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***U.S. ex rel. Cutler v. Cigna Corp.*,**
No. 17 Civ. 7515

Re: Request for Pre-Motion Conference for Defendants' Motion to Dismiss

Dear Mr. Cutler:

We write on behalf of the Defendants to request a pre-motion conference regarding Defendants' intent to move to dismiss. The Amended Complaint alleges that Cigna Medicare violated the False Claims Act ("FCA") by submitting risk adjustment data to the Centers for Medicare and Medicaid Services ("CMS") that was gathered during in-home exams.[1] Defendants seek leave to move to dismiss the Amended Complaint because it is barred by 31 U.S.C. § 3730(e)(4), fails to allege fraud with particularity as required by Fed. R. Civ. P. 9(b), and fails to plausibly allege the basic elements of a claim under the FCA, including falsity and materiality.[2]

Introduction

The Amended Complaint alleges that diagnoses identified by licensed nurse practitioners during in-home exams are *per se* invalid for risk adjustment purposes because the exams are a "data-gathering" effort, *see, e.g.*, Am. Compl. ¶¶ 4, 47–48, 50, 55-57, that supposedly does not involve "treatment," *see id.* ¶¶ 45, 53, 97. The Amended Complaint also attacks the fact that licensed nurse practitioners—working for companies like yours—conduct many of the exams. *See id.* ¶¶ 4, 7, 36, 41. But, since 2013, CMS has repeatedly and publicly discussed and rejected these criticisms. The Amended Complaint, therefore, should be dismissed because it merely repackages substantially the same allegations that have been publicly disclosed many times before.

The Amended Complaint should be dismissed for other reasons as well. Because CMS specifically allows diagnoses from in-home exams, the Amended Complaint has not (and cannot) plausibly allege falsity, materiality, and other required elements of an FCA claim. Further, even though you have already amended this complaint once, the Amended Complaint still fails to meet the particularity requirements of Rule 9(b). For example, you vaguely allege that certain conditions

[1] As you know, you spent three years representing Texas Health Management ("THM")—a company that you partly owned, for which you served as general counsel, and that provided in-home exams to Cigna patients—in litigation against Cigna related to a wholly manufactured and baseless contract dispute. During the course of the contract dispute, you, as counsel to THM, raised an FCA allegation. *See THM v. HealthSpring Life & Health Ins. Co.*, 380 F. Supp. 3d 580, 585 (E.D. Tex. 2019).

[2] In a typical FCA case, we would not contest personal jurisdiction because 31 U.S.C. § 3732(a) authorizes nationwide service and personal jurisdiction. *See* Am. Compl. ¶ 20; *United States ex rel. Thistlethwaite v. Dowty Woodville Polymer, Ltd.*, 976 F. Supp. 207, 210 (S.D.N.Y. 1997). We note, however, that your recent letter to the Court argues that nationwide personal jurisdiction does not exist and that an FCA case must independently establish "minimum contacts with the forum state where the court is located" for each defendant. ECF No. 52, at 1. Although we do not agree, we reserve the right to challenge personal jurisdiction in the Southern District of New York to the extent you continue to argue that personal jurisdiction would not exist in the Middle District of Tennessee.

could not have been assessed during the in-home visits. *See id.* ¶ 47. But, despite the fact that your company had access to thousands of records of in-home exams completed for Cigna Medicare, you fail to identify even a single specific diagnosis for a specific patient that was, in fact, false.

1. Public Disclosures Bar The Amended Complaint

The Amended Complaint merely reiterates allegations that are derivative of prior public disclosures, including extensive regulatory proceedings before CMS, a Medicare Payment Advisory Commission ("MedPAC") review and report, numerous media reports, and prior *qui tam* cases. The FCA provides that a court "shall dismiss" a *qui tam* action "if substantially the same allegations or transactions" were publicly disclosed before the relator filed suit, unless the government objects. *See* 31 U.S.C. § 3730(e)(4).

The Amended Complaint repackages the same criticisms of in-home exams that CMS has considered—and rejected—repeatedly over the years. In-home exams have been a standard industry practice since at least 2010, and CMS has never prohibited them or the submission of the diagnoses that they produce. Since 2013, CMS has publicly described and considered the same potential criticisms that appear in the Amended Complaint. CMS has acknowledged, for instance, that these exams are frequently "conducted in the beneficiary's home." CMS, *2014 Advance Notice* 22 (Feb. 15, 2013). While you allege that the exams are a "data-gathering" exercise, CMS described in-home exams as "a tool to identify enrollee diagnoses" and observed that in-home exams could be "a vehicle for collecting risk adjustment diagnoses without follow-up care or treatment." *Id.* Similarly, in 2014, CMS reported that in-home exams were "typically conducted by healthcare professionals who [were] contracted by [a] vendor" and were "not the beneficiaries' primary care providers." CMS, *2015 Advance Notice* 20 (Feb. 21, 2014). While you allege that exams lacked a treatment component, CMS has stated that "treatment is not a component" of in-home exams. *Id.* In 2015, CMS acknowledged that in-home exams are used to "find and report more diagnosis codes," considered a proposal to exclude those diagnoses, but decided to permit these exams to continue. CMS, *2016 Advance Notice* 139 (Feb. 20, 2015). Having considered all of the criticisms of in-home exams, CMS concluded that these examinations have "significant value." CMS, *2016 Announcement* 145 (Apr. 6, 2015). Not only has CMS thus permitted in-home exams to continue, but Medicare Advantage ("MA") plans must account for such covered services in the data submitted to CMS. *See United States ex rel. Gray v. UnitedHealthcare Ins. Co.*, No. 15-cv-7137, 2018 WL 2933674, at *7 (N.D. Ill. June 12, 2018).

Although this record alone triggers the public disclosure bar, many other public disclosures also predate the complaint. MedPAC published its own analysis and critique of in-home exams. *See* MedPAC, *Report to the Congress: Medicare Payment Policy* 346–53 (Mar. 2016) (describing in-home exams and noting concern that "diagnoses are often based on enrollee self-reporting or cannot be accurately identified with equipment brought into an enrollee's home"). The media also widely covered in-home exams and criticisms of them. *See, e.g.*, Ctr. for Pub. Integrity, *Home Is Where the Money Is for Medicare Advantage Plans* (June 10, 2014). Finally, a number of court cases filed before this action asserted a wide variety of claims regarding in-home exams. *E.g.*, *United States ex rel. Gray*, 2018 WL 2933674, at *3 (dismissing the relator's 2016 complaint alleging that United's in-home program was a "fraudulent scheme intended to increase the capitated payments"); *see also United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 329 (5th Cir. 2011) ("[T]he public disclosures need not name particular defendants so long as they 'alerted the government to the industry-wide nature of the fraud ….'").

Given such an extensive public record, this case is foreclosed. *See, e.g.*, *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993); *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 298 (S.D.N.Y. 2013) (disclosures need only "to set the government squarely upon the trail of the alleged fraud").

2. The Amended Complaint Fails Under Rule 12(b)(6) For Additional Reasons

The allegations also fail under Rule 12(b)(6). The Amended Complaint's generalized and conclusory allegations do not sufficiently allege facts to establish the elements of an FCA violation. They do not identify a single claim for payment, much less a *false* claim. The Amended Complaint does not allege that any diagnosis was actually false and, in fact, resulted in a risk adjustment payment contrary to the applicable payment rules. Without this most basic element of a "false" claim, the Amended Complaint fails to allege an FCA violation. *See United States ex rel. Raffington v. Bon Secours Health Sys., Inc.*, 405 F. Supp. 3d 549, 555 (S.D.N.Y. 2019).

Similarly, the Amended Complaint does not (and cannot) satisfy the FCA's demanding materiality requirement.[3] CMS's public statements make clear that the Agency has been well aware that MA plans submit diagnoses from in-home exams. Moreover, since 2015, CMS has required MA plans to "identify … which diagnoses are from home visits" so that it could "study" the issue, giving CMS the ability to identify the diagnoses made during in-home exams. CMS, *2015 Announcement* 27 (Apr. 7, 2014). As the *Gray* court concluded, CMS's allowance of in-home exams is "strong evidence" that the identification of diagnosis codes in in-home exams is "not material to CMS's determination of capitated payments." 2018 WL 2933674, at *6.

Even more fundamentally, given that CMS expressly considered whether to prohibit diagnoses from in-home exams and did not do so, the Amended Complaint's allegations are implausible, precisely because CMS expressly ***allows*** MA plans to use in-home exams, "regardless of whether follow-up care is provided for those conditions." MedPAC Report, *supra*, at 347. Indeed, you concede that CMS "has not expressly prohibited" diagnosis submissions based on in-home exams. Am. Compl. ¶ 34.

3. The Amended Complaint Also Fails Under Rule 9(b)

Finally, the Amended Complaint, particularly in light of your position as an insider whose company was responsible for completing in-home exams, has not complied with Rule 9(b).[4] A relator must either "(1) provid[e] sufficient identifying information about all the false claims, or (2) provid[e] example false claims." *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 258 (S.D.N.Y. 2014). The Amended Complaint does neither. Although you were a partial owner and general counsel of one of the companies that performed exams for Cigna, the Amended Complaint fails to specify a single diagnosis that was invalid for a single patient on any specified date of service. The Amended Complaint generally describes the 360 program but never identifies *a single instance* in which a 360 exam actually resulted in an inappropriate payment.

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[3] *See Universal Health Servs, Inc.. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003–04 (2016) (discussing the importance of the materiality element of the FCA).

[4] As a threshold matter, the Amended Complaint relies on impermissible group pleading. It collectively defines several different entities as "Cigna-HealthSpring", and then attributes every allegation to that collective. *See SEC v. U.S. Envtl., Inc.*, 82 F. Supp. 2d 237, 241 (S.D.N.Y. 2000). Such group pleading also violates Rule 8(a). *See United States ex rel. Takemoto v. Hartford Fin. Servs. Grp., Inc.*, 157 F. Supp. 3d 273, 281 (W.D.N.Y. 2016) (collecting cases).

Respectfully submitted,

/s/__Eamon P. Joyce_____
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cc: Hon. Kenneth M. Karas (via ECF)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, EX REL. ROBERT A. CUTLER, Plaintiff, v. CIGNA CORP., *et al.*, Defendants.	Civil Action No. 7:17-cv-07515-KMK Hon. Kenneth M. Karas

DECLARATION OF CASEY MCKEON IN SUPPORT OF CIGNA'S LETTER MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a)

I, Casey McKeon, declare and state as follows:

1. I am President of CareAllies, Inc., which is a wholly-owned, indirect subsidiary of Cigna Corporation. I previously held the position of General Manager of National Health Services for Cigna-Healthspring, which is also a wholly-owned, indirect subsidiary of Cigna Corporation. My office is located in Nashville, TN. I have been employed by Cigna Corporation (through its subsidiaries) since June 2011, and I have been based in Nashville, TN since 2015.

2. I am authorized to make the statements in this Declaration, which are true based on my personal knowledge, or upon information and belief, including inquiry of relevant Cigna records and employees.

3. I have reviewed the Amended Complaint filed by relator Robert A. Cutler ("Relator") in this action (ECF No. 12), as well as Relator's letter dated September 14, 2020 and the exhibits thereto (ECF No 52). I understand that Relator's allegations pertain to Cigna's Medicare Advantage ("MA") business and, more specifically, the "360 Exams" provided to Cigna's

Medicare Advantage beneficiaries. Through my employment, I am familiar with Cigna's Medicare Advantage line of business and specifically familiar with the 360 Exam program.

4. One of the defendants named in the Amended Complaint is Cigna Corporation. *See* Am. Compl. ¶ 8. Cigna Corporation is a publicly traded holding company incorporated under the laws of Delaware and headquartered in Bloomfield, Connecticut. Cigna Corporation is the ultimate parent company of the global health service company known as "Cigna." As a holding company, Cigna Corporation does not directly offer any health insurance products.

5. Cigna operates its Medicare Advantage business principally through a company known as Cigna-HealthSpring, Inc. and its subsidiaries ("Cigna-HealthSpring"). HealthSpring was previously an unrelated company and was acquired by Cigna in 2012. Most, though not all, of Cigna's Medicare Advantage operations were acquired through that acquisition.

6. Cigna-HealthSpring maintains its headquarters in Nashville, Tennessee. Since the 2012 acquisition, Cigna-HealthSpring's operational and executive headquarters have been in the greater Nashville area, and since approximately 2015, the primary operating location for all of Cigna's Medicare Advantage business has been 530 Great Circle Road, Nashville, Tennessee, 37228. This includes both operational staff and senior leadership. For instance, the Informatics team that is responsible for collecting and submitting risk adjustment data to the Centers for Medicare & Medicaid Services ("CMS") is located in Nashville.

7. At all times relevant to this action, management of the 360 Exam program was based in the Nashville area. Primary responsibility for the 360 Exam program was with Cigna-HealthSpring's Medicare Data Quality Operations ("MDQO") department and a unit within MDQO, the Chronic Care Quality Initiative ("CCQI"). In addition to the MDQO and CCQI teams, other potentially relevant witnesses in Nashville who may have knowledge regarding the

360 Exam program include, for example, the Chief Medical Officer for Cigna's Medicare Advantage business involved in developing the 360 Exam, compliance and operational personnel, and the former employees who previously held positions within MDQO or CCQI.

8. In addition, many of the central and individual document custodians and repositories that are most likely to be related to this case are maintained in Nashville. To the best of my knowledge, none of the documents or document custodians relevant to this case are located in the Southern District of New York or the state of New York.

9. Many of the electronic systems involved in the operation of the 360 Exam program, such as the databases for storing and reviewing data and documentation regarding the 360 Exams, were developed by, and remain managed by, individuals based in Nashville.

10. It is possible that relevant witnesses may be located in Phoenix, Arizona or Houston, Texas, as those are the areas in which THM performed 360 Exams. Should it become necessary individuals in Phoenix or Houston to participate in this case, Nashville will be a more convenient location for them than New York.

11. Currently, Cigna-HealthSpring "offers Medicare Advantage plans in 18 states, including Alabama, Arkansas, Arizona, Colorado, Delaware, Florida, Georgia, Illinois, Kansas, Missouri, Maryland, Mississippi, New Jersey, North Carolina, Pennsylvania, South Carolina, Tennessee, Texas and the District of Columbia." https://www.cigna.com/newsroom/news-releases/2019/cigna-expands-its-medicare-advantage-offerings-and-benefits-while-minimizing-costs-to-consumers. To date, Cigna-HealthSpring has never operated a Medicare Advantage plan in New York.

12. To the best of my knowledge, no Cigna entity has ever provided Medicare Advantage coverage to residents of New York. To the best of my knowledge, no resident of New York has ever received a 360 Exam. I do not anticipate there being *any* individuals resident in New York who would be a witness in this case or any documents located in New York that would be produced in this case.

13. For these reasons, I believe that it would be more convenient, less burdensome, and less expensive for the Cigna defendants and the individuals who may potentially be called as witnesses to litigate this action in the Middle District of Tennessee.

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I declare under penalty of perjury that the foregoing is true and correct. Executed on the 21st day of September, 2020, in Nashville, TN.

Casey P McKeon

Casey McKeon