UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA *ex rel*. ROBERT A. CUTLER, Plaintiff, v. CIGNA CORP. *et al.*, Defendants.	Civil Action No. 3:21-cv-00748 District Judge Eli J. Richardson Magistrate Judge Jeffrey S. Frensley JURY DEMAND

DEFENDANTS' REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTIONS TO DISMISS THE UNITED STATES' COMPLAINT-IN-INTERVENTION AND RELATOR'S AMENDED COMPLAINT PURSUANT TO RULE 12(b)(6)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes, Rules, and Regulations

Other Authorities

INTRODUCTION

The Government's brief only confirms that there is no basis for the novel theories of False Claims Act ("FCA") liability in this case. Under the FCA, a claim for payment may be "factually" or "legally false." The Government confuses the two theories, but the law is clear that they are distinct. *See, e.g.*, *U.S. v. SouthEast Eye Specialists, PLLC*, 570 F. Supp. 3d 561, 575 (M.D. Tenn. 2021). For "factual falsity," the Government must plausibly allege that Cigna reported to the Centers for Medicare & Medicaid Services ("CMS") conditions, for which it was paid, that it knew its members did not in fact have. The Government's other theories all involve "legal falsity" and are premised on allegations that Cigna knew it falsely certified compliance with Medicare Advantage program requirements that it knew were material to CMS's payment decision. The Government's complaint fails to state a claim under either theory.

Neither the Government nor Relator Robert Cutler have plausibly alleged that Cigna engaged in a scheme to have thousands of licensed clinicians falsely diagnose tens of thousands of medical conditions that patients did not actually have. In support of its factual-falsity claim, the Government alleges that Cigna reported conditions from in-home 360 exams that could not be reliably diagnosed for the first time in the home and were not reported from other encounters with other doctors during the same year. The Government does not allege that clinicians had any financial motive to document any condition falsely; that Cigna asked or incentivized them to do so; or—most importantly—that they did not sincerely believe any member had the condition they documented on Cigna's 360 form or otherwise acted in bad faith. In the absence of such allegations, there is an "obvious [innocent] alternative explanation" for the facts alleged—namely, that clinicians properly and in good faith diagnosed conditions members already had and were being treated for at the time of the 360 visit—and the inference of fraud is therefore "not a plausible conclusion." *Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009).

Even if the Government had adequately pled factually false diagnoses, none of its allegations plausibly establish that Cigna recklessly disregarded the falsity of any diagnosis. As is undisputed, Cigna's vendor contracts required the clinicians who performed the 360 exams to have valid state medical licenses and conduct the exams and diagnose any conditions in accordance with standards of medical practice. Those contracts also required vendors to ensure that the clinicians had all necessary equipment—expressly ***not*** limited to the listed equipment. Critically, the Government does not deny that CMS's guidance to Cigna and other Medicare Advantage Organizations ("MAOs") expressly advised that a clinician's "statement that the patient has a particular condition is sufficient" for the MAO to code that condition, and that the MAO's coding is "not based on clinical criteria used by the provider to establish the diagnosis." *ICD-10-CM Official Guidelines for Coding and Reporting*, § I.A.19. Given all of that, the Government offers no plausible reason why Cigna would have been reckless to rely on the clinicians' conclusions that members had particular conditions.

Beyond its deficient claims of factual falsity, the Government has not plausibly alleged that Cigna's submissions were "legally false" because Cigna supposedly misrepresented its compliance with material payment requirements. The Government alleges that codes Cigna submitted did not comply with coding guidelines and that Cigna falsely attested that its data was accurate. But the Government's opposition does little beyond repeat its strained interpretations of these requirements. Even if the Government's interpretations were correct, Cigna's interpretations of the relevant legal requirements have strong support in the plain text, surrounding CMS guidance, and case law and were therefore objectively reasonable. In the absence of authoritative guidance warning Cigna away from those interpretations, the Government cannot plausibly establish that any violation by Cigna of its legal obligations was reckless or knowing. *U.S. ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649, 652-53 (7th Cir. 2022).

Under *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 192 (2016), the Government's legal-falsity theory is also independently foreclosed by the FCA's "rigorous" materiality requirement. The Government offers no plausible response to Cigna's point that CMS previously considered the same claims advanced here—that MA plans often arrange for members to have in-home health assessments by clinicians who are not the member's primary care provider, do not treat the member during the visit, and have limited diagnostic tools—yet CMS chose to *allow* MAOs to continue using these assessments to report diagnoses. And it continued to accept and pay MAOs based on the diagnoses reported from such home visits.

The Government's claims for unjust enrichment and payment by mistake must also be dismissed. Because the Government has not adequately pled fraud—under any theory—its common-law claims based on such fraud necessarily fail on the same grounds as its FCA claims.

Finally, Cutler has abandoned the only claim on which the Government did not intervene, namely, the contention in his complaint that all diagnoses made in home visits were *per se* invalid. *See* Doc. No. 157 at 1; Doc. No. 169 at 1. Cutler's effort to salvage his complaint is foreclosed by the plain meaning of the Government's filings and the Court's intervention decision. Moreover, his claims are prohibited by the public disclosure bar and fail under Rules 9(b) and 12(b)(6). His request for leave to amend should be denied as futile.

ARGUMENT

I. THE GOVERNMENT HAS NOT PLAUSIBLY ALLEGED THAT CIGNA KNOWINGLY SUBMITTED FACTUALLY FALSE CLAIMS FOR PAYMENT

A. The Government's Alleged Scheme Involving Licensed Clinicians Diagnosing Tens Of Thousands Of Non-Existent Conditions Is Not Plausible

The Government alleges a scheme in which licensed clinicians supposedly documented tens of thousands of non-existent conditions each year during in-home 360 exams. But as Cigna explained, the Government does not allege that clinicians had any financial incentive to falsify

any condition, were ever asked to do so by Cigna, or did not sincerely believe Cigna's members had each of the conditions documented on the 360 forms they signed. And the contracts the Government itself relies on confirm that vendors received a fixed fee per form and that clinicians were required to comply with applicable laws, CMS rules, and ethical standards in conducting the 360 exams. *See* Doc. No. 196 at 18-20, 23-24; Doc. Nos. 197-1 to 197-3.[1] They did not have—and Cigna did not create—a financial incentive to fabricate diagnoses.

The Government disputes none of that. Its theory thus depends on the far-fetched notion that thousands of clinicians would act contrary to standard medical practice and express contractual requirements, placing themselves in significant personal and professional peril, with no financial motive. That is not plausible. Under Sixth Circuit precedent, where a plaintiff's "claim can succeed only if the court 'make[s] inference upon inferences to provide' the facts missing," dismissal is the proper course. *U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.*, 842 F.3d 430, 438 (6th Cir. 2016) (quoting *Mitchell v. Proctor & Gamble*, 2010 WL 728222, at *5 (S.D. Ohio Mar. 1, 2010)).

The Government shrugs off how far its fraud allegations fall short of the facts in the cases discussed in Cigna's motion, Doc. No. 196 at 24-26, saying "there is more than one way to commit fraud," Doc. No. 213 at 24-25, and claiming support in *U.S. ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667 (9th Cir. 2018), because some allegations there overlap. But the fact that some allegations overlap in cases involving home health assessments is not surprising and

[1] Neither the Government nor Cutler objects to this Court's consideration of the vendor contracts as part of the pleadings. While Cutler accuses Cigna of omitting a contract attached to his brief, Doc. No. 214 at 3; Doc. No. 214-2, he ignores that Cigna filed a non-confidential version of the same contract earlier in the case, Doc. No. 123-5 at 14-28. Consistent with this Court's practice, citations to prior filings in this brief rely on the pagination added by the Clerk's Office as of the Electronic Case Filing. *See Ind. Pub. Requirement Sys. v. AAC Holdings*, 2023 WL 2228987, at *1 n.4 (M.D. Tenn. Feb. 24, 2023).

Silingo is fundamentally different than this case. In *Silingo*, the relator alleged the defendant was tampering with and outright forging medical records. *Id*. at 674-75. Here, the Government does not make any remotely similar allegation of affirmative misconduct.

The Government is left claiming Cigna applied "pressure" to "pursue specific, lucrative diagnosis codes." Doc. No. 213 at 23. But as Cigna explained, looking beyond the Government's label, the Government does not dispute that the alleged "pressure" consisted merely of Cigna's tracking vendors' performance against expected population morbidity. Doc. No. 196 at 24. That does not plausibly suggest that Cigna expected vendors to do anything other than what they were contractually and professionally required to do—namely, perform "comprehensive medical assessments" for Cigna's members in accordance with standard medical practice. Doc. No. 197-3 at 14.

Indeed, these allegations are far less than the alleged "pressure" the Ninth Circuit held insufficient to state a claim in *Integra Med Analytics LLC v. Providence Health & Services*, 854 F. App'x 840 (9th Cir. 2021). There, the plaintiff alleged that a consultant trained doctors to document "higher-paying diagnoses" and then "pressure[d]" them "to change their initial assessments" through "leading queries," resulting in much higher rates for the hospital's coding of certain conditions compared to other hospitals even when "controlled for inter-hospital variation … in patient populations." *Id*. at 842-43. The Ninth Circuit rejected that as a plausible basis to infer that "doctors lied about underlying medical conditions" when the clinicians' alleged conduct was also consistent with "lawful 'rational and competitive business strategy.'" *Id*. at 844-45 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007), and discussing *Iqbal*, 556 U.S. at 678-79, 682). Here, the Government does not even allege that Cigna's diagnoses exceeded expected patient morbidity or coding by its peers with respect to any of the conditions at issue.

The Government discounts *Integra* as "a non-precedential Ninth Circuit decision." Doc. No. 213 at 25. But that does not diminish its persuasive value: The judges, including Judge Boggs of the Sixth Circuit, applied binding Supreme Court guidance on plausibility to similar facts, and found the relator's allegations there wanting. If alleged tracking of the type described here were enough to differentiate lawful from unlawful conduct for purposes of stating a plausible FCA violation, *Integra*—on far less marginal allegations—would have affirmed the district court's denial of the defendant's motion to dismiss rather than reversing and remanding the case with instructions to dismiss the complaint. 854 F. App'x at 845.[2]

The Government cites as support *U.S. ex rel. Osinek v. Permanente Medical Group, Inc.*, 2022 WL 16925963 (N.D. Cal. Nov. 14, 2022), and *U.S. ex rel. Ross v. Independent Health Corp.*, 2023 WL 24055 (W.D.N.Y. Jan. 3, 2023). *See* Doc. No. 213 at 24. The stark differences between those cases and this one, however, only make even clearer that the Government's theory here is *not* plausible. In *Osinek*, the Government alleged that Kaiser prompted doctors to add non-existent conditions to charts months after the encounters, citing examples where findings on the original chart directly conflicted with the new diagnosis. 2022 WL 16925963, at *7. Even on those very different facts, the court determined that the Government had plausibly alleged a *broader* scheme of "factual falsity" only as to a single condition—"cachexia"—because Kaiser allegedly prompted doctors to code that condition "over *120 times* more" in one market despite audits showing a 90 percent error rate. *Id*. at *8. The Government alleges nothing like that here and offers no response to Cigna's discussion of *Osinek*. *See* Doc. No. 196 at 24-25.

[2] The Fifth Circuit held dismissal was likewise proper for FCA claims brought by the same relator against a different hospital premised on similar trainings and pressure directed at physicians, including "tip sheets reminding physicians of how to report high-value" conditions and follow-up requests to "clarify their diagnoses" based on "opportunities where high-value [conditions] might be present." *U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health*, 816 F. App'x 892, 898-99 (5th Cir. 2020).

In *Ross*, the Government alleged that a vendor not only misused addenda (as in *Osinek*) but also reported conditions based solely on sections of a patient's chart such as "Problem Lists" and "Past Medical History" that do not necessarily indicate whether the patient still has the condition. 2023 WL 24055, at *9-10. The Government's theory here, by contrast, concerns only "Current Conditions" the clinicians documented. Doc. No. 197-4 at 4-8. While the Government alleges that the diagnoses were false, it concedes that clinicians "had checked the relevant boxes on the 360 forms" indicating that members had the conditions reported to CMS at the time of the encounter in question, Doc. 213 at 27—exactly what was allegedly missing in *Ross*.

Moreover, as Cigna explained, the facts alleged by the Government have an obvious alternative explanation that requires no inference of widespread incompetence or malfeasance: Clinicians exercising their professional judgment properly assessed and documented conditions Cigna's members had, and were being treated for, based on the patient's prescribed medications, self-reporting, medical history, and physical examination. Doc. No. 196 at 27-28.

The Government dismisses Cigna's "benign" explanation as "dispute[d]," "hypothetical," and "*post hoc*." Doc. No. 213 at 9, 25. But this explanation of the Government's allegations is not "wholly speculative" and does not go beyond the pleadings. To the contrary, it follows from the contracts, which are part of the pleadings, *supra* p. 4 n.1, and required that state-licensed clinicians perform "a comprehensive health assessment" "to review the Member's medical history[,] complete a physical examination, as well as diagnose and suggest care management," and do so "in a manner that complies with" federal and state law, CMS rules, and "applicable ethical standards." Doc. No. 196 at 18-19 (quoting Doc. No. 197-3 at 2, 4-5, 14-15, 17). None of that is, or can be, disputed.

Indeed, the explanation that the clinicians here acted consistent with standard medical practice, as contractually required, is no more "disputed," "hypothetical," or "*post hoc*" than the

explanations found sufficient to defeat the claims at issue in *Iqbal*, *Twombly*, and *Integra*. In *Iqbal*, the Supreme Court held that "invidious discrimination" was "not a plausible conclusion" where the circumstances of the arrests could be explained by "lawful," "nondiscriminatory" justifications for "detain[ing] aliens who were illegally present in the United States and who had potential connections to those who committed terrorist acts." 556 U.S. at 682. In *Integra*, the Ninth Circuit rejected an FCA claim premised on doctors fabricating conditions because an "alternative (and legal) explanation" for the hospital's higher coding rates was that its documentation initiatives were simply "ahead of … [the] industry." 854 F. App'x at 844-45.

Just as in those cases, the facts alleged do not give rise to a plausible inference of wrongdoing. Plausibility demands "more than a sheer possibility that a defendant has acted unlawfully" or "facts that are 'merely consistent with' a defendant's liability." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). In assessing whether that standard has been met, the Court performs "a context-specific task that requires [it] to draw on its judicial experience and common sense," *id.* at 679, and "consider an obvious alternative explanation," *Integra*, 854 F. App'x at 845. The Court "need not accept" that conduct that is consistent with a lawful explanation was therefore unlawful. *Id*.; *see Iqbal*, 556 U.S. at 582; *Twombly*, 550 U.S. at 567-68. "As between th[e] 'obvious alternative explanation'" that clinicians did what was contractually required and consistent with their legal and professional obligations and the Government's theory that they documented tens of thousands of non-existent conditions in conflict with standard medical practice—all because Cigna tracked overall diagnosis data against expected population morbidity—the Government's claim of fraud is "not a plausible conclusion." *Iqbal*, 556 U.S. at 682.

B. The Government Has No Other Viable Theory Of Factual Falsity

The Government separately contends that it "need not allege or ultimately prove that … member[s] did not in fact have" the "condition" at issue. Doc. No. 213 at 28. Even if "members happened to have the relevant conditions," it claims, the "diagnoses" would still be "factually false" because they were supposedly "invalid." *Id*. And it alleges that in submitting such diagnoses for risk adjustment, Cigna did not comply with various provisions of *ICD-10-CM Official Guidelines for Coding and Reporting* ("ICD-10 Guidelines") and *ICD-9-CM Official Guidelines for Coding and Reporting* ("ICD-9 Guidelines") (collectively, "ICD Guidelines") or with the requirement that an officer or employee of each Medicare Advantage Organization ("MAO") certify annually that the risk-adjustment data it submits to CMS is "accurate, complete, and truthful" to that officer or employee's "best knowledge, information, and belief," 42 C.F.R. § 422.504(*l*). *See* Doc. No. 213 at 26-28. That argument confuses factual with legal falsity.

The only "factual" claim for payment in this case is that Cigna's members had the conditions Cigna reported to CMS and, thus, in fact had the "health status" CMS used to "adjust the payment amount" that Cigna received. 42 U.S.C. § 1395w-23(a)(1)(C)(i). Notwithstanding the Government's characterization, there is no "factually false" claim for payment unless "a plan member did not in fact have" the "condition." Doc. No. 213 at 28. All of the Government's remaining allegations depend on its contentions that Cigna knowingly misrepresented its compliance with a legal obligation that it knew was material to CMS's payment decision. No matter what facts must be alleged in support, that substantive theory is "legal falsity." As explained previously and below, *see* Doc. No. 196 at 33-40; *infra* pp. 13-30, the Government's legal-falsity theories fail because they are wrong on the law, and the facts alleged do not violate the cited legal requirements.

C. The Government Fails To Plausibly Allege Scienter

The only factual-falsity theory at issue independently fails because the Government has not adequately pled scienter. The Government does not dispute that Cigna contractually obligated its vendors to ensure that their clinicians had valid medical licenses and conducted 360 exams in accordance with standards of medical practice. Doc. No. 196 at 29-30; Doc No. 197-3 at 2, 4-5, 14-17. In the face of that glaring problem with its theory, the Government fires a scattershot of alleged red flags that Cigna purportedly ignored. Doc. No. 213 at 31-32. Separately or taken together, these allegations do not state a plausible claim of fraud.

First, the Government stresses Cigna's "focus on high-value conditions." Doc. No. 213 at 31. But as Cigna explained, under the Medicare Advantage payment model, Cigna bears the financial risk of care that will be needed by its member; the Medicare Advantage compensation system thus properly incentivizes Cigna to ensure that conditions are identified early, reported to CMS for payment, and properly managed and treated. Doc. No. 196 at 31-32 & n.5. As Cigna explained, *id*. at 32, those incentives—created by the Government—do not plausibly support an inference of improper intention. The Government offers no response.

Second, the Government contends that Cigna reported first-time diagnoses that could not be reliably made in the home without equipment the Government contends was not present. Doc. No. 213 at 31. As discussed, however, the Government does not plausibly allege that clinicians were acting in bad faith—much less that Cigna knew they were—or that any diagnosis was even inconsistent with appropriate clinical assessment of previously diagnosed conditions that were already being treated or managed at the time of the 360 visit. *Supra* pp. 7-8. An in-home diagnosis is thus not a red flag that clinicians lacked required equipment. Indeed, for the latter contention, the Government refers only to the list of equipment specified in Cigna's vendor contracts, arguing that Cigna knew that equipment not listed was not present during the exam.

But those same contracts explicitly required vendors to provide "the necessary equipment and tools to perform" the 360 exams, "including but *not limited* to" the items enumerated. Doc. No. 196 at 29 (quoting Doc. No. 197-3 at 17 (emphasis added)). Such a contractual list is obviously "illustrative, not exclusive," *Trustees of Laborers Pension Tr. Fund v. Metallizers of Mid-Am., Inc.*, 2014 WL 4059864, at *4 (E.D. Mich. Aug. 14, 2014) (quoting *P.R. Mar. Shipping Auth. v. ICC*, 645 F.2d 1102, 1112 n.26 (D.C. Cir. 1981)), and Cigna had every reason to believe based on its contracts that vendors would supply necessary equipment whether listed or not. The Government shrugs off such contractual language as "irrelevant." Doc. No. 213 at 33-34. But it cannot invoke the contracts to allege knowledge that clinicians lacked necessary equipment and then disregard language in the same contracts obligating vendors to supplement the listed equipment as needed.

Third, the Government points to the alleged lack of clinical information on 360 forms. Doc. No. 213 at 32 (citing Doc. No. 178 ¶ 147). But it concedes that the forms contained the clinician's diagnosis; its allegation is therefore limited to the lack of *additional* clinical information from which the coder reviewing the form could verify the *basis* of the diagnosis. But the absence of additional clinical information is certainly *not* a red flag: The ICD Guidelines expressly instruct that a "provider's statement that the patient has a particular condition is sufficient," and that coding is "not based on clinical criteria used by the provider to establish the diagnosis." ICD-10 Guidelines § I.A.19. Contrary to the Government's assertion, Doc. No. 213 at 26, Cigna is not "stretch[ing]" this provision to claim its coders may ignore red flags of falsity or fraud. To the contrary, the point is that a diagnosis made without a provider's clinical reasoning is not a red flag because coding is expressly not conditioned on the presence of such reasoning.

The Government repeats its conclusory assertion that, "in many cases, information on the forms contradicted the purported diagnosis." *Id*. at 18 (citing Doc. No. 178 ¶¶ 147-48). The slim facts alleged, however, do not bear out that assertion. The Government offers, in fact, a single example remotely matching that description: a patient diagnosed with congestive heart failure whose heart was noted as "regular and normal." Doc. No. 178 ¶ 148. As Cigna discussed, that note is entirely consistent with the obvious alternative, innocent explanation that the patient was already being treated at the time of the 360 visit, and the clinician concluded that the condition was being controlled by medication. Doc. No. 196 at 25-26. That example does not plausibly constitute a red flag of falsity for that specific case and certainly not for a scheme involving tens of thousands of alleged false diagnoses. The Government offers no response.

Fourth, the Government alleges that Cigna knew certain diagnoses were not corroborated by other medical encounters from its claims data for its members. Doc. No. 213 at 32 (citing Doc. No. 178 ¶¶ 150-51). Citing the Ninth Circuit's decision in *Swoben,* the Government argues that Cigna should have "'investigate[d]' whether the diagnoses [were] supported." Doc. No. 213 at 34 (citing *U.S. ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1177 (9th Cir. 2016)). But *Swoben* only shows how much is missing from the Government's allegations here. The alleged red flag in *Swoben* was that MAOs failed to investigate diagnoses reported to CMS from provider claims *after those same diagnoses were not identified during a retrospective review of the underlying medical chart for the* ***same*** *encounters*. 848 F.3d at 1170-71. The Government concedes that the medical chart here—the 360 form—*had* the diagnosis; its theory of scienter is that Cigna was nevertheless required to investigate the diagnosis because it was not reported from other, entirely separate encounters. *Swoben* lends no support to that very aggressive theory.

Indeed, the Government does not say why Cigna had reason to analyze its claims data for corroboration in the first place, when CMS policy expressly permits MAOs to submit diagnoses from in-home exams without reports of the same diagnosis from other encounters. *Infra* p. 21-22. Moreover, as explained, the Government does not allege that the data to which Cigna had access reflected all diagnoses from prior health records, other payers, or out-of-network providers. Doc. No. 196 at 20. The Government dismisses this argument as a "red herring." *Id.* at 27. But it fails to explain how a lack of other reports could constitute a red flag when Cigna did not have a full picture of members' diagnoses.

Finally, the Government repeats its allegations regarding various "concerns" by members of Cigna's compliance staff about the "accuracy of the diagnoses being generated" from in-home 360 exams, including the use of the same 360 form for both home and office visits. Doc. No. 213 at 32-33. As Cigna explained, though, the Government never alleges that anyone at Cigna identified specific conditions or circumstances indicative of a first-time diagnosis that could not reliably be made in the home. In any event, at most, Cigna's alleged failure to take steps to avoid potential errors would be negligent—not reckless, as required for FCA liability. *Id*. The Government does not address this flaw in its position.

II. THE GOVERNMENT HAS NOT PLAUSIBLY ALLEGED THAT CIGNA KNOWINGLY SUBMITTED LEGALLY FALSE CLAIMS FOR PAYMENT

Lacking any plausible allegation that clinicians made up diagnoses for non-existent conditions, the Government alleges, alternatively, that Cigna misrepresented that it complied with various legal requirements for submitting risk-adjustment data to CMS. To state a claim based on legal falsity, the Government must allege facts sufficient to show that Cigna "knowingly violated a requirement" that it knew was "material to the Government's payment decision." *Escobar*, 579 U.S. at 181; *SouthEast Eye Specialists*, 540 F. Supp. 3d at 575. The

Government's legal-falsity theory fails at each step: It fails to plausibly allege a violation of either the ICD Guidelines or CMS's data-attestation requirement; it fails to establish that any violation was "knowing"; and it fails to adequately plead that any such violation was material to CMS's payment decision. In response, the Government repeats its strained interpretations of the requirements at issue, mischaracterizes the law on scienter, and downplays the legal significance of CMS's continued payment under the contracts despite its knowledge of all the relevant facts.

A. The Alleged Facts Do Not Violate The ICD Guidelines

As explained in Cigna's motion, the Government's core allegation of falsity is that clinicians documented diagnoses for "serious and chronic conditions" without required "testing, imaging, or other diagnostic steps." Doc. No. 196 at 33 (quoting Doc. No. 178 ¶ 1). That theory is directed at providers' adherence to standard medical practice in reaching a particular diagnosis. Because the Government cannot identify any legal requirement that MAOs verify that specific tests were performed by providers before they may report a diagnosis to CMS for risk adjustment, it accuses Cigna of violating various coding guidelines—none of which is plausibly implicated by the alleged facts.

Indeed, given the poor fit with the issues in this case, the Government urges, as an initial matter, that the Court cannot resolve Cigna's compliance with the ICD Guidelines "on a motion to dismiss" because it entails "a fact-driven inquiry" that "would require determining what took place during individual 360 home visits and analyzing the 360 forms." Doc. No. 213 at 37. That is incorrect. The issue is whether the well-pleaded facts in the complaint, "*accepted* as true" at this stage, state a plausible claim. *Iqbal*, 556 U.S. at 678 (emphasis added). They do not.

1. The clinician's diagnosis is dispositive under the ICD Guidelines

Here, as Cigna explained, the Government concedes that the 360 forms *had* the diagnosis marked for each of the conditions submitted to CMS. Doc. No. 196 at 30; Doc. No. 178 ¶ 147;

Doc. No. 213 at 27. That concession is dispositive under the ICD Guidelines' general provision regarding "Code assignment and clinical criteria," which directs that "[t]he provider's statement that the patient has a particular condition is *sufficient*" and that coding "is *not* based on clinical criteria used by the provider to establish the diagnosis." ICD-10 Guidelines § I.A.19 (emphases added). Thus, the complaint's allegation that clinicians failed to include "clinical findings … except for the checked box recording the purported condition," Doc. No. 213 at 37, does not show that Cigna improperly coded the diagnosis under the ICD Guidelines. CMS has stated unambiguously that the diagnosis "is sufficient" without the addition of "clinical criteria." The alleged absence of reported test results therefore does not plausibly allege a violation.

Scarcely acknowledging § I.A.19, the Government tries to muddy the waters by pointing to a host of other provisions, including ones not cited in the complaint. But none of these provisions alters—much less overrules—§ I.A.19's unequivocal and controlling statement that a clinician's diagnosis is sufficient and does not depend on the use of particular clinical criteria.

The Government argues that Cigna "violated the ICD Guidelines' prohibition on coding diagnoses 'characterized as probable, suspected, questionable, working diagnoses, or the like.'" Doc. No. 213 at 38 (quoting Doc. No. 178 ¶ 79). But as Cigna showed, that argument ignores the provision's actual language, which prohibits coding "diagnoses *documented* as 'probable,' 'suspected,' 'questionable,' 'rule out,' 'compatible with,' 'consistent with,' or 'working diagnosis' or other similar terms indicating uncertainty." ICD-10 Guidelines § IV.H (emphasis added); *see* ICD-9 Guidelines § IV.I; Doc. No. 196 at 34-35. The Government does not allege that any diagnosis on the 360 forms was accompanied by any such markers of uncertainty. It thus fails to allege any violation of this provision.

In response, the Government cites three provisions not mentioned in the complaint to the effect that a diagnosis must be "definitive." Doc. No. 213 at 38-39 (citing ICD-10 Guidelines

§§ I.B.4, I.B.18, IV.D; ICD-9 Guidelines §§ I.B.6, IV.E). Those provisions—which deal with coding signs and symptoms "when a related definitive diagnosis has *not* been established," ICD-10 Guidelines § I.B.4; ICD-9 Guidelines § I.B.6 (emphasis added)—have no application here. The Government does not allege that a definitive diagnosis was lacking and fails to allege facts that would support such a conclusion. Instead, it argues that the diagnosis required clinical corroboration not presented on the 360 form. As explained above, however, that issue is clearly resolved by § I.A.19, which instructs coders that the diagnosis is dispositive and that coding is not based on "clinical criteria" used to establish the diagnosis. The prohibition on coding questionable diagnoses itself requires coding "to the highest degree of certainty." ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I. Absent allegations that the 360 form indicated a diagnosis was merely "probable," "suspected," or the like, the Government offers no reason why the diagnosis was *not* definitive or that Cigna knew it to be so.

Nor does the Government even allege that clinicians documented particular conditions while doubting the validity of the diagnoses. In passing, the Government says that Cigna could not rely on clinicians' "rote recording" of self-reported diagnoses or prescribed medications on 360 forms. Doc. No. 213 at 28. But the Government cites nothing in the ICD Guidelines directing licensed clinicians how to practice medicine. And there is no affirmative allegation that any clinician acted in bad faith, nor do the alleged facts plausibly suggest that in-home 360 exams generated diagnoses that were not the result of clinicians' exercise of "professional medical skill and judgment," *id*., which the contracts, again, also required, *supra* p. 7.

The Government relies on other CMS guidance to argue that Cigna could not rely on "prescriptions alone." Doc. No. 213 at 28-29. But the guidance the Government cites is about *coding* from "alternative data sources" "such as pharmacy records." CMS, *2008 Risk Adjustment Data Technical Assistance Participant Guide* § 3.2.4. There is no allegation Cigna did that. The

Government's own allegations start from the premise that Cigna coded from the *diagnoses* on the *forms*. And the same CMS guidance makes clear that a "clinician's diagnosis" is "sufficient." *Id*. That guidance does not prohibit *clinicians* from reviewing a patient's medications alongside other information to make a diagnosis. The Guidance makes clear that the clinician's judgment is the touchstone. Indeed, the Government never explains why a clinician would *need* to repeat tests required only to establish a diagnosis for the first time if a patient has reported a prior diagnosis and, in the clinician's professional medical judgment, the patient's medical history, prescribed medications, and physical examination all corroborate that the condition is present and being treated or managed.

Left without any factual or legal basis to question the diagnoses, the Government's last resort is to allege that the "documentation" supporting the diagnosis was somehow lacking, relying on statements in the ICD Guidelines' preamble and elsewhere underscoring "the importance of consistent, complete documentation" and advising that such "documentation should describe the patient's condition, using terminology which includes specific diagnoses as well as symptoms, problems, or reasons for the encounter." Doc. No. 213 at 39-40 (quoting ICD-10 Guidelines at 1, § IV.C). The problem for the Government is that, by its own admission, each of the conditions at issue was documented "using terminology [for] specific diagnoses." The facts alleged thus do not plausibly support a violation of any documentation requirement.

The Government responds that "[t]he question is … whether there was any clinical information recorded on the 360 form to support the diagnosis and satisfy the ICD Guidelines' documentation requirement." Doc. No. 213 at 40-41. But the only lack of "support" it alleges with any particularity is, once again, the absence of tests required for a first-time diagnosis, and the ICD Guidelines do not require that. To the contrary, once again, § I.A.19 deems the presence of the diagnosis "sufficient." *See* Doc. No. 196 at 35*; supra* p. 11. The Government disputes

none of that. The complaint therefore fails to plausibly allege that Cigna violated the ICD Guidelines in coding and reporting these diagnoses to CMS.

2. The ICD Guidelines do not require treatment at the time of the encounter to code and report a diagnosis

Alternatively, the Government cites two provisions that it argues require *concurrent* treatment to make a diagnosis eligible for submission to CMS. Neither provision can bear the weight the Government puts on it.

First, the Government relies on a provision directing coders to "[c]ode all documented conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management." ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K. According to the Government, this provision does not allow MAOs "to 'confirm' a previously made diagnosis for a chronic condition" unless it "affect[ed] patient care, treatment, and management *during the visit*." Doc. No. 178 ¶ 154 (emphasis added). As Cigna explained, Doc. No. 196 at 36, the plain text refutes this interpretation because "at the time of the encounter" modifies only the clause that the conditions "coexist." The clause "affect patient care, management or treatment" does not require that conditions be treated *during the visit*, but only that there be evidence of care, such as documentation of a clinician's current assessment or a medication indicating that the condition is being treated or managed. The rest of the provision, moreover, makes clear that this language is intended to distinguish *current* conditions from "conditions that were previously treated and no longer exist," which may *not* be coded except as "history codes." ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K. The Government has no meaningful response.

Instead, the Government argues that its "claims do not depend on this reading" because, it asserts, the conditions here "did not 'require or affect patient care[,] treatment or management' *during the entire service year*." Doc. No. 213 at 38 (emphasis added). That conclusory factual

assertion is entitled to no credit and is not supported by the complaint. But in any event, the Government brief's new pronouncement that treatment must be provided at some point "during the entire service year" rewrites the provision to say something else it does not say.

Second, in an effort to backstop its concurrent-treatment requirement, the Government tries out a different section of the ICD Guidelines, one that provides that "[c]hronic diseases treated on an ongoing basis may be 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; Doc. No. 213 at 39. The Government asserts in its brief that this language means that "chronic conditions may be coded … *only* if they require care and treatment," a reading it contends "makes sense in the risk-adjustment payment system" because "*only* conditions that require care and treatment should result in increased costs." Doc. No. 213 at 39 (emphases added). The Government's argument contorts both the text and the payment context. First, as a textual matter, by inserting the word "only," the Government inverts an otherwise permissive "may." As courts have recognized, "'may' does not, on its face, mean 'may only,'" and "no reasonable construction of 'may' results in an absolute limitation" here. *FDIC v. Canfield*, 967 F.2d 443, 446 (10th Cir. 1992). Without the addition of "only," there is no reason a diagnosis may not be coded "as many times as the patient received treatment" and on other occasions, such as annual health screenings, at which treatment is generally not provided. The Government's reading also turns on its head CMS's prospective payment model, effectively requiring treatment costs as a condition for payment when the model itself pays MAOs *not* for the costs incurred in treating their members, but based on diagnoses from the prior year that predict likely *future* costs in the coming (payment) year, whether or not it turns out that those costs are actually borne by the plan.

Indeed, as Cigna explained, surrounding provisions of the ICD Guidelines regarding "diagnostic services," including the specific provision governing health screenings like the 360

exams here, permit any diagnosis "discovered during the screening" to be coded without the provision of treatment. Doc. No. 196 at 37 (quoting ICD-10 Guidelines § I.C.21.c.5). In response, the Government argues only that clinicians could not "discover" the conditions without required tests that it alleges were unavailable in the home setting, Doc. No. 213 at 40, but that is irrelevant to whether *treatment* was a coding requirement for any diagnosis reported from a health screening, such as the 360 exams here.[3] The Government "fails to respond" to the point and thus "concedes" it. *ARJN #3 v. Cooper*, 517 F. Supp. 3d 732, 750 (M.D. Tenn. 2021).

And it makes sense that treatment at the time of the visit is not required to code a diagnosis. As explained in Cigna's motion, Doc. No. 196 at 37, CMS requires MAOs to report members' diagnoses each year even for chronic conditions that do not go away, recognizing that conditions like congestive heart failure and rheumatoid arthritis—two of the very conditions the Government focuses on—may be "managed by ongoing medication" or "not impact every minor healthcare episode." CMS, *2008 Risk Adjustment Data Technical Assistance Participant Guide* § 6.4.1. Even without needing other treatment in a given year, CMS expects that such conditions would "likely" be reviewed and reported as "part of a general overview of the patient's health." *Id*. The Government offers no response.

As Cigna also explained, Doc. No. 196 at 37-38, a district court rejected a relator's similar argument regarding the provision the Government largely relies on for coding "all conditions that coexist at the time of the encounter/visit, and require or affect patient care, treatment or management." ICD-10 Guidelines § III; *see U.S. ex rel. Rasmussen v. Essence Grp. Holdings Corp.*, 2020 WL 4381771, at *6-7 (W.D. Mo. Apr. 29, 2020). The Government dismisses *Rasmussen* in a footnote as "non-precedential" and not focused on "the language at

[3] And as noted above, the Government's allegations based on missing tests are not plausible. *See supra* pp. 14-18.

issue here." Doc. No. 213 at 38 (quoting *Ross*, 2023 WL 24055, at *8). But *Rasmussen*'s reading of the ICD Guidelines was central to its reasoning. In rejecting the relator's argument that "a diagnosis can be coded only if the patient received treatment for that condition within the past year," the court quoted § I.A.19's language that "the provider's diagnostic statement" is "sufficient" to conclude that such treatment is not a coding prerequisite. 2020 WL 4381771, at *6. And it construed the provision on which the Government relies to mean only "that conditions should not be coded if they 'no longer exist.'" *Id*. at *7. All of that, the court explained, makes sense because MAOs are paid prospectively for conditions reported in the prior year to account for "treatment … needed in the ensuing year—even if no treatment was needed in the prior year." *Id*. at *6 n.10. The Government does not respond to any of these points.[4]

Indeed, as Cigna explained in discussing CMS's judicially noticeable statements about in-home health assessments, *see* Doc. No. 196 at 14 n.1, 15-18, CMS specifically studied the general *lack* of treatment and considered requiring subsequent confirmation by other treating physicians before accepting diagnoses from in-home exams; however, it ultimately chose to *allow* diagnoses from such assessments to be submitted for payment and elected *not* to require treatment or confirmation from other encounters. *See* CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter* ("*Advance Notice CY 2015*"), 19-21 (Feb. 21, 2014); CMS, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates*

[4] Nor does *Ross* support the Government. As discussed, the allegations there involved coding parts of the medical record that may not reflect a diagnosis of current conditions. *Supra* p. 7. On those very different facts, *Ross* held only that whether "documented conditions" require or affect patient care turns on the "documentation" and cannot be based purely on speculation by coders. 2023 WL 24055, at *7-8. Nothing in *Ross* suggests that contemporaneous treatment is a coding requirement or that Cigna's coders were obligated to look beyond a 360 form to other claims data before coding a documented diagnosis.

and Medicare Advantage and Part D Payment Policies and Final Call Letter, 145-46 (Apr. 6, 2015). That is undisputed and makes clear that diagnoses reported solely from in-home exams, without the provision of treatment, are no less "valid" for risk adjustment.

B. The Alleged Facts Do Not Violate CMS's Data-Attestation Requirement

Nor has the Government plausibly alleged that Cigna's submissions of certain 360 diagnoses violated its obligation to "certify (based on best knowledge, information, and belief) that the [risk-adjustment] data it submits under § 422.310 are accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*)(2). The Government interprets this provision to require that CMS second-guess licensed clinicians by, for example, searching for other reports of the same diagnosis from other medical encounters, or even blanket-overruling certain diagnoses due to a presumed lack of tests or equipment or other valid clinical basis for a diagnosis unless explicitly documented on the 360 form. *See* Doc. No. 178 ¶¶ 150-51.

As Cigna explained in its Motion, CMS simply does not exact such scrutiny as a condition for MAOs to certify the accuracy of their data. When CMS first promulgated the data-attestation requirement, it explained in response to public comments on the proposed rule that it had "restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of the *coding*." 65 Fed. Reg. 40170, 40251 (June 29, 2000) (emphasis added). It did so to avoid a "legal trap" for MAOs and because the "accuracy of the coding"—unlike the myriad factors that may have gone into a clinician's professional medical judgment—is "information that [MAOs] are, or should be, in the position to know." *Id.*

The Government responds that CMS's statement was limited to "innocent mistakes, not a knowing fraudulent scheme or reckless conduct," and claims that Cigna is not innocent because it "designed [the 360] program." Doc. No. 213 at 42. But that has nothing to do with the proper legal interpretation of the attestation requirement. The Government cannot credibly dispute that

the attestation requirement refers to *coding* accuracy, not *clinical* accuracy, which requires only that "[t]he diagnosis must be coded according to" the ICD Guidelines. CMS, *Medicare Managed Care Manual*, ch. 7, § 40 (2020). Nor can it dispute that, under the ICD Guidelines, coding depends on "the provider's diagnostic statement," not on the "clinical criteria used by the provider to establish the diagnosis." ICD-10 Guidelines § I.A.19.

Citing *Swoben*, the Government asserts that "courts have … rejected Cigna's reading of this administrative history." Doc. No. 213 at 42. But *Swoben* did not address CMS's language interpreting "accuracy" to mean *coding* accuracy, and the rest of the decision in no way "reject[s]" it. To the contrary, *Swoben* was about MAOs' alleged failure to investigate diagnoses previously reported to CMS, but not identified during subsequent "retrospective reviews" of a patient's chart. 848 F.3d at 1175. It did not remotely suggest that to certify the accuracy of their data, MAOs must look beyond the diagnoses that the clinicians themselves made and investigate the clinical tests performed and identify the equipment available at each encounter.

As Cigna has already shown, the attestation requirement simply reaffirms CMS's expectation that MAOs will make "best efforts" to ensure that their risk-adjustment data is complete and that the diagnoses they report to CMS are accurately coded, in accordance with ICD Guidelines. *Medicare+Choice Program*, 65 Fed. Reg. at 40251, 40312. The Government has not plausibly alleged that Cigna failed to undertake such "best efforts" to ensure compliant coding.

C. The Government Cannot Establish Scienter For Its Legal Falsity Claims

Cigna believes that its readings of the ICD Guidelines and data-attestation requirement are correct. At a minimum, the strong arguments supporting those readings show that these requirements are at most ambiguous, and Cigna's interpretations are "objectively reasonable." Doc. No. 196 at 41-42; *see id.* at 34-40. Nor does the Government identify authoritative

guidance warning Cigna away from its interpretations. Doc. No. 196 at 42. Under the objective scienter standard set forth in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), and applied by several courts to claims similar to the Government's here, the Government cannot plausibly establish that Cigna acted recklessly, much less knowingly, and its legal-falsity claims should accordingly be dismissed. *Id*. at 41-43. The Government has no persuasive response.

The Government briefly asserts that the ICD Guidelines and data-attestation requirements "unambiguously barred" Cigna from reporting the diagnoses at issue. Doc. No. 213 at 42-43. But it offers no substantive support for that assertion. In contrast, Cigna showed that its own reading of the ICD Guidelines has a clear textual foundation and was explicitly adopted by at least one district court in *Rasmussen*, Doc. No. 196 at 41-42—the same indicia of objective reasonableness that the Supreme Court identified in *Safeco*, 551 U.S. at 69-70. The Government "fails to respond" and therefore "concedes th[e] point." *ARJN #3*, 517 F. Supp. 3d at 750.

Tellingly, given its strained readings of the relevant legal requirements, the Government devotes the bulk of its response to arguing that *Safeco* does not apply at all. Doc. No. 213 at 43-45. But it is unable to identify a *single* recent case rejecting *Safeco*'s application in the FCA context. That is no surprise, because *every* court of appeals that has considered the question—not just the Seventh Circuit, as the Government incorrectly suggests, *id*. at 44-45—has held that *Safeco*'s objective-reasonableness inquiry extends to FCA claims like the Government's here. In *U.S. ex rel. Purcell v. MWI Corp*., 807 F.3d 281 (D.C. Cir. 2015), for example, the D.C. Circuit explained that "establishing even the loosest standard of knowledge, i.e., acting in reckless disregard of the truth or falsity of the information, is difficult when falsity turns on a disputed interpretive question." *Id*. at 288 (internal quotation marks omitted). In that FCA case, the D.C. Circuit considered, as part of the scienter analysis, whether the defendant had a "reasonable but erroneous" interpretation of its "legal obligations" and whether there was "authoritative

guidance" warning the defendant away from its "otherwise reasonable interpretation." *Id*. at 288-90 (internal quotation marks and alterations omitted).

The Third, Eighth, and Ninth Circuit have also applied *Safeco* in FCA cases—as the Government grudgingly admits in a footnote, Doc. No. 213 at 45 n.14. *See U.S. ex rel. Donegan v. Anesthesia Associates of Kansas City, PC*, 833 F.3d 874 (8th Cir. 2016); *U.S. ex rel. Streck v. Allergan, Inc*., 746 F. App'x 101 (3d Cir. 2018); *U.S. ex rel. McGrath v. Microsemi Corp*., 690 F. App'x 551 (9th Cir. 2017). And a district court in the Fourth Circuit is in accord, in a decision that was affirmed by an equally divided court of appeals. *See U.S. ex rel. Sheldon v. Forest Laboratories, LLC*, 499 F. Supp. 3d 184 (D. Md. 2020), *aff'd by equally divided court sub nom. U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873 (4th Cir. 2022) (en banc). The Government insists that this authority is "contrary to the case law of other circuits," Doc. No. 213 at 44-45, but that argument does not withstand scrutiny. The Government first cites *U.S. ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148 (11th Cir. 2017), Doc. No. 213 at 44, but its reliance on *Phalp* is misplaced. That case did not purport to hold that *Safeco* does not apply; indeed, it did not even cite *Safeco*. It observed only that "scienter is not determined by the ambiguity of a regulation and can exist even if a defendant's interpretation is reasonable." *Phalp*, 857 F.3d at 1155. But that view is entirely consistent with *Safeco*, which itself recognizes that a defendant could have a reasonable interpretation of an ambiguous regulation but nonetheless possess the requisite scienter because "authoritative guidance," for example, from a court of appeals or the relevant agency, conferred actual knowledge of the proper interpretation. 551 U.S. at 70. And in *Phalp*, the court went on to affirm the grant of summary judgment to the defendants on the ground that the plaintiff had not adduced sufficient evidence of such knowledge. 857 F.3d at 1156-57.

Moreover, the Eleventh Circuit itself has not read *Phalp* to reject *Safeco*. In a subsequent FCA case, it discussed *Phalp* and went on to apply *Safeco* in a decision cited by Cigna that the Government simply ignores. *See Olhausen v. Arriva Med., LLC*, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022), *pet. filed*, No. 22-374 (U.S. Oct. 18, 2022); Doc. No. 196 at 43. Consistent with the law of other circuits, the Eleventh Circuit in *Olhausen* affirmed the dismissal of an FCA complaint on scienter grounds because the defendant had "an objectively reasonable interpretation" of the relevant rules and there was no authoritative guidance to the contrary. 2022 WL 1203023, at *2.

The Government's reliance on *U.S. v. Chen*, 402 F. App'x 185 (9th Cir. 2010), is similarly misplaced. Doc. No. 213 at 44. The Ninth Circuit did not purport to address *Safeco* there; in fact, it agreed that "a defendant who relies on a good faith interpretation of a regulation is not subject to liability." *Chen*, 402 F. App'x at 188 (internal quotation marks omitted). And, as stated, a subsequent Ninth Circuit panel had no trouble applying *Safeco* in an FCA case. *See McGrath*, 690 F. App'x at 552.

Nor—contrary to the Government's suggestion, Doc. No. 213 at 44-45—has the Sixth Circuit held that *Safeco* does not apply in FCA cases. In *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc*., the Sixth Circuit held that a complaint adequately pled scienter where it alleged, among other things, that a defendant instructed employees to ignore compliance concerns; the defendant acknowledged that some doctors might not feel "comfortable" with the defendant's billing practices; and a supervisor raised concerns that the defendant's practices may trigger an audit. 892 F.3d 822, 837-38 (6th Cir. 2018). These alleged facts, the court concluded, "support the inference that the defendants were on notice that their claim-submission process was resulting in compliance problems." *Id*. at 838. There was no suggestion, however, that the relevant requirements were ambiguous and no discussion of the defendant's interpretation of

those requirements. *Prather* did not address—or even cite—*Safeco*, nor did it purport to decide whether defendants had a reasonable interpretation of an ambiguous regulation or whether they had been warned off an interpretation by authoritative guidance.

In short, every court of appeals to consider the issue has held that *Safeco* applies to FCA cases. For good reason. As explained in Cigna's motion, *Safeco*'s discussion of "willful" violations of the Fair Credit Reporting Act addressed the same common-law mental states Congress codified in the FCA. Doc. No. 196 at 41; *see U.S. ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 465 (7th Cir. 2021), *cert. granted*, 143 S. Ct. 644 (2023). Citing the dissent in *Schutte*, the Government argues that the FCA is different because, it says, "subjective bad faith [is] central to fraudulent intent." Doc. No. 213 at 44. The Government does not deny, however, that both statutes encompass knowing and reckless violations. Here, the Government has not alleged subjective bad faith, and while it now accuses Cigna of "*post hoc* interpretation of the relevant legal requirements," it is the Government that announces—for the first time in this enforcement posture—novel readings of Medicare Advantage program requirements that conflict with their plain text and CMS's own guidance and administration of the Medicare Advantage program, including in-home health assessments.

Finally, the Government urges the Court not to apply *Safeco* because the Supreme Court granted certiorari in *Schutte*. *Id.* at 43-44. While that may be a reason to reserve decision on the motion until after *Schutte* is decided, it is no reason to ignore the chorus of lower-court decisions applying *Safeco* in FCA cases.

D. The Government Has Not Adequately Pled Materiality

The Government also fails to plausibly allege that any supposed violation of the ICD Guidelines or the data-attestation requirement was material to CMS's payment decision. The

facts alleged and CMS's judicially noticeable statements all suggest—to the contrary—that any alleged non-compliance was immaterial under *Escobar*'s three factors. 579 U.S at 193-95 & n.5.

First, the Government does not establish that CMS regulations make compliance with ICD Guidelines or the data-attestation requirement material. It points to two regulations: 42 C.F.R. § 422.504(*l*), which requires Cigna to certify that the risk-adjustment data is "accurate, complete, and truthful, and 42 C.F.R. § 422.310(d)(1), which requires Cigna to submit risk-adjustment data that conform to "all relevant national standards" such as the ICD Guidelines. Doc. No. 213 at 39. Cigna already demonstrated that § 422.504(*l*) is not dispositive of materiality, Doc. No. 196 at 34, and the Government offers nothing new. The Government's argument as to § 422.310(d)(1) is even weaker, because that regulation does not designate compliance as a condition of payment. The Government's sweeping theory of materiality—that, in effect, any violation of a relevant regulation is material—is exactly what the Supreme Court rejected in *Escobar*.

Second, the Government fails to rebut Cigna's argument that CMS paid Cigna despite knowing all relevant details about the 360 Program. The conclusory assertion that CMS did not know of the "[i]nvalid [d]iagnoses when it made payments based on them," Doc. No. 213 at 47, proves nothing. The complaint itself alleges that Cigna disclosed the details of its 360 Program to CMS in June 2013. Doc. No. 178 ¶ 168. The Government repeats its allegation that Cigna "omitted … the focus on revenue-generation, the lack of medical care provided during the home visits, and the lack of testing to confirm diagnoses." Doc. No. 213 at 19. But, as Cigna showed, CMS's public statements following its meeting with Cigna and other MAOs leave no doubt that CMS knew that diagnoses for precisely the "serious, complex conditions" at issue here were being submitted from in-home health assessments, including by Cigna; the clinicians conducting those assessments typically were not the member's primary care provider, did not treat the

member during the visit, and had limited diagnostic tools; the diagnoses reported from those assessments were often the only report of the diagnosis during a given service year; and diagnoses made during those assessments were often "based on enrollee self-reporting" and included conditions that could not "be accurately identified" for the first time "with equipment brought into an enrollee's home." Doc. No. 196 at 16-18, 44-45. That CMS continued to pay claims with knowledge of these facts is "strong evidence" that the alleged requirements were not material. *Escobar*, 579 U.S. at 195.

Third, the Government tries to argue that the diagnoses violated the "essence" of Cigna's "bargain" with CMS. Doc. No. 213 at 48-49. Its argument, however, rests on the untenable conclusion that *any* misrepresentation as to compliance with guidance connected to a diagnosis code is inherently material because the "entire risk-adjustment system relies on the submission of accurate diagnosis codes." *Id.* at 48. But the materiality standard should be "rigorous" and "demanding," *Escobar*, 579 U.S. at 194, and cannot be satisfied by that kind of facile assertion. The issue is not the importance of accurate diagnosis codes *generally*, but the materiality of the alleged misrepresentations *specifically*. Here, CMS knew all of the issues DOJ raises, allowed the practices at issue, and paid based on the diagnosis codes they produced. As Cigna explained, the allegations here do not plausibly establish that the contract turned on the use of certain diagnostic tests, the provision of treatment, or reports by other treating physicians confirming a diagnosis. Doc. No. 196 at 45.[5]

[5] Nor is it enough that the Complaint alleges that Cigna "improperly received tens of millions of dollars in risk adjustment payments," Doc. No. 178 ¶ 15; *see* Doc. No. 213 at 48-49 (suggesting that this consideration speaks to whether noncompliance goes to the essence of the bargain). While it is true that a few district courts have considered allegations going to the total magnitude of the alleged fraud, the question when considering whether noncompliance with treatment and testing requirements goes to the "essence of the bargain," *Prather*, 892 F.3d at 834, looks just to whether the parties would have considered the noncompliance a central part of the contract. The

Contrary to the Government's suggestion, Doc. No. 213 at 46-47 n.15, the district courts' decisions in *U.S. ex rel. Poehling v. UnitedHealth Group, Inc.*, 2018 WL 1363487 (C.D. Cal. Feb. 12, 2018) and *U.S. ex rel. Swoben v. Scan Health Plan*, 2017 WL 4564722 (C.D. Cal. Oct. 5, 2017), are directly on point as to the materiality of the data-attestation requirement. The Government tries to distinguish them as turning on inadequate pleadings. But the same inadequacy is present here; the allegations in the Government's complaint fall far short of plausibly establishing materiality, even with all inferences drawn in the Government's favor. The Government attempts to argue otherwise by pointing to a single paragraph of the Complaint that pleads that the Risk Adjustment Attestations were material to payment. But that is a legal conclusion masquerading as a factual allegation.

III. THE GOVERNMENT'S COMMON-LAW CLAIMS FAIL

Finally, the Government's common-law claims for unjust enrichment and payment by mistake should be dismissed—both because the underlying fraud allegations are implausible and because quasi-contract claims are unavailable here, where the Government does not allege that any payments were made outside of a valid contractual relationship. For all of the reasons stated above and in Cigna's motion, the Government has not adequately pled fraud. Its quasi-contract claims "premised upon [that] fraud" thus "necessarily fail as well." *U.S. v. Anesthesia Servs. Assocs.*, 2019 WL 7372511, at *10 (M.D. Tenn. Dec. 31, 2019).

Dismissal of the common-law claims is also necessary because the Government's common-law claims arise entirely out of the parties' contract. "A valid contract defines the obligations of the parties as to matters within its scope, displacing to that extent any inquiry into

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Medicare Advantage payment model belies any argument that noncompliance with those requirements is, or could be, contemplated as essential to the bargain because MAOs are not paid for the costs they incurred in treating members. *See* Doc. No. 196 at 45-46.

unjust enrichment." *Restatement (Third) of Restitution & Unjust Enrichment* § 2(2) (2011). Where the allegations establish that a contract exists, a quasi-contract remedy is unavailable, *see* Doc. No. 196 at 47, and quasi-contract claims pled in the alternative "must be supported by, at the very least, an allegation that there is no valid contract." *U.S. ex rel. Morsell v. Symantec Corp.*, 130 F. Supp. 3d 106, 129 (D.D.C. 2015). The Government attempts to bypass this principle by arguing that its common-law claims also relate to alleged violations of statutory and regulatory obligations. But that goes only to the nature of the alleged fraud, not to whether the Government paid the money under the terms of a contract. The FCA does not concern just any inequitable or fraudulent conduct, but conduct that specifically relates to claims for payment. *See U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007). There is no dispute that in this case all of the claims for payment—the relevant factor in the analysis—arise out of a contract. To the extent the Government's out-of-circuit cases suggest quasi-contract remedies are available in that situation, they are mistaken.

The Government also invokes an amorphous principle that special rules apply to the Government when it asserts common-law claims. Contrary to what the Government says, it is not entitled to proceed on quasi-contract claims when the allegations admit the existence of a contract governing the parties' dispute. "The fact that the federal government retains the right to raise common law claims like any other plaintiff … does not mean that the government is entitled to proceed with common law claims where private plaintiffs would be barred." *U.S. v. Savannah River Nuclear Sols., LLC*, 2016 WL 7104823, at *27 (D.S.C. Dec. 6, 2016); *see also U.S. ex rel. Doughty v. Oregon Health & Scis. Univ.*, 2017 WL 1364208, at *7 (D. Or. Apr. 11, 2017) (similar).

None of the Government's cited authorities persuasively establishes entitlement to a special rule. First, the Government cites to *U.S. v. Omnicare, Inc.*, 2021 WL 1063784, at *13

(S.D.N.Y. Mar. 19, 2021), where the defendants argued that federal common law could not provide the bases for the common-law causes of action after *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938)—which is not at issue in this case. It then points to *Agility Public Warehousing Co. v. U.S.*, 969 F.3d 1355, 1365 (Fed. Cir. 2020), for the proposition that the Government has a right "arising separate and apart from statute, regulation, or contract" to recover funds it paid. But *Agility* addressed a situation in which there was *no* contract to which the United States was a party; Iraq was the party to the contract, and the United States was acting as Iraq's agent. For this reason, *Osinek*, 2022 WL 16925963, at *18, which the Government cites and which relies on *Agility*, is respectfully mistaken. While the "Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid," *Omnicare*, 2021 WL 1063784, at *13—including by quasi-contract claims when no contract with the Government exists—such claims are foreclosed where, as here, such a contract exists.

IV. THE COURT SHOULD DISMISS ANY REMAINING CLAIMS BY CUTLER

Cutler's opposition to Cigna's motion to dismiss leaves no doubt that his complaint should be dismissed. *First*, the Government intervened on all claims except for one that contends that all diagnoses are *per se* invalid, which Cutler has now abandoned. *Second*, his claims are precluded by the public disclosure bar. *Third*, Cutler's allegations fall far short of what Rule 9(b) requires. *Fourth*, Cutler's complaint fails to state a claim under Rule 12(b)(6).

A. Cutler Has Abandoned The Only Claim On Which The Government Did Not Intervene

Where the Government intervenes as to certain claims, its complaint supersedes the relator's and "becomes the operative complaint as to all claims in which the government has intervened," and the relator's "continues to be the operative" pleading only for "non-intervened claims." Doc. No. 196 at 48 (quoting *U.S. v. SavaSeniorCare, LLC*, 2016 WL 5395949, at *15

(M.D. Tenn. Sept. 27, 2016)); *see also* Boese & Baruch, *Civil False Claims and Qui Tam Actions* § 4.04[B] (2022); *Thornton v. Nat'l Compounding Co.*, 2019 WL 2744623, at *5 (M.D. Fla. July 1, 2019) ("Relator's claims are superseded by the Government's Complaint to the extent that it intervened, and Relator's Second Amended Complaint survives only with respect to non-intervened claims"). As Cigna showed, the only claim on which the Government did not intervene was the *per se* claim on which it had previously "expressly decline[d] to intervene." Doc. No. 196 at 48 (quoting Doc. No. 169 at 1). Cutler has now relinquished that *per se* claim. *See* Doc. No. 214 at 5. His complaint should accordingly be dismissed in full.

Cutler makes two arguments in response. Neither has merit. *First*, he argues that the government elected not to intervene as to certain of his other claims beyond the *per se* theory. *See id.* at 5 n.4. That is incorrect. The Government expressly declined to intervene only "as to the relator's claims insofar as he asserts that when defendants submitted diagnosis codes based on so-called 360 'nurse home visits' to CMS for risk-adjustment payment purposes under Medicare Part C, they committed *per se* violations of the False Claims Act … because the nurse home visits did not involve the provision of medical treatment." Doc. No. 13 at 1. At the time, the Government opted not to make an intervention decision as to Cutler's remaining claims. When it later moved to intervene, it did so "on claims … for which it previously made no intervention decision." Doc. No. 157 at 1. Cutler did not oppose the Government's intervention; he consented to it. *See id.* at 2. And this Court thus granted the Government's motion to intervene as to "all of Relator's claims as to which it did not expressly decline to intervene," that is, "all of Relator's claims" other than one—the *per se* theory—on which the Government had "expressly decline[d] to intervene." Doc. No. 169 at 1.

Cutler's second argument—that his claims "can only be dismissed by the Government if the Government moves to dismiss them"—is a red herring. Doc. No. 214 at 7. Where the

Government has not intervened as to certain claims, it can only dismiss them by motion. But as to the claims on which the Government *has* intervened, the Government is the master of the case, and its complaint *supersedes* the relator's. Cutler cites no authority to the contrary, and the two cases he does cite strongly support Cigna's position. Indeed, in *U.S. ex rel. White v. Mobile Care EMS & Transport, Inc.*, the district court explained that the "government is the master of the claims as to which it intervened," and the relator is limited to non-intervened claims. 2021 WL 6064363, at *10 (S.D. Ohio Dec. 21, 2021). Likewise, *U.S. ex rel. Fischer v. Community Health Network*—which Cutler attaches to his opposition—makes clear that a relator is only "permitted to litigate *non-intervened* claims," whereas the Government assumes responsibility and displaces the relator as the party prosecuting all claims as to which it has intervened. Doc. No. 214-3 at 12 (emphasis added); *see id.* at 10-12.

B. The Public Disclosure Bar Mandates Dismissal Of Cutler's Claims

Even if Cutler could maintain his claims despite the Government's intervention, they would be precluded by the public disclosure bar.[6] As Cigna showed in its opening brief, "substantially the same" allegations as Cutler's were previously made in CMS's advance notices and announcements, the report to Congress in 2016 by the Medicare Payment Advisory Commission ("MedPAC"), other *qui tam* complaints, and media reports. *See* Doc. No. 196 at 48-51. Cutler makes two arguments in response. First, he argues that his claims "do not rely on any public disclosures." Doc. No. 214 at 8. But the legal standard is whether the allegations in the public disclosures were "substantially the same" as his allegations, not whether he relied on

[6] Before moving to dismiss his claims on this ground, Cigna conferred with the Government, which indicated that it did not intend to oppose the public disclosure bar's application to Cutler's claims that differ from its own but reserved its right to oppose or otherwise address the public disclosure bar in response to Cigna's motion. Doc. No. 196 at 49 n.11. The Government's response brief does not address the issue further or indicate any change in its position.

the public disclosures. Second, he argues that the public disclosures did not reveal a "scheme whereby MAOs obtain invalid diagnostic codes by commandeering the actions of the NPs performing the in-home visits." *Id.* Stripped of its bombastic language, that amounts to no more than a conclusory assertion that the public disclosures were not sufficiently specific about how MAOs operated the programs. They were. In 2013 and 2014, CMS reported that MAOs hire vendors to conduct health risk assessments in members' homes through health care professionals who are not the member's primary care provider, do not treat the member during the visit, and have limited diagnostic tools, and CMS was "concerned that these risk assessments could be used as a vehicle for collecting risk adjustment diagnoses without follow-up care or treatment being provided." CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter*, 22 (Feb. 15, 2013); *see Advance Notice CY 2015* at 20. MedPAC's report to Congress in 2016 likewise noted CMS's concerns that in-home HRAs are "used solely as a diagnosis-collection vehicle." MedPAC, *Report to the Congress, Medicare Payment Policy*, 350 (Mar. 2016). And media reports voiced similar concerns about MA plans "collect[ing] billions of dollars from controversial 'house calls'" during which "doctors and nurses don't offer any treatment." Schulte, Ctr. for Pub. Integrity, *Home Is Where the Money Is for Medicare Advantage Plans* (June 10, 2014). Cutler's argument that those disclosures would not put the Government "on notice" of the fraud he alleges is unpersuasive. Doc. No. 214 at 8-9. For years, public disclosures raised concerns that these programs were rife with abuse and were directed at amassing diagnoses. Cutler's allegations are "substantially the same." *U.S. ex rel. Rahimi v. Rite Aid Corp.*, 3 F.4th 813, 823, 826 (6th Cir. 2021). At most, they add "new details to describe essentially the same scheme," which is "not enough to survive the public disclosure bar." *U.S. v.*

Allstate Ins. Co., 2022 WL 3213529, at *10 (E.D. Mich. Aug. 9, 2022) (quoting *U.S. ex rel. Holloway v. Heartland Hospice, Inc.*, 960 F.3d 836, 851 (6th Cir. 2020)).

Cutler's alternative argument that he counts as an "original source" of the information fares no better. Cutler argues only that he "possesses direct and independent knowledge of the information on which the allegations are based." Doc. No. 214 at 9. But to qualify as an original source, Cutler must show that his allegations "materially add[ed]" to the public disclosure and thus that the information he provided was such that it "would affect a person's decision-making, is 'significant,' or is 'essential.'" *U.S. ex rel. Advocs. for Basic Legal Equal., Inc. v. U.S. Bank, N.A.*, 816 F.3d 428, 431 (6th Cir. 2016); *see also U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 551 F. Supp. 3d 27, 46 (E.D.N.Y. 2021), *aff'd*, 2022 WL 17818587 (2d Cir. Dec. 20, 2022). Cutler does not even argue that his allegations materially added to the public disclosures and therefore has not carried his burden on this point.

C. Cutler's Allegations Fail To Comply With Rule 9(b)

In its motion, Cigna showed that Cutler's Complaint does not satisfy Rule 9(b). Doc. No. 196 at 54-55. Cutler fails to meaningfully dispute this point. First, Cutler misleadingly suggests that it "is not necessary" for him to provide a representative example of claims. Doc. No. 214 at 10. That is not the law of this Circuit. *See* Doc. No. 196 at 55 (citing *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 470 (6th Cir. 2011); *Bledsoe*, 501 F.3d at 510). And the case on which Cutler relies says exactly the opposite of what he argues: "When a relator alleges such a 'complex and far-reaching fraudulent scheme' to induce the government into making payments, … *Bledsoe* ... requires the relator's complaint to include specific examples of the defendant's claims for payment from the federal government." *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th Cir. 2008).

Simply put, his argument runs headfirst into what the Sixth Circuit has said must be alleged under Rule 9(b).[7]

Lacking any particularized allegations of actual claims for payment, Cutler asks the Court to rely on the Government's allegations concerning exemplar claims for payment. According to Cutler, "[w]hile those examples pertain only to intervened claims, they would apply equally to the allegations in Relator's Complaint because the intervened claims are a narrow subset of Relator's claims." Doc. No. 214 at 9-10. This bizarre argument turns both the Federal Rules of Civil Procedure and the FCA on their heads. As an initial matter, Cutler provides no authority for the proposition that the sufficiency of one complaint can be measured by the allegations made in another. It makes no sense to allow Cutler to support his non-intervened claims—which he himself argues are broader than the Government's claims—with particularized allegations the Government has made as to a narrower set of claims (which Cutler is no longer even permitted to maintain now that the Government has intervened).

D. Cutler's Complaint Fails To State A Claim

Even if there were non-intervened claims that Cutler did not abandon, survived the public disclosure bar, and complied with Rule 9(b)—none of which is the case—such claims would still fail for the same reasons as the Government's. Indeed, Cutler disclaims reliance on any theory

[7] *See Chesbrough*, 655 F.3d at 470 (identifying a "strict requirement that relators identify actual false claims" based on prior Sixth Circuit precedent, even while acknowledging the possibility that, under specific circumstances not present here, a more relaxed version of Rule 9(b) might apply); *Sanderson*, 447 F.3d 873, 874, 877-79 (6th Cir. 2006) (affirming dismissal of complaint alleging defendant misallocated hospital debt because it failed to identify any specific fraudulent cost reports). Cutler cites *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750 (6th Cir. 2016), but makes no effort to explain how that case supports his argument. In any event, *Prather* entailed specific allegations detailing several patient examples and relator's personal knowledge of the defendant's billing practices, *see id.* at 769-71. None of that is present here.

of factual falsity, *see* Doc. No. 214 at 12, and the legal falsity theories set forth in his opposition fail for the same reasons as the Government's. Indeed, the notion that clinicians deliberately violated standards of medical practice to make medically invalid diagnoses is even less plausible for Cutler because he does not in any way limit his theory and instead argues that "[a]ll diagnosis codes" from in-home 360 exams were invalid. Doc. No. 12 ¶ 56.

E. Leave To Amend Should Be Denied

Cutler requests leave to file a second amended complaint "should the Court determine that additional details are necessary." Doc. No. 214 at 1. But Cutler did not file a motion for leave to amend and did not adhere to this District's requirements for such a motion, which must include "the reasons supporting the proposed amendments and the substance of the amendments sought." M.D. Tenn. Local Rule 15.01.

Even if the request were procedurally proper, leave to amend should be denied. Although "a court should freely give leave when justice so requires, the right to amend is not absolute or automatic." *Tucker v. Middleburg-Legacy Place*, 539 F.3d 545, 551 (6th Cir. 2008). "[L]eave to amend is properly denied if the proposed amendments would be futile and would not withstand a Rule 12(b)(6) motion to dismiss." *Lee v. Stewart*, 2020 WL 6054336, at *5 (M.D. Tenn. Mar. 26, 2020), *report and recommendation adopted*, 2020 WL 4333746 (M.D. Tenn. July 28, 2020), *aff'd*, 2021 WL 6932349 (6th Cir. Aug. 24, 2021); *see also Miller v. Calhoun Cnty.*, 408 F.3d 803, 817 (6th Cir. 2005). That is the case here. Cutler's proposed amendment fails to remedy any of the defects that prove fatal to his complaint. As an initial matter, Cutler does not argue that the proposed amendment has any bearing on (1) whether he has abandoned the only non-intervened claim, (2) the public-disclosure-bar analysis, or (3) whether his complaint fails to state a claim. If the Court grants dismissal on any of those grounds, there is therefore no basis to grant his request for leave to amend.

Cutler argues only that the proposed amendment adds allegations for representative examples of the false claims at issue. Doc. No. 214 at 10 (citing Doc. No. 214-4 ¶¶ 102-105). But his new allegations merely point the Court to a list—"more than 2,452 pages" long—for all diagnosis codes Cigna supposedly submitted to CMS in 2015 for certain members enrolled in plans in East Texas. Cutler then makes a conclusory assertion that "[b]y comparing this list against the 360 forms that were completed for these same members … in 2016, one can find specific submissions that were made to CMS in 2015 that were false." Doc. No. 214-4 ¶¶ 104-105. Such conclusory assertions do not satisfy Rule 9(b)'s requirement to provide representative examples of actual claims for payment. *See supra* pp. 36-37 & n.7.

Cutler's new allegations do describe a single patient who, he alleges, did not have certain medical conditions in 2016 that were reported to CMS in 2015. *See* Doc. No. 214-4 ¶ 105. But he does not explain how an in-home vendor's omission of certain diagnoses in 2016 that were reported in 2015 provides a representative example of a false claim for payment from an in-home exam; if anything, it does just the opposite. Even assuming it were an example of a false claim, which he has not adequately pled, Cutler also fails to explain how it falls outside the claims on which the Government intervened. Indeed, because the conditions at issue are heart failure and chronic kidney disease, and Cutler's allegation is that the patient did not have these conditions, the example would seem to fall squarely within the Government's claims. Nor does he provide any details about how his allegation concerning this one patient substantiates, or even meaningfully relates to, his expansive theory of fraud. Because Cutler's proposed amendment fails to cure the defects of his complaint, his request for leave to amend should be denied.

CONCLUSION

For all of these reasons, the Court should dismiss the Government's complaint-in-intervention and Cutler's amended complaint and deny Cutler's request for leave to amend.

Dated: March 17, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on March 17, 2023, I electronically filed the foregoing document with the Clerk of Court using this Court's CM/ECF system, which will send a Notice of Electronic Filing to the following:

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