS does so even though it recognizes that a substantial number of diagnosis codes in the fee-for-service program are unsupported. In one recent study, for example, CMS determined that for some conditions, the proportion of diagnosis codes in the fee-for-service program that lack adequate medical record support could be 90 percent or even higher. *See* Center for Medicare and Medicaid Services, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits – Technical Appendix* 6–8, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf (finding, for example, that in a sample of fee-for-service diagnosis codes submitted for HCC45, Disorders of Immunity, 87.5 percent of those codes were "discrepant," and that 100 percent of codes submitted for quadriplegia or other extensive paralysis, cystic fibrosis, and amputation status, lower limb/amputation complication, were "discrepant"). Overall, more than one-third of the diagnosis codes CMS examined in the fee-for-service program were unsupported. *See id.* And that was just one agency-published study; the true rate could be even higher.

Because CMS measures risk in the fee-for-service program using a methodology that treats *all* diagnosis codes as indicative of risk, the Medicare statute prohibits it from adopting a methodology in the Medicare Advantage program under which it would disregard comparable

indications of risk, at least without accounting for the difference. Otherwise, as the 1,000-beneficiary hypothetical above illustrated, CMS would end up paying substantially less in the Medicare Advantage program to insure a given population than it would have spent to care for that same population in traditional Medicare—underpaying Medicare Advantage insurers and capitated providers like Sutter and PAMF, and ultimately undermining the sustainability of the program. Indeed, the D.D.C. held that "[t]his inequity" would be "inevitable" if CMS were permitted to "set[] Medicare Advantage rates based on costs that are presumed, based on traditional Medicare diagnosis codes, to be associated with particular health status information that is not verified in underlying patient records," but then only pay Medicare Advantage participants for the subset of codes that had been verified. *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 185. To prevent a violation of the Medicare statute, therefore, "CMS cannot subject the diagnosis codes underlying Medicare Advantage payments to a different level of scrutiny than it applies to its own payments under traditional Medicare." *Id.* at 186. CMS would be free to compare the rate of unsupported codes in a Medicare Advantage provider's data to the rate of unsupported codes in the fee-for-service data and treat the *difference* as resulting in an overpayment, but it cannot treat *all* unsupported codes as resulting in overpayments: An overpayment exists "when, and only when, the error rate for a Medicare Advantage contract is greater than the CMS error rate" in traditional Medicare. *Id.* Indeed, as the D.D.C. pointed out, that was exactly the approach that CMS itself had originally agreed to undertake in its own Risk Adjustment Data Validation audits. *See id.*

The D.D.C. is not the only court to have reached this conclusion. Earlier this year, the Central District of California addressed a similar issue in a False Claims Act case brought against a group of Medicare Advantage plans. *See United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-86997, 2019 WL 2353125 (C.D. Cal. Mar. 28, 2019). In that case, as here, the government claimed that there is a legal duty in the Medicare Advantage program to delete unsupported diagnosis codes whenever they are identified, and filed a motion for partial summary judgment seeking a ruling to that effect. The court denied the motion, holding that the government failed to establish any such duty. Drawing on the *UnitedHealth*

case from the D.D.C. as "persuasive authority," and discussing the "inevitable" underpayment that would result if CMS were permitted to require deletion of all unsupported diagnosis codes in the Medicare Advantage program without adjusting for the presence of such codes in the fee-for-service program, the court held that "the Court cannot determine that it is clear as a matter of law that United was required to delete unsubstantiated diagnosis codes." *Id.* at *7, *9.

As these cases show, the key to determining whether a Medicare Advantage participant has submitted invalid diagnostic data that has resulted in overpayments is a *comparison* of that data to the data that CMS itself uses in the traditional fee-for-service program. Because an overpayment exists "when, and only when, the error rate for a Medicare Advantage contract is greater than the CMS error rate" in traditional Medicare, *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 186, it is impossible to determine whether an overpayment exists without considering both the rate of unsupported codes in the Medicare Advantage participant's data *and* the comparable rate of unsupported codes in the fee-for-service program. Here, however, the Complaint-in-Intervention makes no allegations whatsoever about the rate of unsupported diagnosis codes in the fee-for-service data, nor does it allege that the rate of unsupported codes in the data submitted by Defendants was higher than that fee-for-service rate (or even make allegations about the *overall* rate of unsupported diagnosis codes in Defendants' data). Given that "False Claims Act plaintiffs must . . . plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)," *Escobar*, 136. S. Ct. at 2004 n.6, the failure to include allegations on these crucial points means that the Complaint-in-Intervention must be dismissed for failure to identify any false claims or the existence of any overpayments that were improperly retained.

B. The Government Fails To Allege That Defendants Identified Any Overpayments Or Knowingly Submitted Materially False Claims Or Statements

By basing its complaint on the improper premise that *every* unsupported code results in an overpayment, the government also ignores a second problem with its theory: It cannot allege, with the particularity that Rule 9(b) requires, that Defendants had "identified" any overpayments or that they *knew* they were submitting materially false claims or statements.

1. The Government Fails To Allege That Defendants "Identified" Overpayments And Then Failed To Return Them Within 60 days

To allege viable reverse false claims theories (as it attempts to do in Counts I and II of the Complaint-in-Intervention), the government must allege that Defendants failed to comply with an "obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). Here, it alleges that the obligation arose from the "retention of a[n] overpayment." *Id.* § 3729(b)(3); *see* Complaint-in-Intervention ¶ 23. By law, the obligation to return an overpayment does not arise until "the date which is 60 days after the date on which the overpayment was identified." 42 U.S.C. § 1320a-7k(d)(2); *see also id.* § 1320a-7k(d)(3) ("An overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31) for purposes of section 3729 of such title."). Accordingly, to succeed on these counts, the government must allege that Defendants actually "identified" overpayments and then failed to return them within 60 days.

The government has not satisfied that requirement, for multiple reasons. *First*, the Complaint-in-Intervention does not allege that Defendants had any reason to believe that their overall rate of unsupported codes exceeded the rate of unsupported codes in the fee-for-service program; indeed, as noted above, it is far from clear that it does. Without that knowledge, Defendants had no way of definitively determining whether they had been overpaid. *See* Part III.A, *supra*.

Second, the government does not allege that Defendants *actually identified* any unsupported diagnosis codes and yet failed to return the payments that had been based on them within 60 days.[5] To the contrary, the Complaint-in-Intervention acknowledges that when Defendants identified specific codes that they could conclusively determine were unsupported, they deleted those codes—thousands of them. *See, e.g.*, Complaint-In-Intervention ¶ 90

[5] The government does point to a handful of specific unsupported codes which it offers as "examples of false claims," Complaint-in-Intervention ¶ 133, but it does not allege that Defendants identified those unsupported codes and then failed to delete them or otherwise return any overpayments that had resulted from them.

(acknowledging Defendants' "deletion in the electronic medical record system of 777 false diagnosis codes in 2013 and 517 false diagnosis codes in 2014" that were identified through encounter audits); *id.* at ¶ 78 (acknowledging the deletion of 8,000 unsupported diagnosis codes after they were identified by an outside consulting firm); *id.* at ¶ 62 (acknowledging that Defendants "deleted the specific diagnosis codes identified by the Optum and UHG auditors"); *see also* Relator's First Amended Complaint ¶ 99, ECF No. 52 ("Relator's Complaint") (acknowledging that Sutter "delet[ed] thousands of unsupported diagnosis codes found in the Peak Audit").

The government will no doubt point to its allegations that Relator and the auditors she was working with had identified specific codes that they believed were unsupported, but were not permitted to delete them. *See, e.g.*, Complaint-in-Intervention ¶ 108; *see also* Relator's Complaint ¶¶ 138, 139. But those allegations show only that *Relator* was deprived of that authority; as the Complaint-in-Intervention acknowledges, Defendants instead assigned that authority to physicians, who were better positioned to determine whether a given diagnosis code was supported (or, if it was not fully documented, whether the chart should be appropriately modified to support it). *See* Complaint-in-Intervention ¶ 108; *see also* Relator's Complaint ¶¶ 148, 150. The government conspicuously fails to identify any diagnosis code that Defendants identified through that separate process as unsupported and yet failed to delete. And while the government will no doubt argue that *Relator's* belief that a diagnosis code was unsupported should have been reason enough to delete it, Defendants did not have to agree—especially after a second-level audit of diagnosis codes that Relator had declared "unsupported" while assembling this case actually found that 60% of the supposedly "unsupported" diagnosis codes in fact were fully supported by medical records. *See* Relator's Original Complaint ¶ 111.

Unable to point to any overpayments that Defendants identified and failed to return, the government instead bases its allegations on overpayments that it claims Defendants *should have* identified. *See, e.g.*, Complaint-In-Intervention ¶ 62 ("While they deleted the specific diagnosis codes identified by the Optum and UHG auditors, Sutter and PAMF deliberately ignored the much larger coding problems identified by these high audit failure rates . . . ."). But the law does

not make this "should have identified" standard a sufficient basis for False Claims Act liability: Congress provided that an obligation to return an overpayment would arise for purposes of the False Claims Act only once the overpayment was actually "identified," not merely after it *should have been* identified under some post-hoc standard. 42 U.S.C. § 1320a-7k(d)(2). The legislative history shows that was intentional: Under an earlier House of Representatives version of what became Section 1320a-7k(d)(2), any "known" overpayment would have been treated as giving rise to an obligation, with "known" defined to use the standard set out in the False Claims Act (which includes not just actual knowledge but also recklessness and deliberate ignorance). *See* H.R. 3200, 111th Cong. § 1641 (as introduced by the House, July 14, 2009); 31 U.S.C. § 3729(b)(1). But Congress ultimately adopted the Senate version of the bill, which substituted "identified" for "known." Pub. L. No. 111-148, § 6402(a), 124 Stat. 119, at 755 (enacting H.R. 3590, 111th Cong. (2010)). And while CMS tried to undo that legislative choice by adopting a regulation that defined "identified" to include circumstances in which an Medicare Advantage participant "should have" identified an overpayment, *see* 42 C.F.R. § 422.326(c), that regulation has been set aside as unlawful—which is presumably why the government does not invoke it here. *See UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 191.

None of this is to say that CMS lacks recourse: It is free to use administrative and other mechanisms to pursue reimbursement when it believes that it has overpaid a participant in the Medicare Advantage program. (Indeed, as the Relator's Complaint notes, CMS did exactly that with respect to other Sutter affiliates, and Sutter returned $30 million as a result. *See* Relator's Complaint ¶ 147.) But Congress recognized that the False Claims Act's reverse false claim provision, which can give rise to treble damages and substantial civil penalties even in circumstances where the initial submission of a claim was entirely innocent, provides an extraordinary remedy. Congress was unwilling to brandish that remedy except in circumstances where a government contractor had actually "identified" an overpayment and yet failed to return it. The government has not alleged any such scenario here.

2. The Government Fails To Allege That Sutter "Knowingly" Submitted Materially False Claims Or Statements

The government also asserts false claim theories under Sections 3729(a)(1)(A) and (B) in Counts III and IV of the Complaint-in-Intervention. To support those theories, the government must adequately allege that Defendants "knowingly" submitted false claims or statements, meaning that they knew (or were reckless or deliberately indifferent to) the falsity of the claim or statement at the time it was submitted. 31 U.S.C. § 3729(a)(1)(A)-(B). The Complaint-in-Intervention cannot satisfy that requirement.

The government's allegations focus largely on individual unsupported diagnosis codes. *See, e.g.*, Complaint-In-Intervention ¶ 60 ("UHG and Optum auditors identified HCC 82 . . . as an outlier and determined that 27 out of 30 of the patient records containing diagnosis codes mapping to this HCC were erroneous, invalid, unsupported or otherwise false in one audit (a 90% failure rate) in October 2012."). Crucially, however, the Complaint-in-Intervention does not identify a *single* diagnosis code that it alleges Defendants had identified as false at the time it was submitted. Instead, it points to supposedly inadequate audits and a purported failure to address "red flags regarding false claims." Complaint-in-Intervention ¶¶ 10, 62.

Here again, the allegations are insufficient. As the government acknowledges, Defendants' practice—implemented by Relator herself—was to employ retrospective, backward-looking audits, rather than attempting to perform audits on a real-time basis before codes had been submitted. *See* Complaint-in-Intervention ¶¶ 71-75, 78-79, 83-88. For example, when Relator performed her first audit of 62 diagnosis codes in June 2013, "[a]ll of these codes had been submitted by PAMF for reimbursement" by the time she performed the audit. Complaint-in-Intervention ¶ 72. Similarly, in 2014, a consultant engaged by several Medicare Advantage plans provided Defendants with the results of audits performed on diagnosis codes from 2012 and 2013. *See id.* at ¶ 78. And in July 2014, Relator performed an audit of diagnosis codes that had been submitted more than a year earlier, in March 2013. *See id.* at ¶ 83. Those audits represented Defendants' good-faith efforts to identify unsupported codes and delete them when identified in order to ensure that Defendants' rate of unsupported codes did not exceed CMS's

comparable rate. But they certainly did not give Defendants retroactive knowledge that they were submitting unsupported codes before those codes had even been submitted.

Perhaps because it cannot identify any unsupported diagnosis codes that Defendants submitted despite *knowing* they were unsupported, the government also seems to rely on the theory that Defendants violated the False Claims Act by submitting false certifications attesting to the "accuracy, completeness, and truthfulness" of their risk adjustment data based on their "best knowledge, information, and belief." 42 C.F.R. §§ 422.504(l)(2), (l)(3); *see, e.g.*, Complaint-in-Intervention ¶ 126. To the extent that the government intends to rely on that certification as a basis for its affirmative false claim theory, however, the certification cannot help it, for at least three reasons:

First, the Complaint-in-Intervention fails to "identify the corporate officers who signed the attestations or allege that those individuals knew or should have known that the attestations were false." *United States ex rel. Swoben v. Scan Health Plan*, CV 09-5013, 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017). Both of those allegations are necessary under the False Claims Act's "strict[ly] enforced" knowledge standard. *Escobar*, 136 S. Ct. at 2002. Indeed, the Central District of California dismissed a similar government complaint, involving a nearly identical certification of data accuracy, on exactly that basis. *See Swoben*, 2017 WL 4564722, at *6.

Second, because of the comparative rather than absolute nature of risk adjustment, CMS has long recognized that Medicare Advantage participants "are coding 'accurately' when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared." CMS, Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies 20 (April 6, 2009), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2010.pdf. It would be objectively reasonable for a provider to understand that its certifications represented only that it had no reason to believe that its rate of unsupported diagnosis codes was any higher than the comparable rate in fee-for-service data—and there are no facts alleged in the Complaint-in-Intervention suggesting that anyone acting for the Defendants had reason to believe that their rate of

unsupported codes was higher than the rate in the fee-for-service program. Were the certification interpreted differently—to require the certifying party to attest to its "belief" that there were *no* unsupported codes in the data that it was submitting—then no participant in the Medicare Advantage program would *ever* be able to submit the certification, since even CMS has recognized that the presence of at least some unsupported codes is "inevitable." 2004 Medicare Managed Care Manual § 111.7, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R47MCM.pdf ("The Department of Justice, the Office of Inspector General, and CMS acknowledge that the volume and variety of data make some inaccuracies inevitable . . . ."). And because Defendants' certifications are subject to that objectively reasonable interpretation, they cannot be liable for those certifications under a fraud statute like the False Claims Act that applies only to knowing or reckless violations of the law: As the Supreme Court has explained, "Congress could not have intended" to "treat . . . as a knowing or reckless violator" a defendant "who followed an interpretation that could reasonably have found support in the court." *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47, 70 n.20 (2007); *see also United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017) (applying *Safeco* to scienter requirement of False Claims Act).

Third, and for similar reasons, the government does not and cannot allege with the requisite particularity that any falsity in Defendants' certifications would have been material to the government's decision to pay.

To be sure, the government alleges in general terms that the supposed falsity it has alleged was "material." *See, e.g.*, Complaint-In-Intervention ¶ 11. But as the Supreme Court recently confirmed in *Escobar*, the False Claims Act's materiality standard is "demanding," and must be backed up by particularized allegations in the complaint. 136 S. Ct. at 2003, 2004 n.6. "[A] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* at 2003. Nor is it sufficient that the government "would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* at 2003. Instead, to satisfy the False Claims Act's materiality standard, a complaint must allege with particularity that the

defendant's supposed violations "are so central . . . that the [government] would not have paid these claims had it known of these violations." *Swoben*, 2017 WL 4564722, at *6 (quoting *Escobar*, 136 S. Ct. at 2004).

The government cannot satisfy that standard with respect to the certifications to which it points here. Indeed, two other federal district courts confronting this precise question have concluded that risk adjustment certifications of this sort are *not* material.

In *Poehling*, the government alleged that the defendants' attestations to the accuracy of risk adjustment data submitted to CMS were material to the government's payment decision because the attestations were a "reminder" to defendants of their obligation to submit valid data. *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, 2018 WL 1363487, at *9, *11. But the court concluded these allegations could not meet *Escobar*'s heightened materiality standard because the government had not alleged that the attestations had a "direct impact" on CMS's risk adjustment payments. *Id.* at *9. Similarly, in *Swoben*, the court held that under *Escobar*, the government was required to allege that CMS would have refused to make risk adjustment payments if it had known the certifications were false. *See id.* Because the government failed to do so, it failed to meet the materiality requirement. *See id.*

In light of *Poehling* and *Swoben*, it is especially clear that the bare allegations of materiality presented here are insufficient. The Complaint-in-Intervention alleges only that Defendants' signed certifications reflect "the importance of accurate information" for CMS and "are a condition of payment by CMS," Complaint-in-Intervention ¶ 126. As noted, however, the Supreme Court has decisively rejected the argument that a particular certification is material merely because it is designated "as a condition of payment." *Escobar*, 136 S. Ct. at 2003. And the government does not even *attempt* to allege that CMS would have refused to make risk adjustment payments had it known Defendants' certifications were false, let alone plead "with plausibility and particularity" specific facts supporting such an allegation. *Id.* at 2004 n.6.

IV. CONCLUSION

The government's allegations in this case ignore the design of the Medicare Advantage program and the implications of that design as recognized by multiple federal courts. That is no

accident: Under a proper understanding of the program, the government *cannot* make out an actionable claim for fraud, especially with the particularity that Rule 9(b) demands. It has not alleged any actual overpayments, has not alleged that Defendants *identified* any such overpayments, and has not alleged that any knowingly false submissions had a material effect on the government's payment decisions. Just as other courts have done in recent cases where the government attempted to proceed on similarly faulty allegations, this Court should dismiss the government's claims.

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By: */s/ Katherine A. Lauer*

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