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

UNITED STATES OF AMERICA, EX REL. ROBERT A. CUTLER,	)	
Plaintiff,	)	**Case No. 3:21-cv-748**
v.	)	**JUDGE RICHARDSON**
	)	**MAGISTRATE JUDGE FRENSLEY**
CIGNA CORP. et al,	)	
	)	**FALSE CLAIMS ACT**
Defendants.	)	**JURY DEMAND**

RELATOR'S REPLY TO DEFENDANT'S RESPONSE IN OPPOSITION TO RELATOR'S MOTION FOR LEAVE TO AMEND

The Relator, Robert A. Cutler, files this Reply to Defendants' Response in Opposition to Relator's Motion for Leave to Amend. In response to Defendants' allegations that Relator did not follow the Local Rules requiring a meet and confer, counsel for Relator respectfully disagrees. In February of this year, the parties conferred on Relator's request to file the exhibits to the proposed amended complaint under seal. At that time, counsel for Defendants clearly informed counsel for Relator both verbally and through written communication that they would not consent to the proposed Amended Complaint. Once the Court issued its order (Doc. 234) that Relator's proposed Amended Complaint would only be considered with an accompanying Motion to Amend, counsel for Relator did not see the need to ask Defendants a second time as to what their position was. Relator's counsel, however, did confer with the government for its position. Given the prior discussions in February, counsel for Relator considered that to satisfy the Local Rules. Regardless, this should not be grounds for denial of the Motion to Amend as nothing would have been altered had a second, duplicative meet and confer occurred.

In addition, the fact that Relator did not move to amend while this case was pending in the Southern District of New York also is not grounds to deny the motion. This is because Relator could not have moved to amend in that district. Defendants asked the court to stay the proceedings pending the outcome of the Motion to Transfer which Judge Karas granted at a conference which was held on November 12, 2020. (Docs. 45, 70). This ruling accords with a longstanding practice within the Second Circuit. The courts have held that where a case is to transfer to another district, it is more appropriate and in the interests of justice for a motion to amend to be heard in the jurisdiction to which the case will be transferred. *See, e.g., Yovel-Bash v. Wellesley Asset Secured Portfolio, Inc.*, No. 12-CV-5280 JMA, 2013 WL 4781539 at *1 (E.D.N.Y. Sept. 5, 2013); *Keitt v. New York City*, 882. F. Supp. 2nd 412, 426 (S.D.N.Y. 2011); *Fellner v. Cameron*, No. 09-CV-98S, 2010 WL 681287 at *7 (W.D.N.Y. Feb. 24, 2010).

Turning to Defendants' argument that granting the motion would be "futile," Defendants continue to misrepresent that Relator is asserting a "per se" challenge to using diagnoses from in-home visits for risk adjustment purposes. (Doc. 238, Defs.' Resp., p. 8.) On multiple occasions, Relator has explained why this is not the case. Yet this has not stopped Defendants from continuing to mischaracterize the legal theories in the Amended Complaint. Relator will not waste this Court's time entertaining Defendant's recycled arguments. If the Court wishes to review Relator's response to them, Relator draws the Court's attention to page 5 of his opposing memorandum to Defendants' Motion to Dismiss. (Doc. 214.) Defendants' argument regarding futility lacks merit because it attacks a legal theory which is not being asserted by Relator. Defendants also erroneously argue that the amendment does not overcome the public disclosure bar because Relator does not explain how the information affected a person's decision-making or materially added to publicly disclosed information. Relator does not need to meet these requirements because the information on which

his claims are based was not publicly known and he disclosed the information to the Government in confidence. *See* 31 U.S.C. § 3730(e)(4)(B)(i). It is evident from the proposed Second Amended Complaint that the "information" that supports the claims is the innerworkings of the 360 program, *not* the simple fact that the nurses were diagnosing conditions in a member's home. This information includes the processes that took place behind the scenes – for example that Defendants were dictating the manner for conducting a 360 and using training exercises to condition nurses to find certain diseases – which were not known to the public. Indeed, the very fact that Defendants moved the Court in the Southern District of New York to seal documents that described how diagnoses were made only goes to show that they themselves knew that the information was not publicly known.

Defendants also attack Relator's representative examples as insufficient for Rule 9(b) purposes, claiming that "an in-home vendor's omission of certain diagnoses" does not show the that false claims were submitted in 2015. (Doc. 238, Defs.' Resp., p. 11.) But this is a mischaracterization of the documents. The 2016 form does not "omi[t]" certain diseases, rather it shows that the nurse made observations which are inconsistent with the existence of those diseases.[1] The nurse practitioner reviewed this patient's signs and symptoms and indicated that his heart was "normal" and that abnormal findings were "[n]egative." The patient's own self-evaluation of his medical history did not list any heart or kidney problems. It simply stated that he had a cataract in his left eye. Defendants are also mistaken in their belief that conditions for "a single patient" do not show representative examples for Rule 9(b) purposes. (*Id.*) Each false condition reported to CMS represents a separate claim. *See* 31 U.S.C. § 3729(b)(2). Therefore,

[1] It should be noted that there is a distinction between observations and diagnoses (i.e. the medical conclusions based on the observations). Relator is claiming that the diagnoses rendered as a result of a 360 are not sufficiently supported by the observations, not that the observations themselves are flawed.

Relator has provided 3 false claims that were submitted by way of a 360.[2] These claims characterize the type of chronic diseases which were being diagnosed through the 360 Program without sufficient clinical support. Any diagnoses picked at random from the pool of claims submitted to the government by way of a 360 that was performed would likewise be unreliable. [3] *U.S. ex rel. Bledsoe v. Community Health Sys.*, 501 F. 3d 493, 511 (6th Cir. 2007).

Defendants also challenge Relator's representative examples in that they do not "link" to a legal theory in the case. Clearly this is not true. As alleged in paragraph 43 of the proposed Second Amended Complaint, the list of codes, or the document referred to as the "Historical HMR," was designed to be used specifically by nurses performing in-home 360s as a "cheat sheet" that would allow nurse practitioners to duplicate diagnoses from year to year. As such, each of the codes on the list derived from an actual in-home 360 that was performed for that specific member in 2015. The representative examples also show that the Historical HMR contains false diagnoses on which nurses were directed to rely. (S*ee* Doc 214-4, Amended Compl. at ¶¶ 71, 87).[4]

Defendants also argue that Relator does not explain how the claims in his amendment are different than the Government's claims. This difference was outlined in Relator's opposing memorandum to the Motion to Dismiss (Doc. 214, p. 7). The Government case is limited only to those claims for conditions which "required specific testing or imaging to be reliably diagnosed" (*Id.*). However, Relator is pursuing all other false claims that were submitted to the Government. This includes every diagnosis which was obtained by a 360 conducted in the patient's home, even conditions that could be diagnosed by the nurse practitioners without testing/imaging, and those

[2] Namely systolic congestive heart failure, chronic kidney disease and hypertensive heart disease with heart failure.
[3] It should be noted that there is a distinction between observations and diagnoses (i.e. the medical conclusions based on the observations). Relator is claiming that the diagnoses are not sufficiently supported by the observations, not that the observations themselves are flawed.
[4] Again, Relator is not arguing that diagnoses rendered by a nurse practitioner from an in-home visit are "per se" invalid. Rather, the manner in which the 360s were performed is what renders the diagnoses invalid.

diseases in which any required testing/imaging was performed. These conditions are false because as stated in the proposed Second Amended Complaint, nurse practitioners were not permitted by their employers or Defendants to diagnose any diseases at all, they were inadequately trained to diagnose chronic diseases (particularly mental and behavioral disorders), they were restricted in exercising professional judgment, and they were directed to follow protocols which required them to diagnose diseases which could be linked to cursory signs and symptoms.[5] Accordingly, all the diagnoses rendered by the nurse practitioners are either false or unreliable.

The final argument raised by Defendants for denying the Motion to Amend is undue delay. However, the courts have repeatedly held that this by itself is not grounds for denying a motion to amend, particularly where, as here, the plaintiff has good cause for the delay. *See Flanery v. Marquette Transp. Co., LLC*, No. 5:20-CV-162-TBR, 2021 WL 5496859 *2 (W.D. Ky. Nov. 23, 2021). In addition, the Court has established a deadline for filing motions to amend. Consequently, Defendants cannot claim undue delay. *See- United Rentals (N. Am.) Inc. v. Conti Enterprises, Inc.*, No. 3:15-CV-298 (JCH), 2015 WL 7257864 at *3 (D. Conn. Nov. 17, 2015); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962) (stating that "In the absence of any apparent or declared reason—such as *undue* delay...the leave sought should, as the rules require, be 'freely given.'" (emphasis added)).

For the reasons stated, Relator's Motion to Amend should be granted.

Respectfully submitted this 30th day of May, 2023.

/s/ Tara L. Swafford

[5] Again, diagnoses rendered by a nurse practitioner are not "per se" invalid. Rather, the restrictions imposed by the nurse practitioners' employers and Defendants is what renders the diagnoses invalid. It bears repeating that none of these illicit practices were known outside of Defendants' organization until they were reported to the Government by Relator.

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CERTIFICATE OF SERVICE

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on this 30th day of May 2023.

/s/ Tara L. Swafford
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