IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

CIGNA CORPORATION, BRAVO HEALTH MID-ATLANTIC, INC., BRAVO HEALTH PENNSYLVANIA, INC., CIGNA HEALTH & LIFE INS. CO., CIGNA HEALTHCARE OF CALIFORNIA, INC., CIGNA HEALTHCARE OF COLORADO, INC., CIGNA HEALTHCARE OF CONNECTICUT, INC., CIGNA HEALTHCARE OF GEORGIA, INC., CIGNA HEALTHCARE OF NORTH CAROLINA, INC., CIGNA HEALTHCARE OF SOUTH CAROLINA, INC., CIGNA HEALTHCARE OF ST. LOUIS, INC., HEALTHSPRING OF FLORIDA, INC., and HEALTHSPRING LIFE & HEALTH INS. CO.,

Defendants.

Case No. 3:21-cv-00748
JUDGE RICHARDSON
MAGISTRATE JUDGE FRENSLEY

JURY DEMAND

THE UNITED STATES OF AMERICA'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS AND REGULATORY MATERIALS

RULES

LEGISLATIVE MATERIALS

OTHER AUTHORITIES

Plaintiff the United States of America (the "United States" or the "Government") respectfully opposes the motion, ECF No. 195, filed by defendants Cigna Corp. and its affiliates (collectively, "Cigna"), to dismiss the Government's complaint-in-intervention, ECF No. 178 ("Compl."), alleging violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), and the common-law theories of unjust enrichment and payment by mistake.

The Government alleges Cigna fraudulently submitted false and invalid patient diagnosis codes to improperly inflate payments it received from the Medicare Part C program, also called the Medicare Advantage Program. Under its "360 comprehensive assessment" program, Cigna contracted with medical providers to visit its Medicare Advantage plan members at home. As Cigna acknowledged, the "primary goal" of these visits was diagnosis "code capture," rather than providing "chronic care or acute care management." Cigna developed trainings for the visits, issued guidance on when to report the diagnoses, designed the check-the-box forms its vendors would complete and submit to Cigna, and pressured its vendors to record lucrative diagnoses on these forms. During these cursory home visits, the providers conducted no comprehensive physical exams, but instead largely relied on patients' self-assessments and responses to basic screening questions.

Based on the completed check-box forms, Cigna submitted for payment tens of thousands of false and invalid diagnoses—the "Invalid Diagnoses"—for serious, complex conditions that: (a) were identified based only on the home visits; (b) required specific testing or imaging to be reliably diagnosed, which was not performed; (c) were not supported by the scant information recorded on the form completed by the vendors; and (d) were not reported by other healthcare providers who treated the plan member during the year in which the home visit occurred. Cigna knew these diagnoses could not be reliably made in a home setting and did not comply with

regulatory requirements for coding diagnoses. Nonetheless, it submitted them to the Centers for Medicare and Medicaid Services ("CMS"), part of the U.S. Department of Health and Human Services ("HHS"), which paid Cigna tens of millions of dollars as a result.

Ignoring the standard of review on a motion to dismiss, Cigna disputes or ignores the Government's allegations, offers hypothetical explanations for its misconduct, and misinterprets binding regulations and guidance. Many of its arguments have been rejected by other courts in similar cases. This Court should do the same.

First, the Government plausibly alleges that Cigna's submission of the Invalid Diagnoses was factually false. The complaint includes detailed allegations regarding the limitations of the in-home visits, the inability of the vendors to reliably diagnose the serious medical conditions at issue, and the lack of support for the reported diagnoses. By submitting the Invalid Diagnoses, Cigna misrepresented that its plan members had been reliably diagnosed with these conditions during the home visits. Cigna further mispresented that these diagnoses comported with guidelines for coding medical conditions, including the requirements that diagnoses actually require or affect "patient care, treatment, or management," and that, after an initial diagnosis, chronic conditions may only be coded when treated during a visit. The Court should reject Cigna's suggestion that, as a matter of law, the diagnoses cannot be factually false merely because its paid vendors checked boxes on Cigna-created forms. Cigna also submitted false risk-adjustment data and falsely certified its accuracy.

Second, the Government adequately alleges that Cigna's submissions of the Invalid Diagnoses were legally false because Cigna violated the regulatory requirement that diagnoses comply with coding guidelines, and because it knowingly submitted false attestations to CMS each year misrepresenting the accuracy and truthfulness of the diagnosis data it submitted. These

false claims and attestations were plainly material to CMS's decision to pay Cigna because the agency calculated the payments for each Medicare Advantage plan member based on the reported diagnoses.

Finally, the Government properly alleges common-law claims arising from Cigna's conduct, as the Government would not have paid Cigna if it was aware of Cigna's submission of the Invalid Diagnoses, and it would be inequitable for Cigna to retain the resulting payments.

BACKGROUND

A. Legal and Regulatory Background

1. The Medicare Advantage Program and Its Risk-Adjustment Payment System

Under Medicare Advantage ("MA"), an alternative to traditional Medicare's fee-for-service coverage, *see* Compl. ¶¶ 42-44, CMS pays Medicare Advantage Organizations ("MA Organizations") that operate healthcare plans, which in turn pay healthcare providers for treating members enrolled in their plans. *Id.* ¶ 45. The private insurers provide coverage in exchange for CMS payments of "a fixed monthly fee per person enrolled in the program—regardless of actual healthcare usage." *United States ex rel. Osinek v. Permanente Med. Grp., Inc.*, __ F. Supp. 3d __, No. 13 Civ. 3891, 2022 WL 16925963, at *1 (N.D. Cal. Nov. 14, 2022).

To participate in the MA program, every MA Organization must execute a written contract with CMS. Compl. ¶¶ 2, 44; *see* 42 U.S.C. § 1395w-27(a). These contracts require MA plans to operate "in compliance with the requirements of applicable Federal statutes, regulations, and policies," including CMS's *Medicare Managed Care Manual*.[1] *Id.* ¶ 48 (brackets omitted). As discussed below, these requirements include submitting diagnosis data in conformance with

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.

required guidelines and making annual attestations to CMS certifying the accuracy and truthfulness of the diagnosis data. *Id.* ¶¶ 46, 48, 58. CMS pays MA Organizations using a risk-adjustment system based on their plan members' predicted healthcare costs, accounting for demographic factors and members' health status. *Id.* ¶¶ 49-57 (citing 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. §§ 422.2, 422.308(e)). MA Organizations receive higher payments for plan members with more serious health conditions, using a model known as Hierarchical Condition Categories to calculate risk scores, *see id.* ¶¶ 49-57, which reflects the costs associated with caring for patients in each category, and assigns higher values to those that include diagnoses with higher treatment costs, *id.* ¶¶ 53-54 (citing 42 C.F.R. § 422.2).

Each year, MA Organizations submit diagnosis codes to CMS for each plan member, *id.* ¶ 57, and adding unique risk-adjustment-eligible codes generally increases CMS's payment for a member, reflecting the predicted additional cost of treatment, *id.* ¶¶ 55-56. The model is prospective, using diagnosis codes assigned to each plan member in a given year to determine CMS's payments for the following year. *Id.* ¶ 59. This "ensure[s] that MA Organizations are paid more for sicker enrollees expected to incur higher healthcare costs and less for healthier enrollees expected to incur lower costs." *Osinek*, 2022 WL 16925963, at *2 (internal quotation marks omitted).

2. The ICD Guidelines

MA Organizations must submit diagnosis codes to CMS according to the International Classification of Diseases Official Guidelines for Coding and Reporting (the "ICD Guidelines"). Compl. ¶ 58 (citing 42 C.F.R. § 422.310(d)(1); 45 C.F.R. § 162.1002).[2] These guidelines impose

[2] Specifically, 42 C.F.R. § 422.310(d)(1) provides that risk-adjustment data must "conform[] to relevant national standards," and 45 C.F.R. § 162.1002(b)-(c) adopts the ICD Guidelines as a

requirements and limitations on what diagnoses may be coded for each medical encounter. *Id.* ¶ 78. Conditions may be coded in connection with outpatient visits (including home visits) only if they are documented and both (1) exist at the time of the visit and (2) "require or affect patient care[,] treatment or management." ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K;[3] *see* Compl. ¶ 80. Additionally, after initial diagnosis, chronic conditions—a category that includes many of the unsupported diagnosis codes at issue—may only be "coded and reported as many times as the patient *receives treatment and care* for the condition(s)." *Id.* (quoting ICD-10 Guidelines § IV.I; ICD-9 Guidelines § IV.J) (emphasis added in the complaint). Diagnoses that are only probable, suspect, questionable, or otherwise uncertain or provisional may not be coded. *Id.* (citing ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I). And prior conditions that no longer exist may be coded with "history codes," but only "if the historical condition . . . has an impact on current care or influences treatment." ICD-10 Guidelines § IV.J; *see* ICD-9 Guidelines § IV.K; Compl. ¶ 79.

The ICD Guidelines require diagnoses to be supported by adequate documentation in the medical record. Compl. ¶¶ 83-86. Indeed, the ICD Guidelines specify that "'accurate coding cannot be achieved'" absent "'complete documentation in the medical record.'" *Id.* ¶ 83 (quoting ICD-10 Guidelines at 1). "[T]he documentation should describe the patient's condition, using

---

national standard during the relevant period. *See id.* ¶ 77; *see also United States ex rel. Ross v. Indep. Health Corp.*, No. 12-CV-299S, 2023 WL 24055, at *7 (W.D.N.Y. Jan. 3, 2023).

[3] During the relevant period, the Ninth Revision of the ICD Guidelines ("ICD-9") applied through October 1, 2015, and thereafter the Tenth Revision ("ICD-10") applied. Compl. ¶ 58 (citing 45 C.F.R. § 162.1002). The fiscal year 2011 edition of the ICD-9 Guidelines is available at https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf, and the 2015 edition of the ICD-10 Guidelines is available at https://www.cms.gov/medicare/coding/icd10/downloads/icd10cm-guidelines-2015.pdf.

terminology which includes specific diagnoses as well as symptoms, problems, or reasons for the encounter." ICD-10 Guidelines § IV.C; ICD-9 Guidelines § IV.C.

MA Organizations are responsible for the accuracy and the truthfulness of diagnosis codes submitted for each member. Compl. ¶ 57 (citing 42 C.F.R. § 422.504(i)(1)). "[A]s CMS [has] made clear, [MA] organizations have always had an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data and an obligation to undertake due diligence to ensure the accuracy, completeness, and truthfulness of encounter data submitted to CMS." *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1174 (9th Cir. 2016) (internal quotation marks and brackets omitted). Indeed, the ICD Guidelines specifically state that "[a] joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses." ICD-10 Guidelines at 1; ICD-9 Guidelines at 1.

3. CMS's Concerns Regarding Diagnoses Made During Home Visits

Since at least 2013, CMS has expressed concerns that MA Organizations might improperly use home visits "'as a vehicle for collecting risk adjustment diagnoses without follow-up care or treatment being provided to the beneficiary by the plan.'" Compl. ¶ 166 (quoting CMS, *Advance Notice of Methodological Changes for Calendar Year 2014*, at 22 (Feb. 15, 2013) ["2014 Call Letter"][4]). CMS advised that such visits would not comport with its expectations, since they would not "measur[e] health status that is related to plan liability," and "it is not clear that there is plan liability associated with the provision of treatment" for the diagnoses arising from these visits. 2014 Call Letter at 22.

[4] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2014.pdf.

Given these concerns, CMS for a time considered disallowing for payment purposes the use of diagnosis codes collected solely in connection with home visits. Compl. ¶ 166 (citing CMS, *Advance Notice of Methodological Changes for Calendar Year 2015* at 21 (Feb. 21, 2014)[5]). Ultimately, the agency required MA Organizations to "flag" such codes in their submissions. *Id.*; *see* CMS, *Announcement of Calendar Year 2016 Medicare Advantage Capitation Rates and Final Call Letter* at 144 (Apr. 6, 2015) ["2016 Final Call Letter"].[6] In choosing this option, CMS reiterated its concern that MA Organizations might improperly use home visits "'primarily for the gathering of diagnoses for payment rather than to provide treatment and/or follow-up care to beneficiaries.'" Compl. ¶ 166 (quoting CMS, *Announcement of Calendar Year 2015 Medicare Advantage Capitation Rates and Final Call Letter* at 27[7] (Apr. 7, 2014) ["2015 Final Call Letter"][8]). To mitigate this risk, while preserving the potential benefits of home visits, CMS "strongly encourage[d]" MA Organizations to "adopt, as a best practice, a core set of components for the in-home assessments they perform," while reminding them of CMS's continued concerns. 2016 Final Call Letter at 145; *see* Compl. ¶ 166. These best practices included conducting home-environment reviews, making referrals and scheduling appointments with appropriate healthcare providers, and verifying that necessary follow-up care was provided. 2016 Final Call Letter at 146. CMS suggested that the best practices, in addition to the flagging requirement, would incentivize MA Organizations to use home visits for appropriate purposes. *Id.* at 145.

---

[5] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2015.pdf.

[6] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf.

[7] The complaint cites page 28 of the document, but the quoted language appears on page 27.

[8] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2015.pdf.

4. MA Organizations' Attestation Requirements

CMS requires MA Organizations to attest annually that their risk-adjustment submissions are "accurate, complete, and truthful" based on the "best knowledge, information, and belief" of high-ranking company officials. 42 C.F.R. § 422.504(*l*). The attestation requirement is also included in MA Organizations' contracts with CMS. Compl. ¶¶ 70-71. MA Organizations must thus make "good faith efforts to certify the accuracy" of the data they submit. *Id.* ¶ 72 (quoting HHS, Health Care Financing Admin., *Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) ["HHS, *Medicare+Choice Program*"]). CMS also requires MA Organizations to enter into electronic data interchange agreements in which they attest to the accuracy of the data (even if another entity submits data on their behalf). *Id.* ¶ 67.

Both CMS regulations and relevant contracts expressly designate these annual attestations as a condition of payment. *Id.* ¶ 94 (citing 42 C.F.R. § 422.504(*l*)). To ensure the underlying data is accurate, CMS and HHS's Office of Inspector General ("HHS-OIG") periodically audit MA Organizations and require them to submit plan members' medical records to validate the diagnosis codes. *Id.* ¶¶ 91-93. Through these audits, "CMS seeks to confirm that its payments to [MA Organizations] are correct by retrospectively spot-checking the data submissions going back several years" and "compar[ing] a sample of their reported diagnosis codes to the underlying medical charts and records for the relevant beneficiaries." *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 877 (D.C. Cir. 2021). MA Organizations "must return to CMS any payments that an audit reveals were based on unsupported diagnoses—that is, diagnoses reported to CMS but that the audit found lack support in the relevant beneficiaries' medical record documentation." *Id.*

B. Factual Background

According to Cigna's chief medical officer, the company's 360 program was "originally created" to achieve "revenue generation" by adding risk-adjustment diagnosis codes that had not otherwise been submitted to CMS. *Id.* ¶ 105. As part of the program, Cigna contracted vendors that sent healthcare professionals ("Vendor HCPs")—typically nurse practitioners, but sometimes physician assistants or registered nurses—to visit Cigna plan members' homes. *Id.* ¶ 107. Cigna identified which plan members would receive home visits, and, based on data analysis, prioritized those it believed would likely generate significant revenue increases. *Id.* ¶ 108. From the beginning, Cigna viewed the program as a vehicle to identify "diagnostic coding opportunities." *Id.* ¶ 126. And as late as 2017, the company internally acknowledged that the program's "primary goal" was "administrative code capture and not chronic care or acute care management." *Id*.

During the 360 home visits, which often lasted less than half an hour, Vendor HCPs completed a Cigna-created form (the "360 form") that included a check-the-box, multi-page list of a wide range of medical conditions. *Id.* ¶¶ 109-13, 115. The Vendor HCPs largely relied on plan members' self-assessments and responses to basic screening questions, did not perform comprehensive physical exams, and did not review (and could not even access) the members' complete medical records or histories; rather, they had only limited information regarding medication and diagnosis history based on encounter data submitted by other providers in prior years. *Id.* ¶¶ 6, 110. The purpose of the visit was not to provide medical care or treatment—indeed, Cigna contractually prohibited that. *Id.* ¶ 111. And, as Cigna knew, the Vendor HCPs typically had only basic medical equipment, such as a stethoscope and blood-pressure cuff, and not the equipment needed to diagnose many of the serious, complex medical conditions listed on the 360 form. *Id.* ¶ 114. The Vendor HCPs were also not permitted to order diagnostic tests or

refer plan members to other providers who would. *Id.* ¶ 5. Despite these limitations, the Vendor HCPs were tasked with "diagnosing" serious, complex medical conditions that can be difficult to detect, including congestive heart failure; metabolic diseases; diabetes with various complications; autoimmune diseases; chronic kidney disease; and neurological disorders. *Id.* ¶¶ 5, 7, 117.

Cigna exercised extensive control over the home visits program and dictated the manner in which the Vendor HCPs conducted the visits. *Id.* ¶ 8. As noted above, it selected the plan members to be visited, and barred Vendor HCPs from exercising independent medical judgment on patient care. *Id.* ¶ 121. Cigna designed the 360 form the Vendor HCPs were required to complete, which was the primary purpose of the visit. *Id*. ¶¶ 113, 115. Cigna also developed the Vendor HCP training to ensure the providers would focus on diagnosing the conditions Cigna prioritized, and offered vendors guidance on how to diagnose specific conditions. *Id.* ¶¶ 122-23. Once the Vendor HCPs completed the 360 forms, Cigna's coding teams collected them and assigned diagnosis codes for submission to CMS. *Id.* ¶¶ 5, 119.

Cigna pressured its vendors to maximize the number of high-value diagnoses recorded. *Id.* ¶ 132. It closely tracked the volume and nature of the diagnoses generated during each vendor's home visits, and tracked how those diagnoses affected risk-adjustment payments. *Id.* ¶ 9. When vendors failed to deliver the expected level of lucrative diagnosis codes, Cigna provided training to improve their "performance." *Id.* Cigna even tracked individual healthcare providers' rates of diagnosing certain high-value conditions, and suggested those who performed poorly should be "weed[ed] out." *Id.* ¶¶ 12, 137-38. In addition, Cigna carefully monitored its return on investment from the program by comparing what it paid to the vendors to perform the visits to the additional risk-adjusted payments generated from the resulting diagnoses; for

example, in 2014, the company projected a profit of about $61.8 million from home visits that cost it about $18.8 million. *Id.* ¶¶ 128, 130.

Cigna's 360 home visit program generated false diagnoses of serious, complex medical conditions—the Invalid Diagnoses—which, to reiterate, are the sole subject of the Government's complaint, and (a) were based only on home visits; (b) required specific testing or imaging to be reliably diagnosed, which was not performed; (c) were not supported by the form completed by the vendors; and (d) were not reported by any other healthcare provider who saw the plan member during the year in which the home visit occurred. *Id.* ¶ 7. According to Cigna's own clinical guidelines—as well as those of professional groups, such as the American College of Rheumatology and American College of Cardiologists, and government bodies such as the National Institutes of Health—accurately diagnosing these conditions requires special testing or other diagnostic steps that were not administered or ordered. *Id.* ¶¶ 142-46. The 360 forms themselves lacked findings or information to support the purportedly diagnosed conditions, and in many cases, information on the forms contradicted the purported diagnosis. *Id.* ¶¶ 147-48. Based on Cigna's knowledge of the nature of the home visits and the content of the 360 forms, there was no sound basis for it to believe that plan members had been reliably diagnosed with the medical conditions recorded on the forms or that they had received care or treatment for them during the visit. *Id.* ¶ 140. Nevertheless, Cigna included the Invalid Diagnoses in the risk-adjustment data it submitted to CMS—and falsely certified the data was accurate and truthful. *Id.*

Moreover, the Invalid Diagnoses did not comport in several respects with the ICD Guidelines. *Id.* ¶¶ 153-58. They did not "require or affect patient care[,] treatment or management," and previously diagnosed chronic conditions were not cared for or treated, ICD-10 Guidelines §§ IV.I, IV.J; ICD-9 Guidelines §§ IV.J, IV.K, as the plan members received no

care or treatment for the conditions during the home visits or at any other time during the relevant year, Compl. ¶¶ 155. These conditions were also (at most) merely suspected or probable, as confirmatory laboratory or other tests had not been performed, *id.* ¶ 156, and were not based on "complete documentation in the medical record," *id.* ¶ 157 (quoting ICD-10 Guidelines at 1); *see id.* ¶¶ 82-83, as they were based only on checked boxes on the 360 forms, which did not include substantiating information, *see id.* ¶ 158.

Cigna's false submissions were made knowingly. *Id.* ¶ 159. The company structured the 360 home visit program in a manner that created a significant risk of generating Invalid Diagnoses by asking the Vendor HCPs to diagnose serious, complex conditions that ordinarily cannot be diagnosed in a home setting without performing necessary testing, imaging, or other diagnostic steps. *Id.* ¶ 160. Cigna was well aware of the limitations of the in-home visits described above and received and reviewed the 360 forms before submitting the false diagnosis codes. *Id.* ¶ 160-61. In addition, Cigna's compliance staff expressed concerns about the reliability and accuracy of diagnosis data stemming from 360 home visits, but the company nonetheless continued submitting the Invalid Diagnoses. *See id.* ¶¶ 162-64.

Senior Cigna executives also knew of the concerns CMS had expressed about MA Organizations' submission of diagnosis codes from home visits solely to increase risk-adjustment payments. *Id.* ¶ 167. In an attempt to mitigate these concerns, in 2013 Cigna provided CMS with a description of its 360 home visit program, but omitted important details about the program, including the focus on revenue-generation, the lack of medical care provided during the home visits, and the lack of testing to confirm diagnoses. *Id.* ¶ 168.

Cigna executives nonetheless signed and submitted the required attestations as to the accuracy and completeness of the diagnosis codes it submitted to CMS during the payment years

in question. *See id.* ¶¶ 73-75. The Government's complaint includes seven specific examples of false claims that Cigna submitted based on Invalid Diagnoses that did not conform with the ICD Guidelines. *Id.* ¶¶ 169(a)-(g).

C. Procedural Posture

Relator Robert A. Cutler ("Relator") filed this FCA *qui tam* action on October 2, 2017, under seal in the U.S. District Court for the Southern District of New York. ECF Nos. 1, 94. He amended his complaint in June 2019. ECF No. 12 ("Relator Compl."). In February 2020, the United States notified the New York district court it declined to intervene on some of Relator's claims, and decided not to intervene at the time as to the remainder. ECF No. 13. In August 2020, that court unsealed the case. ECF Nos. 11, 14. Cigna moved to transfer venue of this action to this District, ECF No. 71, and the New York district court granted the motion in September 2021. ECF No. 127. In January 2022, the United States moved to partially intervene in this case for good cause, ECF No. 157, and this Court granted the motion in August 2022, ECF No. 170. The United States filed its complaint-in-intervention on October 14, 2022. ECF No. 178. Cigna filed the instant motion to dismiss the United States' and Relator's complaints on December 16, 2022. ECF No. 198.

ARGUMENT

I. Standard of Review

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Claims are facially plausible when their factual content allows the court to reasonably infer that the defendant is liable for the alleged wrong. *Id.* In deciding a motion to dismiss, a court must accept the plaintiff's factual allegations as true and draw all reasonable inferences in its favor. *Doe v.*

Baum, 903 F.3d 575, 581 (6th Cir. 2018). The complaint's factual allegations, when taken as true, must simply "be enough to raise a right to relief above the speculative level." *Ass'n of Cleveland Fire Fighters v. City of Cleveland*, 502 F.3d 545, 548 (6th Cir. 2007). Those allegations must give rise to a claim that is plausible; but "the plausibility standard is not akin to a 'probability requirement.'" *Iqbal*, 556 U.S. at 678; *see also Twombly*, 550 U.S. at 555-57.

II. The Government Adequately Alleged that Cigna Violated the False Claims Act

A. Elements of the Government's FCA Claims

Under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" is liable to the Government, 31 U.S.C. § 3729(a)(1)(A), as is a person who knowingly causes false records or statements to be made that are material to a false claim, *id.* § 3729(a)(1)(B). "To plead a claim under the [FCA], the plaintiff must sufficiently allege that: (1) the defendant made a false statement or created a false record; (2) with scienter; (3) that was material to the Government's decision to make the payment sought in the defendant's claim; and (4) that the defendant submitted to the U.S. government causing it to pay the claim." *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 830 (6th Cir. 2018) (internal quotation marks omitted). A claim for payment may be either factually false, when it misrepresents the facts underlying the claim seeking payment by the government; or it may be legally false, which occurs it misrepresents its "compliance with a statutory, regulatory, or contractual requirement." *United States v. SouthEast Eye Specialists, PLLC*, 570 F. Supp. 3d 561, 575 (M.D. Tenn. 2021) (internal quotation marks omitted). The same misconduct may give rise to both factually false and legally false claims. *Osinek*, 2022 WL 16925963, at *6 & n.2; *United States v. Crumb*, No. 15 Civ. 655, 2016 WL 4480690, at *14 (S.D. Ala. Aug. 24, 2016).

B. The Government Adequately Alleged Cigna's Claims Were Factually False

Cigna's argument that the Government does not sufficiently allege it submitted factually false claims selectively misreads or ignores important allegations, and improperly offers alternative explanations for its misconduct. Cigna also erroneously asserts that the Invalid Diagnoses could not be false because Vendor HCPs supposedly exercised independent medical judgment in checking boxes on Cigna's 360 form. Cigna further claims its submission of factually false claims was not knowing, though its scienter is evident in the very design and purpose of its home visit program. These arguments fail because Cigna's contentions rely on alternative facts that conflict with the complaint, or at least raise factual disputes that cannot be resolved on a motion to dismiss. *See Ross*, 2023 WL 24055, at *8.

1. Cigna's Claims Arising from the Invalid Diagnoses Were Factually False

a. Cigna Ignores and Mischaracterizes Allegations Showing that the Invalid Diagnoses Were Factually False

Cigna improperly recharacterizes the complaint and understates its own misconduct in arguing that its 360 home visit program did not generate factually false diagnosis data. *See* ECF No. 196 ("Mot.") at 13. But the Government plausibly alleges that Cigna's home visit program predictably generated tens of thousands of false Invalid Diagnoses. Compl. ¶ 15. Given the specific criteria describing the Invalid Diagnoses at issue and the Government's numerous supporting factual allegations, *id*. ¶ 7, the complaint plausibly alleges that the Invalid Diagnoses were unreliable and factually false, rendering them invalid for risk-adjustment purposes.

The Government's claims are limited to the narrowly defined Invalid Diagnoses, whose elements each support an inference of factual falsity:

- The Invalid Diagnoses were based solely on 360 home visits, and were not reported by any other healthcare provider who saw the patient that year. *Id.* ¶ 7(a), (d). During the home visits, the Vendor HCPs were not allowed to, and did not, treat the purportedly diagnosed medical conditions or any other conditions. *Id.*

¶ 150. Indeed, in many instances, according to Cigna's own data, no other healthcare provider treated the plan member or reported the relevant conditions for years before or after the home visit, if ever. *Id.*

- The Invalid Diagnoses were of serious, complex conditions that required specific testing or imaging to be reliably diagnosed, which was not performed. *Id.* ¶ 7(b). And the Vendor HCPs could not even refer plan members to other providers for such diagnostic testing or imaging, *id.* ¶¶ 112, 114, which might have allowed a merely suspected diagnosis to be confirmed. The complaint provides illustrative examples of conditions for which Cigna submitted diagnoses though it knew the Vendor HCPs had not performed tests required by Cigna's own clinical guidelines—which match standards from widely accepted medical professional societies. *Id.* ¶¶ 142-46. To take one example, the 360 form included various stages of chronic kidney disease, a condition whose diagnosis—according to the company's own clinical guidelines, as well as guidance from the National Institutes of Health—"relies heavily on laboratory evaluation and diagnostic imaging," including blood and urine testing. *Id.* ¶ 143. Yet Cigna knew its Vendor HCPs did not perform or order such tests. *Id.*; *see also id.* ¶¶ 144-46 (similar examples for other conditions that required blood testing and imaging that was not performed, and other missing "objective data").

- The Invalid Diagnoses were not supported by the information documented on the 360 form itself. *Id.* ¶ 7(c).

And this is just the start. Other allegations support the inference that Cigna's submission of the Invalid Diagnoses misrepresented that plan members had been reliably diagnosed with the relevant conditions during the home visits. For example, Cigna did not provide the Vendor HCPs with access to the members' complete medical records or medical history, undercutting their ability to make reliable diagnoses. *Id.* ¶ 110. Moreover, the 360 home visits themselves were cursory, further casting doubt on the reliability of the resulting diagnoses: visits often lasted no more than 30 minutes, *id*. ¶ 109; the Vendor HCPs relied largely on plan members' self-assessments and responses to basic screening questions; and they did not perform a comprehensive physical exam, *id*. ¶¶ 6, 110. Further, Cigna pressured Vendor HCPs to pursue specific, lucrative diagnosis codes, rather than exercising their independent clinical judgment. Cigna provided training that focused on the specific high-value conditions Cigna prioritized, *id*. ¶ 122; evaluated vendors' performance based on their rates of diagnosing certain conditions, *id*.

¶¶ 121, 133-34; and required "performance improvement plans" for Vendor HCPs who generated "lower than expected disease prevalence," *id*. ¶ 137. Each of these allegations separately—and all of them together—clearly support an inference that the Invalid Diagnoses are factually false. Thus, Cigna's argument that the Government's factual falsity claim is based solely on the Vendor HCPs' lack of diagnostic equipment, Mot. at 13, ignores most of the complaint and attacks a straw man.

A few recent decisions support the Government's position. In one, a district court concluded the Government had adequately pled factual falsity by alleging that an MA Organization submitted unreliable and inaccurate diagnoses where medical records did not support the diagnosis. *See Osinek*, 2022 WL 16925963, at *6. The court concluded the MA Organization's submission was factually false in at least two respects: because it submitted diagnosis codes for a condition its members did not have, and because the reported diagnoses codes did not comply with the ICD Guidelines. *Id*. at *6, 8. In another case, the court concluded that the Government had "state[d] both factually false and express false-certification FCA claims" when it alleged "that Defendants' practices resulted in the knowing submission of inaccurate diagnosis codes." *Ross*, 2023 WL 24055, at *10.

Instead of addressing the Government's allegations, Cigna compares this case to others in which courts denied motions to dismiss and discusses factors in those cases that the Government does *not* allege here. Mot. at 13-16. But it "improperly inverses the pleading standard" to draw inferences against the Government based on the absence of certain allegations. *Prather*, 892 F.3d at 834. To take one example, while the Government does not claim Cigna explicitly "asked vendors to fabricate diagnoses," or paid its vendors for each additional diagnosis they made, Mot. at 13, the absence of such allegations is immaterial: there is more than one way to commit

fraud. Indeed, the complaint here explains how Cigna pressured its vendors "to maximize the number of high-value diagnoses reported." Compl. ¶ 132. Moreover, the cases Cigna cites confirm that allegations parallel to those here support FCA liability. *See, e.g.*, *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 680 (9th Cir. 2018) (complaint plausibly pled MA Organizations submitted false claims based on invalid diagnosis codes generated through home visits, as "many complex diagnoses cannot be confirmed during brief and non-invasive in-home assessments").

Relying on a non-precedential Ninth Circuit decision, Cigna also invites this Court to dismiss the factual falsity claim because of supposedly benign *post hoc* "obvious alternative explanations." Mot. at 17-18 (citing *Integra Med Analytics LLC v. Providence Health & Servs.*, 854 F. App'x 840, 844-45 (9th Cir. 2021)). For example, Cigna hypothesizes that plan members may have been treated for conditions by out-of-network providers or a Veterans Affairs facility that did not bill Cigna. Mot. at 17. This flies in the face of the pleading standard. Often, a defendant's conduct "has several plausible explanations," and "[f]erreting out the most likely reason for the defendant['s] actions is not appropriate at the pleadings stage." *Watson Carpet & Floor Covering, Inc. v. Mohawk Indus., Inc.*, 648 F.3d 452, 458 (6th Cir. 2011). An "obvious alternative explanation" is relevant only where, relying on the plaintiff's own allegations, it helps "differentiate between facts merely 'consistent with liability' and those sufficient to plausibly allege" a liability case. *SouthEast Eye Specialists*, 570 F. Supp. 3d at 579. Cigna's alternative explanations do not meet that test: they do not explain away the facts alleged in the complaint, but instead offer a wholly speculative narrative that squarely conflicts with the Government's detailed, plausible allegations. *See* Compl. ¶¶ 7-13, 140-48. And in any event, the submission of

false diagnosis codes may give rise to false claims "even if it is possible that some other, unidentified record might support the same diagnosis." *Swoben*, 848 F.3d at 1176-77.

b. The Vendor HCPs' Box-Checking Is Insufficient to Diagnose Conditions for Risk-Adjustment Purposes

Cigna also misapprehends both the ICD Guidelines and the Government's allegations in arguing that a Vendor HCP's mere "statement that the patient has a particular condition is sufficient" to code diagnoses for submission to CMS. Mot. at 18 (quoting ICD-10 Guidelines § I.A.19). As explained above, Cigna had ample reason to doubt the validity of the Invalid Diagnoses the Vendor HCPs recorded. Cigna cites a general rule that medical coders should not reevaluate the clinical criteria that providers use to make a diagnosis. *Id.* at 20 (citing ICD-10 Guidelines § I.A.19). But Cigna stretches this principle beyond its breaking point: in its view, an MA Organization could submit even what it knew or had reason to believe were entirely fabricated diagnoses as long as a provider stated in a medical record that the patient had the condition. Other courts have rejected analogous propositions. *See Swoben*, 848 F.3d at 1174 (rejecting MA Organizations' "attempts to portray themselves as the passive victims of their providers' errors"); *see also Silingo*, 904 F.3d at 680 ("one would expect that a sophisticated [MA Organization] would notice when its [home visit] contractor's work is too good to be true" and resulted in submission of invalid diagnosis codes); *Ross*, 2023 WL 24055, at *10 (complaint adequately alleged that coding based on problem lists or past medical history resulted in knowing submission of invalid diagnosis codes). And Cigna's position conflicts with the ICD Guidelines, which impose an independent obligation on MA Organizations who coded these diagnoses to ensure the diagnoses are properly supported and documented. *See* ICD-10 Guidelines at 1 ("A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation . . . ."). Here, Cigna had reason to know the Invalid Diagnoses were

invalid, even though Vendor HCPs had checked the relevant boxes on the 360 forms: the vendors operated under a program Cigna designed specifically to capture lucrative diagnoses for risk-adjustment payment purposes. Compl. ¶ 127.

Cigna's argument also ignores the Government's substantial efforts to ensure the risk-adjustment data it receives is substantively valid. Given the critical importance of accurate risk-adjustment data to Medicare Advantage payments, CMS and HHS-OIG periodically audit the data. *Id.* ¶ 91. In such audits, CMS reviews the underlying members' medical records to determine whether the diagnosis codes submitted by the MA Organizations are supported by those records. *Id.* ¶¶ 92-93. There would be no point to such an exercise if it were sufficient for a provider merely to list the diagnosis at issue on a form. Indeed, after the Government filed its complaint in this case, HHS-OIG concluded an audit of a Cigna MA plan that found that for ten specific "high-risk" diagnosis groups, most of the risk-adjustment submissions "did not comply with Federal requirements," because "the medical records . . . provided did not support the diagnosis codes," resulting in overpayments.[9] While Cigna argues the ICD Guidelines "do not require supporting clinical information," this is wrong: they expressly state on the very first page that "complete documentation in the medical record" is required for accurate coding. ICD-10 Guidelines at 1; *see Ross*, 2023 WL 24055, at *8 (coding is only appropriate in reliance on "identifiable information or documentation"). Indeed, HHS-OIG rejected the same argument when Cigna made it in response to the recent audit findings: "Medicare requirements are clear that in order for a diagnosis code that has been submitted to CMS to be appropriately included in

[9] *See* HHS-OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-Healthspring of Tennessee, Inc. (Contract H4454) Submitted to CMS* (Dec. 2022) ["OIG 2022 Audit Report"], https://oig.hhs.gov/oas/reports/region7/71901193.pdf.

the calculation of the risk score, the diagnosis needs to be documented in, and supported by, an acceptable medical record." OIG 2022 Audit Report at 33.

For these reasons, and contrary to Cigna's argument, Mot. at 13, the Government need not allege or ultimately prove that each Invalid Diagnosis represents a medical condition a plan member did not in fact have. To the extent any members happened to have the relevant conditions, the Invalid Diagnoses were still factually false. As noted below, after initial diagnosis, chronic conditions may only be coded and submitted for risk-adjustment purposes if the patient "receives treatment and care for the condition(s)" during the visit in question. *See infra* Part II.C.1.a. And Cigna knew the Vendor HCPs did not provide treatment or care during these visits, and could not make the diagnoses in question using appropriate clinical standards and consistent with the ICD Guidelines. *See* Compl ¶¶ 160-65. As a result, the Invalid Diagnoses were false and invalid for risk-adjustment purposes. *See Ross*, 2023 WL 24055, at *10; *Osinek*, 2022 WL 16925963, at *6.

Finally, Cigna is wrong to suggest that Vendor HCPs could rely exclusively on patient self-reporting or medication review to make diagnoses. Mot. at 1, 17. Cigna cannot purport to rely on the "professional medical skill and judgment" of its Vendor HCPs, *id.* at 1, if that "judgment" consisted simply of the rote recording of plan members' own reporting of their past diagnoses or medications previously prescribed. Such "diagnoses" also violate the ICD Guidelines requirement, discussed in the next subsection, that a diagnosis may be coded only when it "requires or affects patient care[,] treatment or management." Compl. ¶¶ 154-55 (citing ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K) (brackets omitted). As to medications in particular, CMS has specifically instructed MA Organizations not to rely on prescriptions alone in making a diagnosis for risk-adjustment purposes, specifying that a documented clinical

diagnosis is also required. *See* CMS, *2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations—Participant Guide* § 3.2.4 ["CMS, *2008 Participant Guide*"][10] ("For example, a prescription for an ACE inhibitor [a drug], alone, is not considered sufficient for the sole data source of 'clinical evidence' of congestive heart failure (CHF); instead, the medical record needs to document an appropriate clinician's diagnosis of CHF during the data collection period.").

c. Cigna's Submission of Invalid Diagnosis Codes Under the ICD Guidelines Resulted in Factually False Claims

Cigna also submitted factually false claims by submitting diagnosis codes that were invalid under the ICD Guidelines. While Cigna's motion addresses the ICD Guidelines only under the rubric of legal falsity, *see* Mot. at 24-28, its submission of the Invalid Diagnoses resulted in both factually and legally false claims, *see Osinek*, 2022 WL 16925963, at *6. The factual falsity arose because the relevant claims for payment were based on medical conditions that (whether or not the member in fact had them) did not "require or affect patient care[,] treatment or management," as the ICD Guidelines require, or for previously diagnosed chronic conditions, were not treated during the home visits. Compl. ¶ 155 (citing ICD-10 Guidelines §§ IV.I, IV.J; ICD-9 Guidelines §§ IV.J, IV.K). Cigna's submission of codes stemming from the Invalid Diagnoses to CMS thus constituted factually false representations regarding what occurred during the home visits, because the reported diagnoses did not affect the patient's "care[,] treatment or management" during the visit and the condition was not actually treated by the Vendor HCPs. *See Osinek*, 2022 WL 16925963, at *6; *cf. United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F. Supp. 3d 734, 761-62 (W.D. Tex. 2020) (concluding

[10] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012183293-yv-participant-guide-publish_052909.pdf.

that submission of invalid medical-procedure codes required by regulation resulted in false claims for payment), *reconsidered in part on other grounds*, 2022 WL 80293 (W.D. Tex. Jan. 7, 2022); *United States v. Semrau*, 693 F.3d 510, 530-31 (6th Cir. 2012) (concluding that submission of invalid medical-procedure codes resulted in materially false claims under criminal healthcare fraud statute).

d. Cigna's Attestations Were Factually False

Cigna also does not address a separate basis for factual falsity: the Government's claim, under 31 U.S.C. § 3729(a)(1)(B), that Cigna knowingly made false annual risk-adjustment attestations that were material to its false claims for payment. Compl. ¶ 180. Specifically, Cigna executives were required each year, as an express condition of payment, to certify, based on their best knowledge, information, and belief, that the risk-adjustment data submitted to CMS was accurate, complete, and truthful. 42 C.F.R. § 422.504(*l*); *see* Compl. ¶¶ 68-75.

Cigna knowingly structured the 360 home visit program in a manner that created a significant risk of generating invalid and inaccurate diagnoses, as explained below. *See infra* Parts II.B.2, II.C.1.b. Because Cigna was "on notice that [its] data included a significant number of erroneously reported diagnosis codes," it could not "certify, based on the best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS." *Swoben*, 848 F.3d at 1175. Cigna executives nonetheless signed and submitted these attestations to CMS. Compl. ¶ 181. Cigna's broad attestations to "the accuracy, completeness, and truthfulness of relevant data" were factually false for purposes of the Government's separate claim under § 3729(a)(1)(B). *See Swoben*, 848 F.3d at 1175 (certifications pursuant to 42 C.F.R.

§ 442.504(*l*) may give rise to claims under both § 3729(a)(1)(A) and (a)(1)(B)).[11]

2. Cigna's Factually False Submissions Were Made Knowingly

Cigna also misreads the complaint in arguing that the Government did not sufficiently allege it made factually false submissions with the requisite scienter. Mot. at 18-22. The complaint amply alleges that the company created and operated the 360 home visit program in order to generate certain diagnoses without regard to their truth so as to improperly generate revenue, while ignoring red flags. *See* Compl. ¶¶ 124-39, 160-65. This more than satisfies the FCA's "knowing" standard, which encompasses defendants who "act[] in deliberate ignorance of the truth or falsity of the information" or "in reckless disregard of the truth or falsity of the information," 31 U.S.C. § 3729(b)(1)(A)(ii)-(iii), with no requirement for "proof of specific intent to defraud," *id.* § 3729(b)(1)(B). On a motion to dismiss, scienter need only be alleged generally. *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 515 (6th Cir. 2022); Fed. R. Civ. P. 9(b).

Here, as explained in the previous subsection, Cigna directed its Vendor HCPs to focus on high-value conditions and targeted specific plan members for home visits in order to increase payments from CMS. Compl. ¶ 108. Cigna solicited diagnoses from the Vendor HCPs that, based on the company's own clinical guidelines, would have been impossible to make given the cursory nature of the home visits, the basic medical equipment the Vendor HCPs possessed, and the limited medical information regarding the plan member available to them in advance of the home visit. *Id.* ¶¶ 140-46. And Cigna knew the Vendor HCPs could not order necessary

[11] Significantly, "[w]hen it adopted the 'best knowledge, information, and belief' standard in 2000, CMS made clear this was the same standard as the one establishing liability under the [FCA]—i.e., that it encompasses not only actual knowledge of falsity but also reckless disregard and deliberate ignorance." *Id.* at 1174 (citing HHS, *Medicare+Choice Program*, 65 Fed. Reg. at 40,268).

diagnostic testing or imaging, or make referrals to other providers for this purpose. *Id.* ¶¶ 112, 114, 121. Furthermore, the 360 forms themselves did not contain information supporting the diagnoses, such as clinical findings, patient symptoms, or test results. *Id.* ¶¶ 147-48. Cigna's own coders—not the vendors—reviewed the 360 forms and selected the diagnosis codes to submit to CMS. *Id.* ¶ 147. And Cigna knew or should have known—because it had the data for its members relating to other encounters—that, for each of the Invalid Diagnoses, no other provider had reported the diagnosis for any encounters during the relevant service year, and often not for years before or afterwards. *Id.* ¶¶ 150-51. At a minimum, these allegations plausibly give rise to an inference that Cigna was reckless about the truth or falsity of the Invalid Diagnoses, or deliberately ignored whether they were true or false.

The complaint further sufficiently alleges scienter because Cigna—which operated a sophisticated Medicare Advantage business that received billions of dollars each year from CMS and was well aware of CMS program requirements, *id.* ¶ 159—knew of the problems with the Invalid Diagnoses yet continued to submit them. Congress intended the FCA to impose liability on, among others, "persons who ignore 'red flags' that the information [they provide to the Government] may not be accurate." *United States ex rel. Wuestenhoefer v. Jefferson*, 105 F. Supp. 3d 641, 668 (N.D. Miss. 2015) (quoting H.R. Rep. No. 99-660 (1996)). The complaint alleges that from the early days of the home visit program, Cigna's compliance staff expressed concerns about the reliability and accuracy of the diagnoses being generated, including the fact that Cigna asked providers to make the same diagnoses and compete the same 360 form regardless of whether the assessment occurred in the plan member's home or at a physician's medical office, despite the fact that the form included conditions the company recognized could not be diagnosed at home. *See, e.g.*, Compl. ¶ 162 (compliance manager proposed that the

company "filter [] out on the back end" those conditions that "should never be diagnosed in the home"); *id.* ¶ 163 (compliance staff raised risk of reporting "diagnoses that cannot be diagnosed in a home visit"); *id.* ¶ 164 (corporate vice president "discussed" with the chief medical officer the possibility of "developing a separate 360 exam form" for home visits to "reduce risk" from an "evaluation" and "coding standpoint"). Cigna's inaction in the face of these concerns—particularly given its obligation to attest that its risk-adjustment data was accurate and truthful, *id*. ¶ 159—evidences at least a reckless disregard for the truth and accuracy of the Invalid Diagnoses. And, as alleged, Cigna knew of CMS's concerns about MA Organizations' use of home visits to increase payments without providing medical care, *id.* ¶¶ 166-67, but made a presentation to CMS about its 360 home visit program that omitted key information, including the company's revenue-generation purpose and the lack of medical care during the visits, *id.* ¶ 168.

Cigna's arguments to the contrary ignore or distort key allegations or manufacture alternative explanations for its misconduct. First, the Government does not "perversely assume" that Cigna knew its vendors lacked the medical equipment needed to diagnose the conditions. Mot. at 19. Rather, Cigna was well aware the Vendor HCPs lacked this equipment and did not perform (or order) necessary diagnostic tests to render the diagnoses at issue: The company designed the 360 home assessment program, set forth in its contracts a limited set of equipment that the Vendor HCPs were required to bring to the home visits, and received and reviewed the 360 forms which would have referenced the diagnostic tests and the results had they been performed. Compl. ¶¶ 114, 141, 161. Cigna argues the contractually required equipment list was a "floor, not a ceiling," Mot. at 19, but it contract interpretation is irrelevant given the

Government's well-pleaded factual allegations that the Vendor HCPs lacked the equipment to conduct the testing and imaging needed to reliably make the Invalid Diagnoses.

Second, Cigna argues it could not know which diagnoses were "new" based on its own claims data, because (it speculates) some of the Invalid Diagnoses might be validated by claims submitted to plan members' previous health plans or by Veterans Affairs facilities that treated members but do not bill Cigna. Mot. at 20. This is a red herring: what matters for Cigna's scienter is what it knew or should have known based on the information available to the company, not hypothetical facts it did not bother to investigate. And Cigna had numerous reasons based on the information it had to doubt the validity of the Invalid Diagnoses. Cigna's fact-free speculation that some diagnoses might be supported by records from a hypothetical provider who did not bill its plan does not undercut its recklessness in submitting the Invalid Diagnoses based solely on the 360 form. For just this reason, the Ninth Circuit has rejected the same argument, concluding that an MA Organization's reckless disregard for the accuracy of its submissions attaches when it knows or should know of reasons to doubt their accuracy, and cannot be cleansed later "even if it turns out that the diagnosis is supported by other medical records." *Swoben*, 848 F.3d at 1177. The plan's contemporaneous failure "to investigate" whether the diagnoses are supported "makes its broad certification regarding the accuracy, completeness, and truthfulness of submitted data false." *Id*.

Third, Cigna complains that MA Organizations should not have to "second-guess their providers' clinical assessment of patients without any evidence of fraud or incompetence." Mot. at 21. This argument might have some force for a genuine medical encounter, where (for example) a patient's self-selected healthcare provider exercised independent clinical judgment to document and report a diagnosis, and treat the patient for that condition. *See, e.g.*, Compl. ¶ 45.

By contrast, in Cigna's 360 home visit program, the Vendor HCPs were not independent. Instead, they were retained by Cigna's vendors; received Cigna's training and guidance on how to conduct the home visits and report diagnoses; used Cigna's 360 form; could not exercise independent clinical judgment or deliver medical care or treatment; and were carefully monitored by Cigna to ensure they met corporate objectives. *Id.* ¶¶ 111, 121, 137-38. In other words, the Invalid Diagnoses did not result from an arm's-length relationship between an MA Organization and healthcare providers exercising independent clinical judgment in providing medical care or treatment. Indeed, Cigna made sure by its design of the program that the Vendor HCPs lacked the information necessary to even make such judgments.

Nor, as Cigna claims, Mot. at 21, is the Government seeking to impose an improperly high clinical standard for making diagnoses. Indeed, many of the Invalid Diagnoses did not meet the clinical standards Cigna itself set—standards that comport with clear professional guidance, *id*. ¶¶ 140-46, and which Cigna purportedly expected Vendor HCPs to follow, *see* Mot. at 19 (citing contracts). While Cigna argues that its vendor contracts required 360 forms to include clinical support for all reported diagnoses, Mot. at 9, the Government's claims are limited to the Invalid Diagnoses, *i.e.*, those that "were not supported by the information documented on the 360 form completed by the Vendor HCPs," Compl. ¶ 7; *id.* ¶¶ 148-49. And Cigna cannot overcome the Government's well-pleaded factual allegations, including references to specific patient examples, *id.* ¶ 169, by arguing that a contract purportedly required its vendors to include such support.

C. The Government Adequately Alleged Cigna's Claims Were Legally False

As noted above, a claim for payment submitted to the Government is "legally false" when the defendant submits a claim that misrepresents its "compliance with a statutory, regulatory, or contractual requirement." *SouthEast Eye Specialists*, 570 F. Supp. 3d at 575

(internal quotation marks omitted). The Government alleges that Cigna violated CMS regulations and its contract with CMS by submitting diagnoses that did not comply with the ICD Guidelines and by falsely attesting each year to the accuracy of its risk-adjustment data submissions. Cigna made these submissions knowingly; the Court should reject Cigna's arguments that the applicable legal requirements were ambiguous, and that they can be interpreted in an "objectively reasonable" (albeit incorrect) manner to justify Cigna's misconduct. And finally, Cigna's false claims were plainly material to CMS's payment decisions because the payments were calculated based on the diagnosis codes, and the agency did not have actual knowledge of Cigna's fraudulent conduct—the submission of the Invalid Diagnoses—when it made the payments in question. The Government has thus adequately alleged that Cigna submitted legally false claims to CMS.

1. The Invalid Diagnoses Are Legally False Claims

The Government asserts that the Invalid Diagnoses Cigna submitted to CMS were legally false in two respects: because the Invalid Diagnoses did not comply with the ICD Guidelines, *see* Compl. ¶¶ 77-83, 153-58; and because Cigna falsely certified that the diagnosis data was accurate and truthful in the legally required attestations it submitted to CMS, *see id.* ¶¶ 68-75, 150-52, 171-73. Cigna's motion fails to undermine either of these bases for its FCA liability.

a. Cigna Violated the ICD Guidelines in Coding the Invalid Diagnoses

The complaint alleges that Cigna submitted codes for the Invalid Diagnoses for risk-adjustment purposes that did not conform in several respects with the ICD Guidelines. Initially, Cigna does not dispute that it was legally required to follow those guidelines when submitting diagnosis codes to CMS. *See id.* ¶ 58 (citing 42 C.F.R. § 422.310(d)(1); 45 C.F.R. § 162.1002); *see also Osinek*, 2022 WL 16925963, at *10-14 (concluding that MA Organizations are required to comply with ICD Guidelines both by regulation and through their contracts with CMS). And

Cigna also does not dispute that a failure to comply with the ICD Guidelines would support a legal falsity claim, *cf.* Mot. at 23-27, as several courts have concluded, *see Ross*, 2023 WL 24055, at *7-8; *Osinek*, 2022 WL 16925963, at *14. To the extent Cigna argues that the Invalid Diagnoses in fact satisfied the ICD Guidelines, "[d]etermining whether a documented condition meets the guideline[s] . . . involves a fact-driven inquiry," *Ross*, 2023 WL 24055, at *8, which would require determining what took place during individual 360 home visits and analyzing the 360 forms. These issues cannot be resolved on a motion to dismiss.

As discussed above, the ICD Guidelines permit coding "documented conditions" diagnosed during outpatient visits only when those conditions exist "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; *see* Compl. ¶¶ 80, 154; *Ross*, 2023 WL 24055, at *7. The Government squarely asserts that the Invalid Diagnoses do not satisfy these criteria. First, they were not sufficiently documented since they were not supported by clinical findings or any other information on the 360 form, except for the checked box recording the purported condition. Compl. ¶¶ 13, 77-83, 147, 157-58. Second, Cigna's vendors could not and did not perform the requisite testing, imaging, or other diagnostic steps needed to determine whether the condition in fact existed at the time of the encounter. *Id.* ¶¶ 7, 79-80, 140-46, 156. And third, the conditions did not require or affect patient care, treatment, or management during the home visit, or even at any other point during the year in which the home visit occurred, as evidenced by the fact that no other healthcare provider reported or provided care or treatment to the plan member for the condition that year. *Id.* ¶¶ 7, 13, 155.[12]

[12] Cigna's argument that MA Organizations may submit diagnosis codes even if they do not require care or treatment relies on an inapposite district court decision. Mot. at 28 (citing *United*

Cigna misconstrues the Government's allegations as based solely on the lack of treatment or care during the home visits themselves, which (it contends) is not a requirement. *See* Mot. at 25-26. To be clear, the relevant ICD Guidelines provision states that the condition must "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, indicating that the condition indeed must require or affect care, treatment, or management at the visit in question. But the Government's claims do not depend on this reading: as alleged, each Invalid Diagnosis did not "require or affect patient care[,] treatment or management" during the entire service year. This is evidenced by the fact that these conditions were not "reported by any other healthcare provider" who saw the plan member during the relevant year, Compl. ¶ 7; *see id.* ¶¶ 150-51, in addition to the fact that no care or treatment was provided in the home visit itself, during which Vendor HCPs were explicitly prohibited from doing so, *see id.* ¶ 111. Indeed, in many instances, no other provider reported the condition for years before or after the relevant date of service year. *Id.* ¶ 150. Thus, even if Cigna's interpretation of this ICD Guideline were correct, the complaint still adequately alleges that the Invalid Diagnoses did not comply with it.

Cigna also violated the ICD Guidelines' prohibition on coding diagnoses "characterized as probable, suspected, questionable, working diagnoses, or the like." *Id.* ¶ 79 (citing ICD-10 Guidelines § IV.H; ICD-9 Guidelines § IV.I). Read in conjunction with the requirement that only

---

States ex rel. Rasmussen v. Essence Grp. Holdings Corp., No. 17 Civ. 3273, 2020 WL 4381771, at *6-7 (W.D. Mo. Apr. 29, 2020)). That case concluded only that a regulatory provision governing the "[d]eadlines for submission of risk adjustment data," 42 C.F.R. § 422.310(g), does not itself require that a condition have been treated during the preceding year, *see Rasmussen*, 2020 WL 4381771, at *6. As other courts have held, *Rasmussen* "addressed an entirely different subsection" of the CMS regulations from the one the Government principally relies on here, 42 C.F.R. § 422.310(d)(1). *Osinek*, 2022 WL 16925963, at *13; *see Ross*, 2023 WL 24055, at *8 n.6 (declining to rely on *Rasmussen* because it is "non-precedential and not explicitly focused on interpreting the language at issue here"). Accordingly, the Court should disregard it.

conditions that exist at the time of the visit and require or affect patient care, treatment, or management may be coded, *see* ICD-10 Guidelines § IV.J; ICD-9 Guidelines § IV.K, this provision precludes the submission of diagnosis codes that are not definitive and supported by medical documentation. *See also* ICD-10 Guidelines §§ I.B.4, I.B.18, IV.D; ICD-9 Guidelines §§ I.B.6, IV.E (discussing the appropriate coding when "a definitive diagnosis" has not been established). Given the premise of the MA risk-adjustment system—to carefully calibrate payments based on expected costs—it would make little sense for CMS to accept questionable or working diagnoses as a basis for calculating its payments to MA Organizations.

Cigna also violated the ICD Guidelines provision governing the coding of chronic conditions, a category that includes many of the Invalid Diagnoses. This provision states that "[c]hronic conditions treated on an ongoing basis may be coded and reported *as many times as the patient receives treatment and care* for the condition(s)." ICD-10 Guidelines § IV.I (emphasis added); *see* ICD-9 Guidelines § IV.J; Compl. ¶ 80. While Cigna argues this provision is "not restrictive" as to when chronic conditions may be coded, Mot. at 26, the provision establishes that, after an initial diagnosis, chronic conditions may be coded (and thus reported to CMS) only if they require care and treatment, and does not permit them to be coded merely to note a previous diagnosis. *See* Compl. ¶ 154. This makes sense in the risk-adjustment payment system, in which only conditions that require care and treatment should result in increased costs for the MA plan. *See, e.g.*, *Osinek*, 2022 WL 16925963, at *2; *Ross*, 2023 WL 24055, at *2.

The Government further alleges that the Invalid Diagnoses violated the ICD Guidelines' medical record documentation requirement. *See* Compl. ¶¶ 13, 82-83, 147, 157-58. As the introduction to the ICD Guidelines states, "[t]he importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation

accurate coding cannot be achieved." ICD-10 Guidelines at 1; *see id.* § IV.C (documentation "should describe the patient's condition, using terminology which includes specific diagnoses as well as symptoms, problems, or reasons for the encounter"); ICD-9 Guidelines § IV.C (same).[13] The Invalid Diagnoses were not supported by the information recorded on the 360 forms themselves, and accordingly they were not "documented" as required by the ICD Guidelines. Compl. ¶¶ 13, 157-58.

Cigna wrongly relies on ICD Guidelines provisions governing the submission of codes arising from screening or diagnostic services. Mot. at 27 (citing ICD-10 Guidelines § IV.K). While a "condition . . . *discovered* during [a] screening" may be coded, *see* ICD-10 Guidelines § I.C.21.c.5 (emphasis added); *id.* § IV.Q (cross-referencing § I.C.21), the Vendor HCPs simply could not "discover" any such conditions within the meaning of the ICD Guidelines, because they did not perform or order the necessary testing or imaging to diagnose the serious, complex medical conditions at issue, as discussed above. *See* Compl. ¶¶ 7, 140-46, 156; *see also* Part II.B.1, *supra*.

While Cigna seeks to fault the Government for not citing any ICD Guidelines provision that requires particular clinical tests or findings before an MA Organization may submit a diagnosis to CMS, Mot. at 23, 25, this is mere misdirection. The question is not whether the ICD Guidelines require specific tests before submitting a diagnosis, but rather whether there was any clinical information recorded on the 360 form to support the diagnosis and satisfy the ICD

[13] CMS has repeatedly emphasized the importance of medical documentation, including by advising MA Organizations they must ensure that "'[a]ll diagnosis codes submitted must be documented in the medical record,'" Compl. ¶ 82 (quoting CMS, *Medicare Managed Care Manual*, ch. 7, § 40 (rev. 118, Sept. 19, 2014)), and making clear that certain types of records are inadequate, *see* CMS, *2008 Participant Guide* § 7.2.4.1 (including "list[s] of patient conditions" among "medical records and types of documentation [that] are not acceptable for risk adjustment data validation").

Guidelines' documentation requirement. The Government alleges that there was not, and the complaint offers several illustrative examples where the 360 form did not substantiate Invalid Diagnoses reported to CMS. *See* Compl. ¶¶ 13, 157-58, 169(a)-(g).

b. Cigna Falsely Attested to the Accuracy of Its Risk-Adjustment Data

Cigna also violated its legal obligation—an express regulatory and contractual condition of payment—to attest, based on its senior executives' best knowledge, information, and belief, to the accuracy and truthfulness of the risk-adjustment data it submitted to CMS. *See* 42 C.F.R. § 422.504(*l*); *see also* Compl. ¶¶ 69-75, 159-68. The attestation requirement expressly incorporates the regulatory provision that requires compliance with the ICD Guidelines. *See* 42 C.F.R. § 422.504(*l*)(2) (referencing "data . . . submit[ted] under [42 C.F.R. § 422.310]"). By submitting data that did not conform with the required coding guidelines, Cigna violated the requirement that it attest to the accuracy and truthfulness of its risk-adjustment data.

These attestations were not only factually false, as discussed in Part II.B.1.d, *supra*, but also legally false certifications. *See Silingo*, 904 F.3d at 681 (holding that MA Organizations' certifications under 42 C.F.R. § 422.504(*l*) "support [an] express false certification claim"); *Swoben*, 848 F.3d at 1173; *see also Osinek*, 2022 WL 16925963, at *6 n.2 (in "appropriate circumstances," the same conduct can be "both factually false and legally false" under the FCA). As discussed above, given Cigna's design of the program and its knowledge of the program's operations and the cursory nature of the home visits, its executives could not truthfully certify the data was accurate, complete, and truthful. Compl. ¶ 151; *see* Part II.B.1.d, *supra*. Therefore, the company's attestations to the accuracy, completeness, and truthfulness of the risk-adjustment data were legally false certifications. *See Ross*, 2023 WL 24055, at *10 (where MA Organization "knew that codes it submitted did not reflect enrollees' conditions, or . . . knew that the [underlying] data was questionable," this "giv[es] rise to a plausible express false certification

claim"); *see also Swoben*, 848 F.3d at 1173-74; *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1086 n.505 (N.D. Cal. 2020).

Cigna erroneously claims that the attestation only encompasses the accuracy of its own coding of diagnoses submitted by providers, *see* Mot. at 29, and asserts this position is supported by CMS's response to a public comment which stated that the agency had "restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of coding." HHS, *Medicare+Choice Program*, 65 Fed. Reg. at 40,251. But the relevant comment addressed innocent mistakes, not a knowing fraudulent scheme or reckless conduct, and courts have therefore rejected Cigna's reading of this administrative history. *See Swoben*, 848 F.3d at 1169, 1173 ("Certification under § 422.504(*l*) has always required due diligence and good faith," and cannot be made when an MA Organization "demonstrates either 'reckless disregard' or 'deliberate ignorance' of the truth or falsity of the data," such as when it takes "affirmative steps" to "generate and report" inaccurate risk-adjustment data). Here, like in *Swoben*, the Government's allegations do not encompass "innocent" errors or "honest mistakes," but rather a Cigna-designed program that incentivized the submission of Invalid Diagnoses to artificially inflate risk-adjustment payments. *See* Compl. ¶¶ 104-11, 132-39.

2. Cigna's Legally False Claims Were Made Knowingly

The Court should also reject Cigna's alternative argument that it had an "objectively reasonable," even if incorrect, basis for coding the Invalid Diagnoses due to claimed ambiguities in the relevant ICD Guidelines. Mot. at 30-33. Even if objective reasonableness were the relevant framework (which it is not), the requirements at issue—regulations requiring the submission of accurate, complete, and truthful risk-adjustment data, and a certification to that effect, *see* 42 C.F.R. § 422.504(*l*)—and the applicable ICD Guidelines, unambiguously barred Cigna's submission of the Invalid Diagnoses. *See supra* Part II.C.1. Cigna's *post hoc* interpretation of the

relevant requirements is thus not reasonable, and their efforts to read ambiguity into the ICD Guidelines should be rejected, when the relevant provisions, as a general matter, simply require that the reported diagnoses be documented, reliable, and affect or require patient care, treatment, or management. *See supra* Part II.C.1.a. Nor is there anything in the complaint to suggest that, when it made its submissions, Cigna actually believed that the Invalid Diagnoses comported with the ICD Guidelines. Indeed, Cigna knew or should have known these diagnoses were unreliable and were coded despite insufficient testing or other diagnostics. *See* Compl. ¶¶ 159-64.

But more fundamentally, this Court should reject the "objective reasonableness" analysis proposed by Cigna, which is based on a divided Seventh Circuit decision that applied a so-called "objective" standard to whether an FCA claim is legally false. Mot. at 31 (citing *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 468 (7th Cir. 2021)). As the dissent in that case persuasively explained, such a rule would shield FCA defendants from liability based on "objectively reasonable," but incorrect, interpretations of relevant legal requirements—which would perversely "create[] a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a *post hoc* legal rationale" for their misconduct, even in the face of evidence of "subjective bad faith." *Schutte*, 9 F.4th at 473 (Hamilton, J., dissenting).

The Supreme Court recently granted certiorari in *Schutte*, unsettling any persuasive value it had. *See United States ex rel. Schutte v. Supervalu Inc.*, 143 S. Ct. 644 (2023). This Court should decline to follow the Seventh Circuit's holding for several reasons, as the Government argued in urging the Supreme Court to grant review. *See* Br. for the United States as Amicus Curiae, *Schutte*, No. 21-1326, 2022 WL 17548630, at *9-19 (U.S. filed Dec. 6, 2022). First, as discussed above, Congress defined "knowing" to include "deliberate ignorance" or "reckless disregard of . . . truth or falsity," in addition to "actual knowledge," 31 U.S.C. § 3729(b)(1),

plainly intending to reach those who act recklessly or in bad faith, even where claims for payment implicate ambiguous legal conditions. *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154-56 (11th Cir. 2017) (finding "actual knowledge" of falsity where defendant correctly believes it is violating a legal requirement, even if counsel subsequently identify an objectively reasonable (but incorrect) exculpatory interpretation); *see also Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1212 (9th Cir. 2019) (finding "deliberate ignorance" regarding falsity where defendant "failed to make simple inquiries which would alert [it] that false claims are being submitted" (brackets omitted)); *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 744 (10th Cir. 2018) (finding "reckless disregard" as to falsity where defendant disregarded warnings about likely falsity from knowledgeable sources).

Second, the panel in *Schutte* imported the objective reasonableness standard into the FCA from a Supreme Court decision interpreting a statute with a "willful" scienter standard, not a broadly defined "knowing" standard like the FCA, *see Schutte*, 9 F.4th at 464-67 (citing *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47, 50 (2007)), in which "subjective bad faith [is] central to fraudulent scienter," *id.* at 478 (Hamilton, J., dissenting).

Third, *Schutte* is contrary to the case law of other circuits. The Eleventh Circuit has squarely rejected the "objective reasonableness" analysis, holding 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. The Ninth Circuit similarly rejected a defendant's contention that he "lacked knowledge because he based his claims on a reasonable interpretation" of the relevant requirement, based on evidence his interpretation was not held "in good faith"—that is, he did not subjectively believe it. *United States v. Chen*, 402 F. App'x 185, 188 (9th Cir. 2010). And the Sixth Circuit has arguably sided with these circuits: it found

allegations that FCA defendants "knew . . . their conduct was, at least, perilously close to noncompliance . . . support[ed] the inference that the[y] were on notice that their claim-submission process was resulting in potential compliance problems." *Prather*, 892 F.3d at 838. In failing to "conduct . . . an inquiry" into these issues "and instead "push[ing] their employees to ignore problems," "the defendants acted with 'reckless disregard' as to the truth of their certification of compliance." *Id.* The panel majority rejected the argument that the agency had not issued authoritative guidance demonstrating this "potential compliance problem[]" was impermissible. *See id.* at 851-52 (McKeague, J., dissenting).[14]

This Court should thus reject Cigna's alternative argument that its submission of the Invalid Diagnoses was based on an "objectively reasonable," even if incorrect, interpretation of the governing rules—which, in any event, unambiguously precluded Cigna's conduct.

3. Cigna's False Claims Were Material to CMS

Lastly, the Government adequately alleges that Cigna's submission of the Invalid Diagnoses was material to CMS's decision to pay based on this risk-adjustment data. Materiality under the FCA means whether the false statement "ha[s] a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "Materiality 'looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.' Something is material if a reasonable person 'would attach importance to it in determining his choice of action in the transaction' or 'if the defendant knew or had reason to

[14] A few other circuits have followed *Safeco* in FCA cases, though they have not clarified whether the defendant must subjectively believe its alternative interpretation is correct, or whether it may adopt such an interpretation *post hoc*. *See United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, P.C.*, 833 F.3d 874, 879 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290 (D.C. Cir. 2015); *see also United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873 (4th Cir. 2022) (en banc) (affirming district court by equally divided vote).

know that the recipient of the representation attaches importance to the specific matter in determining his choice of action, even though a reasonable person would not.'" *Prather*, 892 F.3d at 831 (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192-93 (2016)) (brackets and some internal quotation marks omitted). In assessing materiality,

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

Id. (quoting *Escobar*, 579 U.S. at 194-95 & n.5). "None of these considerations is dispositive alone, nor is the list exclusive." *Id.* (citing *Escobar*, 579 U.S. at 191-96).

Contrary to Cigna's assertion, Mot. at 34-36, the Government's allegations demonstrate materiality under all of these factors. First, CMS explicitly designated MA Organizations' submission of accurate and properly coded risk-adjustment data, and their certification of such accuracy, as a condition of payment. *See* Compl. ¶¶ 69, 94 (citing 42 C.F.R. § 422.504(*l*)); *see supra* Part II.C.1.b. The relevant regulation states that "*[a]s a condition for receiving a monthly payment*," the MA Organization agrees that its senior officers "must certify (based on best knowledge, information, and belief) that [the risk-adjustment data] are accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*) (emphasis added). Moreover, the risk-adjustment data is submitted pursuant to a regulation that requires that the data conform with "relevant national guidelines," which include the ICD Guidelines, 42 C.F.R. §422.310(d)(1).[15]

[15] In a footnote, Cigna cites two inapposite decisions regarding the materiality of the regulatory data attestation requirement. *See* Mot. at 37 n.10 (citing *United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, No. 16 Civ. 8697, 2018 WL 1363487, at *10 (C.D. Cal. Feb. 12, 2018), and *United States v. Scan Health Plan*, No. 09 Civ. 5013, 2017 WL 4564722, at *6 (C.D. Cal. Oct. 5, 2017)). In those cases, courts found the Government had not adequately pled that

Second, Cigna's arguments about what CMS knew, *see* Mot. at 34-35, are at odds with the pleadings and administrative documents and apply the wrong legal standard. While CMS knew Cigna submitted diagnosis codes based on in-home assessments and did not outright prohibit MA Organizations from doing so, the agency did not have actual knowledge of Cigna's Invalid Diagnoses when it made payments based on them. The agency's actual knowledge of the false claims when it pays them is what is key to determining materiality.

The relevant question is whether the agency, "with *actual knowledge* of the non-compliance, . . . consistently pays such claims." *Prather*, 892 F.3d at 831 (citing *Escobar*, 579 U.S. at 193-95 & n.5) (emphasis added). As the First Circuit held on remand from the Supreme Court in *Escobar*, an agency's "mere awareness of *allegations concerning noncompliance*" do not defeat materiality, as the relevant question is whether the agency "had actual knowledge of the violations at the time it paid the claims at issue." *United States ex rel. Escobar v. Universal Health Services, Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) (emphasis added); *see Poehling*, 2018 WL 1363487, at *12 ("That CMS continued to make risk adjustment payments despite generalized knowledge of Defendants' 'one-way' Chart Reviews and problematic diagnosis codes does not significantly change this analysis. As the Government argues, this generalized knowledge does not amount to actual knowledge of specific invalid diagnoses.").[16]

---

defendants' representations were material to CMS—but did not conclude as a matter of law that attestations of data accuracy were immaterial. The Government's allegations in this case do not contain such gaps. *See, e.g.*, Compl. ¶ 95 ("In addition to the materiality of the diagnosis codes to payment, the annual Risk Adjustment Attestations are also material to payment.").

[16] Other courts have denied defendants' motions where there was a factual dispute regarding whether the agency knew of the fraud when it made the relevant payments. *See, e.g.*, *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 116 (2d Cir. 2021); *United States ex rel. Mackillop v. Grand Canyon Educ., Inc.*, No. CV 18-11192-WGY, 2022 WL 4084444, at *22 (D. Mass. Sept. 6, 2022).

Cigna cannot overcome the Government's materiality allegations on a motion to dismiss unless it could show that CMS actually knew of the Invalid Diagnoses when it made the payments at issue. Contrary to Cigna's argument, such a conclusion cannot be drawn from administrative communications in which CMS expressed general concerns that MA Organizations might improperly use home visits primarily to generate diagnosis codes in order to increase risk-adjustment payments, rather than to provide care or treatment, but chose not to ban the submissions of all codes from home visits. Mot. at 34-35. As alleged, CMS identified these concerns to warn MA Organizations they should not misuse home visits solely as cash grabs and urged them to adopt best practices that would help foster the benefits of such visits (such as home-environment reviews and coordination of care with providers) while minimizing fraud. Compl. ¶ 166 (citing 2015 Final Call Letter at 27); *see also* Background Section A.3; 2016 Final Call Letter at 145-46. Just because CMS recognized the risk that unscrupulous MA Organizations might structure their home visit programs inappropriately, but chose not to reject diagnoses from *all* home visits, does not mean the agency knew of Cigna's Invalid Diagnoses.

Lastly, Cigna's Invalid Diagnoses plainly violated "the essence of [its] bargain" with CMS, given that the integrity of the entire risk-adjustment system relies on the submission of accurate diagnosis codes. "Under MA, risk adjustment payments in the aggregate are obviously substantial. Misrepresentations that affect those payments can undoubtedly have a substantial financial effect on the MA program." *Osinek*, 2022 WL 16925963, at *14; *accord Ormsby*, 444 F. Supp. 3d at 1085-86 ("[w]hen MA Participants submit false risk-adjusting diagnosis codes, CMS pays more money," which "establishes that the diagnosis codes are material"). This is especially the case where the Government alleged that Cigna "improperly received tens of millions of dollars in risk adjustment payments from CMS" based on the false claims at issue.

Compl. ¶ 15; *see Osinek*, 2022 WL 16925963, at *15 (finding "the magnitude of the noncompliance weighs in favor of materiality"); *United States v. Anthem Inc.*, No. 20-CV-2593 (ALC), 2022 WL 4815978, at *6 (S.D.N.Y. Sept. 30, 2022) (finding materiality where the Government "allege[d] that [the defendant's] chart review program resulted in an estimated tens of millions in overpayments per year," and thus that "[t]he financial costs to the Government here are substantial and not merely administrative costs").

Cigna distorts the materiality analysis by arguing that the Government "does not plausibly allege that any noncompliance with treatment and testing requirements went to 'the essence of the bargain' between CMS and Cigna." Mot. at 35. As discussed above, *see* Part II.C. 1.a, the Government does not claim Cigna was contractually or regulatorily required to conduct particular diagnostic tests before submitting diagnosis codes. Instead, the Government alleges Cigna failed to submit accurate and truthful risk-adjustment data that conformed with the ICD Guidelines, and that this failure was material because the data directly impacted CMS's payments to Cigna. *See Osinek*, 2022 WL 16925963, at *14 (concluding CMS guidance on "the importance of complying with the ICD Guidelines" supported materiality).

Materiality is further demonstrated by CMS's and HHS-OIG's regular audits to validate risk-adjustment data by comparing the submitted diagnosis codes with underlying plan members' medical records. *See* Compl. ¶¶ 91-93. Where diagnosis codes are found not to comply with the ICD Guidelines or otherwise lack support, MA Organizations "must return to CMS any payments that . . . the audit found lack support in the relevant beneficiaries' medical record documentation." *Becerra*, 16 F.4th at 877. Moreover, as described in the complaint, the Government has repeatedly pursued legal remedies against MA Organizations and healthcare

providers who submitted, or caused to be submitted, inaccurate and untruthful diagnosis data to CMS. *See* Comp. ¶¶ 96-101 (describing enforcement actions dating back to 2012).

III. The Court Should Permit the Government's Common-Law Claims to Proceed

Finally, Cigna argues that the Government's common-law claims for unjust enrichment and payment by mistake, *id.* ¶¶ 184-89, should be dismissed because the Government has not sufficiently alleged the underlying fraud, and because quasi-contract claims are generally unavailable when contracts expressly govern the relevant conduct. *See* Mot. at 37. It is mistaken on both counts, as several other decisions have recognized in denying motions to dismiss common-law claims in analogous FCA cases. *See Ross*, 2023 WL 24055, at *13; *Osinek*, 2022 WL 16925963, at *18-19; *Ormsby*, 444 F. Supp. 3d at 1086.

First, for the reasons explained above in Part II, the Government's allegations regarding Cigna's submission of the Invalid Diagnoses are more than sufficient to support its common-law claims at this stage. Theories of "payment by mistake and unjust enrichment" are "in essence . . . alternative pleadings to [the Government's] fraud claims under the False Claims Act." *United States v. United Techs. Corp.*, 626 F.3d 313, 323 (6th Cir. 2010). Courts have recognized that "claims for payment under mistake of fact and unjust enrichment may remain in play even if the FCA claims fail" because those common-law claims have lower scienter thresholds. *Crumb*, 2016 WL 4480690, at *17; *see United States v. Mead*, 426 F.2d 118, 125 n.5 (9th Cir. 1970).[17]

[17] Plaintiffs may plead alternative theories of relief, "regardless of consistency." Fed. R. Civ. P. 8(d)(2)-(3). Thus, courts "permit[] the government to proceed with claims alleging FCA violations as well as claims for unjust enrichment or payment by mistake." *United States ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d 69, 79 (D.D.C. 2003) (collecting cases); *see United States ex rel. Bassan v. Omnicare, Inc.*, No. 1:15-CV-4179, 2021 WL 1063784, at *12 (S.D.N.Y. Mar. 19, 2021).

Under a payment by mistake theory, the Government can recover "money it mistakenly, erroneously, or illegally paid from a party that received the funds without right." *United States v. Houston*, No. 2:09-0091, 2011 WL 4899983, at *6 (M.D. Tenn. Oct. 14, 2011) (internal quotation marks omitted). The complaint's allegations here amply demonstrate that "the Government made [relevant] payments under an erroneous belief which was material to the decision to pay," such that "it is entitled to recover the payments." *Mead*, 426 F.2d at 124. In particular, the complaint alleges CMS paid Cigna based on Cigna's submission of invalid diagnosis codes, while under the erroneous belief that the plan members had been properly diagnosed and that the corresponding diagnosis codes complied with the ICD Guidelines. Accordingly, the Government is entitled to recover inflated payments Cigna received due to the resulting increase in plan members' risk scores. *See* Compl. ¶¶ 7-13.

To plead unjust enrichment, as relevant here, the Government must have a reasonable expectation of repayment, and non-repayment would defeat society's reasonable expectation, *Houston*, 2011 WL 4899983, at *7, that "the recipient of fraudulently obtained federal funds should not be expected to retain them," *United States ex rel. Goodman v. Arriva Med., LLC*, No. 3:13-CV-0760, 2020 WL 1433861, at *8 (M.D. Tenn. Mar. 24, 2020); *see also United States v. Bouchey*, 860 F. Supp. 890, 894 (D.D.C. 1994) (unjust enrichment applies where defendant knowingly received a government benefit under "circumstances as to make it inequitable for [it] to retain the benefit without payment of its value" (internal quotation marks omitted)). Cigna unjustly enriched itself by receiving artificially inflated risk-adjustment payments from CMS stemming from its submission of the Invalid Diagnoses, *see* Compl. ¶ 15, and it would be inequitable for the company to retain such payments. In sum, the Government's allegations support its common-law causes of action. *See, e.g.*, *Osinek*, 2022 WL 16925963, at *18

(declining to dismiss unjust enrichment and payment by mistake claims for same reasons the court declined to dismiss FCA claims).

Cigna's second argument—that quasi-contract claims such as unjust enrichment and payment by mistake cannot survive whenever the parties have entered a contract—is both inapplicable and legally incorrect. The Government alleges that, separate from breaching any contractual provision, Cigna violated its independent statutory and regulatory obligations by falsely certifying the accuracy and truthfulness of the diagnosis data it submitted to CMS. *See, e.g.*, Compl. ¶ 176. Where "the government has not simply alleged the violation of the CMS[] contract but also the violation of federal regulations," which could provide a basis for liability even if the contract was not violated, courts have allowed quasi-contractual theories to proceed. *Osinek*, 2022 WL 16925963, at *18; *cf. Ross*, 2023 WL 24055, at *13 (holding quasi-contract claims can proceed where parties disputed whether claims were fully encompassed by their contract). Moreover, "it is long established that the 'Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid.'" *Omnicare*, 2021 WL 1063784, at *13 (quoting *United States v. Wurts*, 303 U.S. 414, 415 (1938)). This is "a right arising separate and apart from statute, regulation, or contract," *Agility Pub. Warehousing Co. v. United States*, 969 F.3d 1355, 1365 (Fed. Cir. 2020), and thus the Government's claim remains valid "even if a quasi-contract claim might ordinarily be barred," *Osinek*, 2022 WL 16925963, at *18. The Court should thus permit the Government's common-law claims to proceed.

CONCLUSION

For the above reasons, the Court should deny Cigna's motion to dismiss the Government's FCA and common-law claims.

Respectfully submitted,

HENRY C. LEVENTIS
United States Attorney for the
Middle District of Tennessee

By: s/ Kara Sweet
KARA F. SWEET
Assistant United States Attorney
719 Church Street, Suite 3300
Nashville, Tennessee 37203
Tel.: (615) 736-5151
kara.sweet@usdoj.gov

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York

By: s/ Jean-David Barnea
JEAN-DAVID BARNEA (pro hac vice)
PETER ARONOFF (pro hac vice)
SAMUEL DOLINGER (pro hac vice)
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Telephone: (212) 637-2679/2697/2677
jean-david.barnea@usdoj.gov
peter.aronoff@usdoj.gov
samuel.dolinger@usdoj.gov

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing was served on February 15, 2023, by electronic means via the Court's electronic filing system, to the following:

Tara L. Swafford
W. Lee Maddux
Elizabeth G. Hart
The Swafford Law Firm, PLLC
321 Billingsly Court, Suite 19
Franklin, TN 37067
tara@swaffordlawfirm.com
lee.maddux@arlaw.com
besty@swaffordlawfirm.com

Charles Speth
David William Ogden
Howard M. Shapiro
Kevin Lamb
Wilmer, Cutler & Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
charles.speth@wilmerhale.com
david.ogden@wilmerhale.com
howard.shapiro@wilmerhale.com
kevin.lamb@wilmerhale.com

J. Alex Little
Thomas K. Potter, III
Burr & Forman, LLP
222 Second Avenue South, Suite 2000
Nashville, TN 37201
alex.little@burr.com
tpotter@burr.com

s/Jean-David Barnea
JEAN-DAVID BARNEA