UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 10-23382-CIV-MORENO/O'SULLIVAN

OLIVIA GRAVES, on behalf of herself
and the UNITED STATES OF AMERICA,

Plaintiff, Relator,

v.

PLAZA MEDICAL CENTERS, CORP.,
HUMANA, INC., and MICHAEL CAVANAUGH,

Defendant.

_____/

REPORT AND RECOMMENDATION

THIS CAUSE comes before the Court on the Defendant Humana Inc.'s Motion for Summary Judgment and Memorandum of Law in Support Thereof (DE# 630, 10/27/16); the Relator's Motion to Strike or, in the Alternative, Limit the Testimony of Leslie Norwalk (DE# 712, 12/28/16), and the Defendant Humana Inc.'s Motion to Exclude Testimony of Dr. Gerard Anderson (DE# 728, 12/28/16). Pursuant to 28 U.S.C. § 636 and Magistrate Judge Rule 1(C), the Honorable Federico A. Moreno referred this matter to take all necessary and proper action as required by law with respect to any and all pretrial matters. (DE# 134, 1/28/15). Having reviewed the defendant's motion, the plaintiff's response, the defendant's reply, the defendant's supplement, and the United States' statement of interest, as well as the evidence in the record, the undersigned recommends that the Defendant Humana Inc.'s Motion for Summary Judgment and

Memorandum of Law in Support Thereof (DE# 630, 10/72/16) be DENIED for the reasons stated herein.

INTRODUCTION

The defendant, Humana Inc. ("Humana" or "defendant"), seeks summary judgment on the relator's claims based on the False Claims Act (2006) ("FCA") and as amended by the Fraud Enforcement Recovery Act of 2009 ("FERA") in the Fourth Amended Complaint. (DE# 382) The relator asserts five counts against Humana. First, the relator alleges that from 2006 through 2011, Humana submitted to the Centers for Medicare and Medicaid Services ("CMS") false diagnosis codes generated by Dr. Cavanaugh and Plaza Medical Centers and that because of the allegedly false diagnosis codes generated by Plaza Medical Centers, Humana made false statements when it certified the accuracy of the risk adjustment data it submitted to CMS during the same period. Second, the relator asserts that Humana concealed and improperly avoided returning overpayments to the government in violation of the reverse false claims provision of the FCA. The relator's five counts against Humana are based on the same diagnosis codes provided by Plaza Medical Centers. Knowledge is an element of each of the five claims asserted against Humana under the FCA and is the only element raised in the summary judgment.

Humana seeks summary judgment on the ground that the relator has failed to carry her burden in opposition to summary judgment because the evidence does not create a genuine issue of material fact regarding Humana's knowledge. The relator maintains that the record evidence presents a fact question for a jury to determine

whether Humana recklessly disregarded its obligations to certify the truth and accuracy of its submissions to CMS regarding Dr. Cavanaugh's and Plaza Medical Centers' patients and whether Humana knowingly failed to remit overpayments due to the false diagnosis codes it submitted to CMS.

The motion is ripe for disposition.

DISCUSSION

I. Legal Standard

The Court, in reviewing a motion for summary judgment, is guided by the standard set forth in Federal Rule of Civil Procedure 56(a), which states, in relevant part, as follows:

> A party may move for summary judgment, identifying each claim or defense--or the part of each claim or defense--on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56 (a).

The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. The moving party bears the burden of meeting this standard. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). That is, "[t]he moving party bears the initial responsibility of informing the . . . court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." U.S. v. Four Parcels of Real Prop., 941 F.2d 1428, 1437

(11th Cir. 1991) (quoting Celotex, 477 U.S. at 323) (internal quotation marks omitted). In assessing whether the moving party has satisfied this burden, the Court is required to view the evidence and all factual inferences arising therefrom in the light most favorable to the non-moving party. Batey v. Stone, 24 F.3d 1330, 1333 (11th Cir. 1994). Summary judgment is appropriate when there is no dispute as to any material fact and only questions of law remain. Id. If the record presents factual issues, the Court must deny the motion and proceed to trial. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970).

II. Material Issues of Fact Exist as to Humana's Knowledge under the FCA

A. Pertinent CMS Regulations

The Centers for Medicare and Medicaid Services ("CMS") require Medicare Advantage Organizations ("MAOs"), like Humana, to attest to the truth and accuracy of the diagnosis data submitted to CMS and to detect and investigate fraud in the Medicare Advantage ("MA") program. The federal regulations require MAOs to "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse…." 42 C.F.R. § 422.503(b)(4)(vi). Among the minimum core requirements that a compliance program must fulfill is the "[e]stablishment and implementation of an effective system for routine monitoring and identification of compliance risks" that "include[s] internal monitoring and audits." 42 C.F.R. § 422.503(b)(4)(vi)(F). Additionally, MAOs like Humana are required to certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the encounter data submitted. 42 C.F.R. § 422.504(l).

Because risk-adjustment data provides the foundation for payment under Medicare Advantage, and because CMS recognizes that "there is an incentive for MA Organzations ["MAOs"] to potentially over-report diagnoses so that they can increase their payment…," 79 Fed. Reg. 1918, 2001 (Jan. 10, 2014), MAOs are required to expressly "certify (based on best knowledge, information, and belief") that the data they submit, including diagnosis codes, is "accurate, complete, and truthful." 42 C.F.R. §422.504(l)(2). Since 2000, the CMS regulations have clearly stated that the certification requirement imposes upon MAOs "an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted" and that MAOs "will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted." 65 Fed. Reg. 40,170, 40, 268 (June 29, 2000); see Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40,170, 40, 268 (June 29, 2000) (CMS stated that MAOs "will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.") Humana's contract with CMS similarly required its Chief Financial Officer or delegate to attest annually "(based on best knowledge, information and belief, as of the date specified on the attestation form) that the risk adjustment data it submits to CMS under 422.310 are accurate, complete and truthful." Relator's AMF ¶ 2.

Humana and the relator filed cross-motions to strike or limit the testimony of the parties' respective expert witnesses.[1] Humana's expert is Leslie Norwalk, an attorney

[1] The crux of the relator's motion to strike Ms. Norwalk's testimony is that her testimony regarding whether Humana satisfied its obligations to submit accurate risk

and former Acting Administrator for CMS. The relator's expert is Dr. Gerard Anderson, a professor of health and policy and management at Johns Hopkins University with a Ph.D. in Public Policy Analysis, a professor of medicine at the Johns Hopkins University School of Medicine, and director of the Johns Hopkins Center for Hospital Finance and Management, who formerly served as an economist at the U.S. Department of Health and Human Services ("HHS") from 1978-1983. Dr. Anderson disputes Ms. Norwalk's testimony and averred that Humana's compliance programs did not comply with CMS regulations in effect from 2005 to 2011 because they were not actually designed to detect fraud. Id. at ¶ 21; see Anderson Decl. (DE# 667-4, 11/21/16). For purposes of Humana's motion for summary judgment, the undersigned is considering the testimony of both expert witnesses. The undersigned will reconsider the parties' respective motions to exclude or limit expert testimony for trial.

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adjustment data and certify the accuracy of risk adjustment data submissions to CMS exceeds the scope of authorization that she received from HHS pursuant to the "*Touhy*" regulations, published at 45 C.F.R. Part 2. Additionally, the relator contends that Ms. Norwalk's testimony as to Humana's purported compliance with its obligations to detect and prevent the submission of fraudulent risk adjustment data in conjunction with her status as an attorney and role as a former Acting administrator for CMS stamps her testimony with the imprimatur of the Government and cloaks it in "talismanic significance" that would be more prejudicial than probative and creates a high likelihood of confusing the jury. Motion to Strike at 3 (quoting Frazier, 387 F.3d at 1263).

Humana seeks to prevent Dr. Anderson from testifying about the CMS regulatory and compliance requirements for MAOs. Humana "does not contest that Dr. Anderson is qualified to provide expert testimony regarding the general operation of the [Medicare Advantage ("MA")] program and the role of MAOs in that program, including Hierarchical Condition Categories ("HCC") risk adjustment payment mode that CMS uses to calculate risk-adjusted premium payments to MAOs." Humana's Motion to Exclude at 2 (DE# 728, 12/28/16).

B. Knowledge under the False Claims Act

To establish presentment claims under the False Claims Act ("FCA"), the Relator "must prove three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with knowledge that the claim was false." United States ex rel. Walker v. R&F Props. of Lake County, Inc., 433 F.3d 1349, 1355 (11th Cir. 2005). Similarly, to prevail on her false certification claims, the Relator "must prove '(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.'" Urquilla-Diaz, 780 F.3d 1039, 1045 (11th Cir. 2015) (quoting United States ex rel. Hendow v. University of Phoenix, 461 F.3d 1166, 1174 99th Cir. 2006). Knowledge is the requisite scienter for both types of FCA claims. See 31 U.S.C. 3729(1)(a)(A)-(B) (2012); 31 U.S.C. 3729 (a)(1)-(2) (2006) (pre-FERA version of the statute). FCA claims do not require "proof of specific intend to defraud." 42 U.S.C. § 3729(b). "The '*sine qua non* of a False Claims Act violation' is the submission of a false claim to the government." Id. (quoting United States ex rel. Clausen v. Lab Corp. of America, 290 F.3d 1301, 1311 (11th Cir. 2002).

Under the FCA, "knowing" and "knowingly" are defined to mean a person who (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. Urquilla-Diaz, 780 F.3d at 1058 (citing 31 U.S.C. 3729 (b) (2006) which used nearly identical language as the post-FERA version of the statute: 31 U.S.C. 3729(b) (2012)). "Although proof of a 'specific intent to defraud' is not required, … the statute's

language makes plain that liability does not attach to innocent mistakes or simple negligence." Id. (quoting 31 U.S.C. 3729 (b) (2006) and citing United States v. King-Vassel, 728 F.3d 707, 712 (7th Cir. 2013)). "Actual knowledge" requires "subjective" awareness of the falsity of the claim, record, or statement. See, e.g. United States ex rel. Folliard v. Govplace, 930 F. Supp. 123, 130 (D.D.C. 2013) (quoting K&R Ltd. Partnership v. Mass. Hous. Fin. Agency, 456 F. Supp. 2d 46, 61 (D.D.C. 2006), aff'd, 764 F.3d 19 (D.C. Cir. 2014)).

"Congress added the 'reckless disregard' provision to the False Claims Act in 1986" in order "to ensure that 'knowingly' captured 'the ostrich type situation where an individual has buried his head in the sand and failed to make simple inquiries which would alert him that false claims are being submitted.'" Id. at 1058 (quoting S. Rep. 99-345, at 21, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5286). In the Eleventh Circuit, "reckless disregard" requires a showing of an "aggravated form of gross negligence." Urquilla-Diaz, 780 F.3d at 1058. The Eleventh Circuit acknowledged that its sister courts' description of "reckless disregard" was consistent with Black's definition that "'a person acts with reckless disregard 'when the actor knows or has reason to know of facts that would lead a reasonable person to realize' that harm is the likely result of the relevant act.'" Id. (quoting King-Vassel, 728 F.3d at 713 (quoting Black's Law Dictionary 540-41 (9th ed. 2009) (footnote omitted)). "Deliberate ignorance" requires an even higher showing and "plainly demands even more culpability than that needed to constitute reckless disregard." Id. at 1058 n.15. The Eleventh Circuit has explained that "Congress did not intend to turn the False Claims Act, a law designed to punish and deter fraud, …

'into a vehicle either 'punish[ing] honest mistakes or incorrect claims submitted through mere negligence' or imposing 'a burdensome obligation' on government contractors rather than a 'limited duty to inquire.'" Id. (quoting United States v. Sci. Applications Int'l Corp., 626F. 3d 1257, 1274 (D.C. Cir. 2010)(quoting S. Rep. 99-345, at 6, 19, 1986 U.S.C.C.A.N. 5266, 5271, 5284).

Because the relator admits that Humana had no actual knowledge, the relator must prove knowledge by showing that Humana acted with reckless disregard or deliberate ignorance of the falsity of the diagnosis codes that Humana submitted to CMS. See Humana's Motion at 19 (citing SUMF ¶ 136; Appendix Tabs K-22, K-25).

C. Whether Humana Acted with Reckless Disregard of the Falsity of the Claims It Submitted to CMS Presents a Material Disputed Fact

Humana maintains that Humana's compliance processes from 2006 through 2011 refute the Relator's argument that Humana acted with reckless disregard or deliberate ignorance. Motion at 20. Humana argues that there is no dispute that Humana's compliance program met or exceeded all of the relevant CMS requirements. Id. (citing SUMF ¶ 140). Humana contends that no jury could reasonably find that Humana acted with an "aggravated form of gross negligence." Id. (citing Urquilla-Diaz, 780 F.3d at 1057-58).

The relator disputes the conclusory opinion that Humana's compliance program met or exceeded all of the relevant CMS requirements**.** The relator argues that whether Humana complied with its obligations to make "good faith efforts" and to implement an effective compliance program presents fact questions that preclude summary judgment.

The undersigned agrees**.**

1. Whether Humana's Compliance Program Satisfied the Governing CMS Requirements Presents a Material Disputed Fact

> Humana's expert, Leslie Norwalk, states in her expert report that:
>
> CMS imposes two different but related compliance obligations on [Medicare Advantage Organizations ("MAOs")]. First, CMS sets general standards to detect, investigate, and correct fraudulent conduct … Second, CMS separately sets standards for MAOs related to the accuracy of risk adjustment data they submit to CMS … Specifically, CMS requires MAOs to submit qualified attestations of the 'accuracy, completeness, and truthfulness' of risk adjustment data based on the MAOs' "best knowledge, information and belief."

Expert Report of Leslie Norwalk ¶¶ 6-7 (DE # 711-1 Ex. 17). Humana contends that the fact that Humana established a compliance program is enough to prevail, that is, to refute the relator's claim that Humana's conduct constituted reckless disregard. The undersigned disagrees because the evidence in the record raises genuine issues of material fact as to whether the shortcomings of the design and application of Humana's compliance program met the CMS regulations or constituted reckless disregard.

Although the relator does not dispute the existence of Humana's compliance program or Special Investigations Unit ("SIU"), the relator argues that "ample evidence supporting scienter falls into two primary categories: (1) Humana's failure to make 'good faith efforts' to certify the accuracy of its data submissions and maintain an 'effective compliance program' as required by law; and (2) the red flags that Humana ignored at the time and continues to ignore in its Motion." Opposition at 5 (Sealed). The relator's expert, Dr. Anderson, testified that Humana either altogether failed to implement a compliance program actually capable of detecting, investigating, or correcting fraud

(Werner Decl. Ex. 21, ¶¶ 80,95,106, 11-12), or failed to adhere to the few policies it established on paper as part of its purported attempt to create such a compliance program. Werner Decl. Ex. 21, ¶¶ 78, 81, 130.

To prove that Humana acted with reckless disregard, the relator submits evidence of the following: "Humana's system, including its audit procedures, was not designed, intended, or reasonably calculated to detect fraud, and Humana: ignored red flags from Dr. Cavanaugh; ignored its own identification of Plaza Medical Centers as an outlier with respect to its Medicare Risk Adjustment ("MRA") scores; ignored evidence that as many as 35% of codes it audited at Plaza Medical Centers could not be validated; routinely violated its policies and failed to implement even its defective procedures as designed; and policed fraud only when fraud was brought to its attention--yet certified the accuracy of its data submissions to CMS." Relator's Opposition (Sealed) at 2. The relator argues that Plaza Medical Center's fraud did not simply slip through a crack in Humana's compliance system. The relator contends that Humana declined to design or implement any meaningful barriers to fraudulent upcoding whatsoever.

The relator argues that neither of Humana's two forms of oversight related to the submission of risk adjustment data—the Medicare Risk Adjustment ("MRA") Review and Provider Data Validation ("PDV") Review—were designed to detect fraud or upcoding, and were therefore incapable of satisfying Humana's obligations to make "good faith efforts" to certify the accuracy of the data to which it was attesting and maintain an "effective compliance program." Relator's Statement of Additional Material Facts ("AMF") ¶¶ 1-3, 4-6, 12-13 (Sealed) (DE # 16, 11/21/16).

The relator argues that Humana's MRA Reviews did not detect International Classification of Diseases 9 codes ("ICD9 codes") that were unsupported or likely to be unsupported by the medical record, but instead were designed to identify diagnostic codes for submission to CMS that providers may have overlooked. Opposition at 9. The relator argues further that such one-way reviews are compelling evidence from which a reasonable jury could conclude that Humana did not make "good faith efforts" to certify the accuracy of its risk adjustment data and did not have an "effective compliance system." Humana disputes that its reviews were "one-way" because Humana's MRA chart reviews "may result in both modification (additions) and deletions of ICD9 codes." Reply at 10 (quoting DE# 663-6, Ex. 48 at HUM-GRA-009738; see also SUMF App'x E ¶6 (citing evidence that MRA Chart Reviews resulted in correction of erroneous diagnosis codes). In contrast, the relator offers evidence that the MRA Review was designed to identify diagnostic codes for submission to CMS that providers may have overlooked. AMF ¶ 6. Using algorithms to identify specific patients with potentially unreported conditions, the relator argues that the goal of Humana's MRA reviews was to increase the capitated payment received by Humana and its providers. AMF ¶ 7.

Rather than reviewing a patient's lab tests, specialist reports, and underlying medical records, Humana's PDV reviewers relied solely on a physician's progress notes to confirm diagnosis; for chronic conditions, they validated the condition so long as its corresponding ICD-9 code appeared in the progress notes, even if those notes did not identify any confirming evidence or treatment plans for the diagnosed condition. AMF ¶ 11.

Humana's PDV and MRA reviewers did not look for fraud, did not understand fraud detection to be a job responsibility, and did not discuss fraud in training. Jane Hebberd, a front-line Coding Facilitator of Humana responsible for conducting PDV audits of providers including Plaza Medical Centers admitted that fraud detection was not part of her job responsibility, that fraud was not discussed during her training, and even that she was not aware that Humana's Special Investigations Unit ("SIU"), the department charged with investigating fraud, existed. Relator's AMF (Sealed) ¶ 12. Elizabeth Zaccharia, now Humana's Manager of MRA Operations, previously performed PDV Reviews of Plaza Medical Centers, testified that she was unaware of any tools given to Humana associates to assist in finding fraud. Id. She also admitted that although Humana associates are taught during an ethics training to report fraud to a telephone number known as Humana's ethics hotline, "[w]e don't do any specific training for fraud." Ms. Zaccharia was also unaware of any Humana reviews that had the "goal" of "going after fraud." Id.; Opposition (Sealed) at 11. Humana complains that the relator "cherry picked" this testimony in light of the policies and procedures Humana had in place to satisfy CMS regulations.

Humana contends that it had a robust compliance system that included: (1) a Chief Compliance Officer with over 20 years of experience and a Compliant Committee that included a Medicare and Medicaid Compliance Officer; 2) dozens of policies, including Humana's internal and external Principles of Business Ethics, Provider Manuals, and Anti-Fraud Plans; 3) Annual Ethics training regarding fraud in addition to specific risk-adjustment ethics training and SIU publications on common fraud schemes;

4) fraud reporting hotlines including the Ethics Help Line; and 5) dedicated investigative resources such as SIU and the Law Department that investigated allegations of wrongdoing. Reply at 5 (citing SUMP App'x B ¶ 1, B-1 to B-2, B-18 to B-64, B-78 to B-87, C-1 to C-15, C-34 to C-35, D-2 to D-7, E-6 to E-11, G-1 to G-2).

In her Opposition, the relator submits evidence that would allow a reasonable jury to find that Humana's general anti-fraud plan was not reasonably designed or utilized to detect fraud. Although Humana has an SIU tasked with "detecting, preventing, and investigating" many types of fraud, the SIU does not engage in any proactive measures to detect fraud. AMF (Sealed) ¶ 12. Rather, the SIU investigates potential fraud only after an individual identifies "something out of the norm for their area" and reports it. Id. at ¶ 15. Debra Rollins, who for thirty years managed a network of more than 600 healthcare providers in South Florida, was not aware of a single case involving a provider's submission of false diagnoses. Id. at ¶ 17. Additionally, Humana's Internal Audit Department, which was responsible for "assist[ing] in the investigation of all significant, suspected fraudulent activities within Humana and notify[ing] management and the audit committee of the results," had no procedures to detect and investigate fraud relating to the submission of risk adjustment data. Id. at ¶¶ 18-19. Ed Henry, Humana's Manager of Finance who has worked for Humana in South Florida for more than 17 years, testified that he never suspected a provider of committing fraud. Id. at ¶ 17, 22. Despite numerous red flags, the SIU never conducted an investigation into Dr. Cavanaugh or Plaza Medical Centers between 2006 and 2011. Id. at ¶¶ 22-34.

The red flags include the following: Dr. Cavanaugh's response "Good, I am trying to buy that house based on MRA scores" when he learned that his MRA scores were actually higher than what he thought in correspondence in 2009 with Humana; Humana's head of Finance, Ed Henry, acknowledged that it was "a crazy thing to put in an email," and attempted to dismiss it as a "poor joke" in his deposition (Id. at ¶ 22); in June 2007, Dr. Cavanaugh expressed excitement to Humana executives over the "good MRA scores" of a new patient who was a former NFL football player (Id. at ¶ 23); in January 2009, Dr. Cavanaugh told Humana that high MRA scores made his business partner Spencer Angel "very happy" and that he hoped to "make [Angel's] month" upon receipt of high scores from Humana. Humana responded it "will have good news for him" (Id. at ¶ 24); most Humana providers do not know their MRA scores as well as Dr. Cavanaugh (Id. at ¶ 26); Dr. Cavanaugh also told Humana he would administer spirometry testing to every patient to increase MRA scores "enough to pay off the [spirometry] machines in triples" (Id. at ¶ 25); Plaza Medical Centers MRA scores were in the top 5 percent in Dade County and Humana considered it an "outlier" (Id. at ¶ 27); Terry Smith, Humana's President of Medicare and Medicaid Products for South Florida, believed that Plaza Medical Centers had a disproportionate share of "high-risk" diabetics as patients (Id. at ¶ 28); between 2008 and 2011, Plaza Medical Centers' validation rates were below Humana's threshold of 90% in 3 or 4 PDV Audits (Id. at ¶ 29); Plaza Medical Centers' rates of invalidity were 20% in 2008, 35% in 2010, and 22% in 2011 (Id. at ¶ 30); the audits revealed the same violations year after year, most notably lack of support in the medical records for the diagnosed condition (42 of 116 codes invalid), which resulted in

instructions from Humana to "support all diagnoses" and implement "compliance and practice standards" (Id. at ¶ 31); Humana failed to conduct re-reviews in contravention of its own internal procedures (Id. at ¶ 32); Humana never reported Plaza Medical Centers' repeated errors to the SIU or otherwise flag Plaza Medical Centers for additional scrutiny as a result of these errors, rather Humana stopped auditing Plaza Medical Centers altogether in 2011 because it was purportedly "doing great" (Id. at ¶ 33); and during the relevant timeframe, Humana did not undertake any investigations or analyses into Plaza Medical Centers' or Dr. Cavanaugh's fraud (Id. at ¶ 34).

The evidence in the record raises genuine issues of material fact as to whether the false submissions that Humana made to CMS based on Plaza Medical Centers and Dr. Cavanaugh constituted reckless disregard under the FCA.

2. Ambiguous Terms in the CMS Regulations

Humana contends that "effective" and "good faith" are ambiguous terms and that the relator fails to cite any CMS guidance regarding their definitions let alone warn Humana away from its interpretation of the governing regulations. Reply (Sealed) at 1. Humana argues that "[a] *qui tam* defendant is entitled to summary judgment if it had an objectively reasonable interpretation of an ambiguous regulation and the relator has offered no proof that the government issued authoritative guidance warning the defendant away from its interpretation." Id. at 1, 7-8 (citing United States ex rel. Purcell v. MWI Corp., 807 F.3d 281, 286-91 (D.C. Cir. 2015)); see Phalp v. Lincare Holdings, Inc., 116 F. Supp. 3d 1326, 1359 (S.D. Fla. 2015) (explaining that "'even if a defendant submits a false claim, if the defendant's interpretation of a statute or regulation was

reasonable, and if there is no authoritative contrary interpretation of the rule, the relator cannot satisfy the knowledge requirement under the False Claims Act.'" (quoting United States ex rel. Parker v. Space Coast Med. Associates, LLP, 94 F. Supp. 3d 1250, 1262 (M.D. Fla. 2015) (collecting cases) (internal quotations omitted)); see United States ex rel. Donegan v. Anesthesia Associates, 833 f.3d 874 (8th Cir. 2016) (affirming summary judgment in favor of defendant on an FCA claim because the record evidence did not provide any meaning for the ambiguous regulatory term at issue).

The relator relies on the CMS regulations found in 42 C.F.R. § 422.504(l)(2) and 42 C.F.R. § 422.503(b)(4)(vi)) that respectively require an MAO like Humana 1) make good faith efforts to certify the accuracy of its data submissions, and 2) maintain an effective compliance program.[2] Opposition 5-7. Additionally, the relator relies on the Ninth Circuit's Swoben decision that rejected the defendant's arguments that the CMS regulations were ambiguous and that the defendant's interpretation was objectively reasonable due to CMS' clear, authoritative guidance that requires MAOs "to undertake 'due diligence' to ensure the accuracy, completeness and truthfulness of encounter data submitted to CMS." Swoben, 832 F.3d at 1099 (citing Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 158 (1982)) "[A]mbiguity alone [does] not shield claimants from FCA liability." United States ex rel. Fox RX, Inc. v. Omnicare Inc., No. 1:11-cv-

[2] Since 2000, the CMS regulations have clearly stated that the certification requirement imposes upon MAOs "an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted" and that MAOs "will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted." Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40,170, 40, 268 (June 29, 2000).

00962-WSD, 2012 WL 8020674, at *9 (N.D. Ga. Aug. 29, 2012) (explaining that ambiguity of regulatory provision "could create an issue of fact as to the defendant's knowledge" under the Eleventh Circuit's decision in Walker and "ambiguity in Part D's coverage of 'off-label' drugs could serve as evidence relevant to Defendants' knowledge of falsity, but does not serve to discredit Relator's *prima facie* allegation of a false claim"). In Universal Health Services, Inc. v. United States, the Supreme Court explained that although "'Congress did not define what makes a claim 'false' or 'fraudulent' [under the FCA] … [i]t is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses.'" Universal Health Services, Inc. v. United States, 136 S. Ct. 1989, 1999 (2016) (quoting Sekhar v. United States, 133 S. Ct. 2720, 2724 (2013)).

In reversing a summary judgment in favor of a defendant on a FCA claim, the Eleventh Circuit held that "any evidence outside the language of a Medicare regulation (including guidance issued by the governmental agency charged with administering the regulatory scheme) can be consulted to understand the meaning of [an ambiguous regulation]." Walker v. R&F Properties of Lake County, Inc., 433 F.3d 1349, 1357 (11th Cir. 2005). "The Supreme Court has held that agency interpretations are 'entitled to respect … to the extent that those interpretations have the power to persuade.'" Id. (quoting Christensen v. Harris County, 529 U.S. 576, 587 (2000)(citation omitted)).

CMS regulations obligated Humana to exercise "due diligence" and "good faith efforts" to certify the accuracy, completeness, and truthfulness of encounter data that Humana submitted to CMS. The CMS requires that MAOs must implement a

compliance program that detects and prevents fraud, waste and abuse. The relator's evidence presents a fact question as to whether Humana satisfied its CMS obligations or not which goes to the issue of whether Humana recklessly disregarded the falsity of the claims it submitted on behalf of its providers, Plaza Medical Centers and Dr. Cavanaugh.

3. Humana Is Not Entitled to Summary Judgment

Humana contends that "absent evidence that Humana was on notice of alleged fraud, allegations that Humana did not precisely follow its own compliance program—the existence of which negates a finding of the requisite scienter—do not establish the knowing submission or certification of allegedly false diagnosis codes in violation of the FCA." Motion at 23. The relator argues that if Humana's position was true, the defendants could always avoid FCA liability simply by implementing a "compliance program," no matter how ineffectual. The relator's expert avers that "[a]lthough minor lapses in policy may be excused, the record evidence here indicates systematic failure to adhere to internal policies, rendering these policies entirely ineffective as … fraud detection measures." Anderson Declaration at ¶ 140 (DE# 663-1).

Humana complains that the relator and her economist "expert never once direct the Court to evidence proving that CMS would endorse her contentions that the alleged defects in Humana's compliance program render that program ineffective or that its data validation efforts were the product of bad faith." Reply at 2. Humana states that the relator "does not contest that Humana maintained data validation and Medicare compliance programs" or that "these programs satisfied the relevant CMS regulatory requirements." Id.

Humana cites United States ex rel. Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103, 110 (3d Cir. 2007) and Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1061-62 (11th Cir. 2015) for the proposition that system failure alone does not establish reckless disregard. In Urquilla-Diaz, the Eleventh Circuit affirmed the entry of summary judgment in favor of the defendant on a False Claims Act because the Court found that the relator's record evidence that an employee modeled Kaplan's policies after those that complied with regulations implementing the ADA rather than the Rehabilitation Act to be immaterial and thus, did not create a fact issue as to reckless disregard. Id. at 1061. The Court explained that "the evidence does not create a jury question about whether [Kaplan] acted with actual knowledge or the aggravated form of gross negligence needed to show scienter under the False Claims Act…." Id. at 1057. The Eleventh Circuit also found that the relator did not submit record evidence to show that an employee who relied on the work of subordinates and "signed the 2004 program participation agreement without independently and specifically verifying that Kaplan's policies complied with the Rehabilitation Act and its implementing regulations" was unreasonable under the circumstances. Id. The Eleventh Circuit rejected the plaintiff's "personal, hypercritical assessments of [two critical employees'] job performance" and concluded that the plaintiff "fail[ed] to identify anything in the record that would allow a reasonable jury to conclude that Kaplan executed the 2004 program participation agreement with reckless disregard for whether its policies violated … the Rehabilitation Act or its implementing regulations." Id. at 1059. In Urquilla-Diaz, the Eleventh Circuit determined that the relator failed to present a jury question due to his "lack of evidence

and Kaplan's robust compliance system that relies upon multiple employees as well as the independent advice of outside counsel" and that Kaplan's "actions contradict [the plaintiff's] contention that Kaplan's compliance certification was made with reckless disregard for the truth." Id. at 1062.

Humana argues that like the defendant in Urquilla-Diaz, Humana has a "robust compliance system" and it is entitled to summary judgment because the relator cannot present a genuine issue of material fact as to whether Humana recklessly disregarded the truth and accuracy of its certification when it submitted false diagnostic codes provided by Dr. Cavanaugh and Plaza Medical Centers to CMS. Humana argues that the relator "cites selectively from a few depositions to leave the misimpression that Humana failed to train employees on the detection of fraud and implemented a compliance program that was only reactive to complaints. But the full record shows otherwise." Reply (Sealed) at 2 (DE# 670, 12/1/16). It is not the Court's role to weigh evidence on summary judgment, but to determine whether any genuine issue of material fact exists. Additionally, the facts are to be construed in the non-movant's favor.

The relator relies upon the Ninth Circuit's decision in United States ex rel. Swoben v. United Healthcare Ins. Co., 832 F.3d 1084, 1098-99 (9th Cir. 2016), amended __ F.3d , 2016 WL 7378731 (9th Cir. December 16, 2016), which held that the CMS guidance is (a) "authoritative" because "it provided clear guidance to [MAOs] … regarding their obligations under [42 C.F.R.] § 422.504(l);" (b) created an affirmative obligation to "undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of *encounter data* [i.e. risk adjustment data] submitted to [CMS];" and (c) imposed an

affirmative obligation to make "good faith efforts to certify the accuracy, completeness and truthfulness of *encounter data* submitted." Id. (citing 65 Fed. Reg. 40,248 (guidance preamble) (emphasis in original)). MAOs are also required to "implement an effective compliance program, which must include measures that … prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. § 422.503(b)(4)(vi). In Swoben, the Ninth Circuit vacated and reversed the district court's dismissal of Swoben's third amended complaint without leave to amend. The Ninth Circuit found that Swoben's theory – "that the defendants designed their retrospective review procedures to not reveal unsupported diagnosis codes, allegedly for no other reason than to avoid reporting that information to the government-- states a cognizable legal theory under the False Claims Act." Swoben, 2016 WL 7378731, at *9. "[W]hen [MAOs] design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS," "especially … when … they were on notice that their data included a significant number of erroneously reported diagnosis codes." Swoben, 832 F.3d at 1096.

On summary judgment, the Court does not weigh the evidence or determine credibility of witnesses. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). The undersigned finds that the record evidence presents genuine issues of material fact for a jury to determine whether the relator can prove that Humana had the requisite scienter, that is "reckless disregard," for FCA liability and whether Humana failed to undertake

measures constituting a "good faith effort" to certify the truth and accuracy of its submissions to CMS and to maintain an effective compliance plan to detect and correct fraud. Because there is sufficient evidence in the record upon which a reasonable jury could find for the non-moving party, the relator, this Court should deny Humana's motion for summary judgment.

III. Reverse False Claims Act - "Retention of Overpayments" (Count X)

The reverse false claims provision imposes liability on anyone who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. 3729(a)(1)(G). "Knowingly" is defined to include "actual knowledge of the existence of the overpayment." 31 U.S.C. 3729(b)(1)(a); 79 Fed. Reg. 29,843, 29,920 (May 23, 2014). In its supplement, Humana cites United States ex rel. Harper v. Muskingum Watershed Conservancy Dist., No. 15-4406, __ F.3d. __, 2016 WL 6832974 (6th Cir. Nov. 21, 2016), which is the first Circuit Court of Appeals to interpret in depth the "knowledge" requirement in the current version of the FCA's reverse false claim provision. In Harper, the Sixth Circuit determined that "'knowingly' must be interpreted to refer to a defendant's awareness of both an obligation to the United States and his violation of that obligation." Id. at *4. In Harper, the Sixth Circuit affirmed the dismissal of the relators' *qui tam* complaint because they failed to allege that the defendant "knowingly" avoided an obligation to transmit property to the United States. Id.

An "obligation" includes "an established duty … arising from … the retention of any overpayment," 31 U.S.C. § 3729(b)(3), including "any overpayment [from Medicare]

retained by a person after the deadline for reporting and returning an overpayment." 79 Fed. Reg. 29,843, 29,918 (May 23, 2014). An "overpayment" is defined as "any funds that a person receives or retains under [the Medicare and Medicaid statutes] to which the person, after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B).

The Patient Protection and Affordable Care Act of 2010 ("ACA") requires a person who receives an overpayment of Medicare or Medicaid funds to report and return the overpayment within 60 days of the date on which the overpayment was identified. 42 U.S.C. § 1320a-7k(d)(1)-(2). "[T]he sixty day clock begins ticking when the provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained, which is compatible with the legislative history of the FCA and the FERA." Kane ex rel. United States v. Healthfirst, Inc., 120 F. Supp. 3d 370, 388 (S.D.N.Y. 2015). In United States ex rel. Keltner v. Lakeshore Medical Clinic, Ltd., No. 11-CV-00892, 2013 WL 1307013, at *4 (E.D. Wisc. March 28, 2013), the court determined that the relator "state[d] a plausible claim for relief under the amended reverse false claim provision of the FCA for overpayments withheld after May 20, 2009. The court explained that "[i]f the government overpaid defendant for … services and defendant intentionally refused to investigate the possibility that it was overpaid, it may have unlawfully avoided an obligation to pay money to the government." Id. at *4 (E.D. Wisc. March 28, 2013).

The 2014 CMS regulation implementing the 60-day provision of the ACA provides that an MAO "has identified an overpayment when [the entity] has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an

overpayment." 42 C.F.R. § 422.326(C); see United States v. Crumb, No. CV 15-0655-WS-N, 2016 WL 4480690, at *17 (S.D. Ala. Aug. 24. 2016). "[R]easonable diligence" includes "proactive compliance activities … to monitor for receipt of payments." 79 Fed. Reg. 29,843, 29, 923 (May 23, 2014). The relator acknowledges, as the United States did in its Amicus Brief (Dkt No. 68) in United States ex rel. Swoben v. United States Healthcare Insurance Co., No. 13-56746 (9th Cir. 2016), that "[a]lthough some of the conduct alleged here predates the enactment of the [ACA] and all of the conduct predates the promulgation of CMS's implementing regulation, these statutory and regulatory overpayment provisions are instructive as to what Congress intended in enacting the reverse-false-claims provision."

In its Motion, Humana does not contest the presentment of false claims to CMS and does not contest that such submissions resulted in overpayments to Humana. See Motion at 18 n.40. Instead, Humana disputes that it had knowledge of overpayments and/or knowingly failed to return them within 60 days from when they were identified. Humana contends that its "voluntary cooperation with DOJ's investigation of Relator's allegations precludes a finding that Humana 'knowingly concealed' or 'knowingly and improperly avoided' the return of alleged overpayments." Motion at 29.

The relator contends that the evidence in the record presents a fact question as to whether Humana recklessly disregarded or deliberately ignored overpayments as early as 2010, that is before the complaint was unsealed, and improperly retained those funds until 2016. Opposition at 21. The relator relies on Humana's November 2010 PDV Review of Plaza Medical Centers which determined that 35% of the 178 audited

diagnostic codes, all of which were previously submitted to CMS, were invalid. AMF ¶ 37. The relator argues that this audit alone revealed that Humana had received overpayment for some, if not all, of the 63 invalid diagnostic codes that Humana identified during the November 2010 audit. Humana waited until February 2016 to submit code deletions for nearly all of those invalidated codes, rather than calculating the resulting overpayments and returning the funds to CMS as it was required to do to avoid liability under 31 U.S.C. § 3729(a)(1)(G). AMF ¶ 37.

Throughout 2010 and 2011, Plaza Medical Centers submitted "Condition and Error Reports" to Humana for certain erroneous codes, which previously had been submitted by Humana to CMS. AMF ¶ 35. Paragraph 35 of the relator's Additional Material Facts cites Exhibit 35 to Mr. Werner's Declaration and paragraphs 15 through 17 of Mr. Farber's Declaration as well as Exhibit 2 thereto. Exhibit 2 is a spreadsheet created by Mr. Farber that contains information from Plaza Medical Center's Condition and Error ("C&E") Reports that it provided to Humana to notify Humana that a certain diagnosis code for a given patient was reported to Humana in error. Mr. Farber averred that "code deletions for 83 codes (highlighted in yellow [on Exhibit 2]) were not timely submitted by Humana after receipt of corresponding Plaza [Medical Centers] C&E Reports." Farber Declar. ¶ 23. Mr. Farber stated further that Humana delayed between three to six years from the date Plaza [Medical Centers] submitted these C&E Reports to submit the required code deletions to CMS. Of these, Humana still has not submitted code deletions for 22 codes for which Plaza [Medical Centers] submitted C&E Reports." Id. Although Humana would have every reason to believe it received overpayments for

these codes from CMS, Humana did not calculate the resulting overpayment or return the funds to CMS. Instead, Humana waited years to submit some of the code deletions to CMS or still has not done so. AMF ¶ 36.

Humana contends that the relator's position that "Humana's mere receipt of the partially unsealed complaint equates to Humana's 'identification' of overpayments,' triggering the 60-day deadline to return such overpayments to CMS" is novel, extreme and not endorsed by any federal court. Motion at 27. The relator disagrees and argues that Humana identified and had knowledge of overpayments even before it received the partially unsealed complaint in 2012. In its discovery response, the relator expressly stated that "Humana became aware of the Overpayments … no later than the time it received the Initial Unsealed Complaint in this Lawsuit" and that Humana "may have" and "should have been aware of the Overpayments at an earlier date." Humana's App'x, Tab K-26 (DE# 632-65).

The relator also relies on the red flags discussed above that should have alerted Humana to investigate whether it had submitted unsupported codes and received corresponding overpayments as a result. Humana did not investigate or analyze Plaza Medical Centers and Dr. Cavanaugh for fraud during the relevant period. AMF ¶ 34. Even after receiving a copy of the relator's complaint in January 2012, Humana did not undertake any investigation. Instead, any investigation of Plaza Medical Centers and Dr. Cavanaugh by Humana that occurred after 2011 was at the direction of Humana's counsel. The evidence in the record presents a fact question for a reasonable jury to determine whether Humana had knowledge of and knowingly retained overpayments for

improper diagnostic codes that were submitted to CMS. The relator contends that Humana's MRA Reviews were similar to the one-sided reviews in Swoben that in practice only captured under-reporting errors that would identify additional diagnosis codes and lead to an increase in payments from CMS. In Swoben, the Ninth Circuit explained that when an MAO designs reviews that either avoid or conceal over-reporting errors, a lack of diligence and an absence of good faith exist. Swoben, 2016 WL 7378731, at *10.

A. Cooperation with DOJ Investigation Does Not Immunize Humana from Liability

Humana contends that its cooperation with the Department of Justice's ("DOJ") investigation of relator's allegations absolves it from reverse false claim liability. Motion at 29-30. Humana maintains that its lack of independent investigation into Plaza Medical Centers and Dr. Cavanaugh was justified because: 1) the government declined to intervene; and 2) neither CMS nor DOJ told Humana to investigate its overpayments. The relator argues that Humana's duty to investigate is independent of the DOJ's investigation. See Crumb, 2016 WL 4480690, at *16 (denying defendants' motion to dismiss in part because "even in 2014, when [defendants] knew the Government was conducting FCA investigations into [defendants'] alleged false claims … defendants 'failed to take any corrective or repayment action'" and, by 2015, had only made partial payments).

The United States decision not to intervene in an FCA case "is not probative of any matter concerning the merits of relator's claims." United States ex rel. Feldman v. van Gorp, No. 03 CIV8135 (WHP), 2010 WL 2911606, at *2 (S.D.N.Y. July 8, 2010).

"Because the government may have a host of reasons for not pursuing a claim, courts do not assume that … [when] the government declines intervention in an FCA case, it does so because it considers the evidence of wrongdoing insufficient or the *qui tam* relator's allegations [of] fraud to be without merit." Id. (internal quotations omitted).

CMS' failure to respond to Humana's letter regarding potentially unsupported risk adjustment data previously submitted by Humana to CMS does not prove that CMS excused or approved Humana's failure to remit overpayments to the government. See, e.g., Southern Stone Co. v. Singer, 665 F. 2sd 698, 703 (5th Cir. 1982) ("[M]ere failure to respond to a letter does not indicate an adoption unless it was reasonable under the circumstances for the sender to expect the recipient to respond and correct erroneous assertions.). Given CMS's "good faith" and "due diligence" mandate to ensure the accuracy of the encounter data MAOs submit to CMS, Humana could not reasonably interpret CMS' silence as condoning total inactivity in response to suspected fraud. The federal regulations obligate MAOs to exercise reasonable diligence, including "proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." 79 Fed. Reg. 29,923 (May 23, 2014).

Construing the evidence in the record in the light most favorable to the relator as non-movant, the undersigned finds that genuine issues of material fact exist as to whether Humana is alternatively liable for its knowledge of overpayments and its failure to return the overpayments to the government. Humana received Condition and Error Reports from Plaza Medical Centers during 2010 and 2011 that identified certain erroneous codes that were submitted to CMS. Humana did not timely submit 83 code

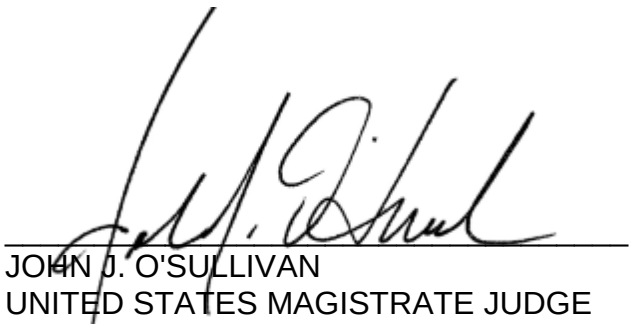
deletions to CMS. Humana delayed between 3 and 6 years from the date Plaza Medical Centers provided the C&E Reports to submit the required code deletions to CMS. As of November 2016, Humana still had not submitted code deletions for 22 codes identified on the C&E Reports to CMS. See Farber Decl., Ex. 2 (AMF ¶35). The evidence in the record presents a genuine issue of material fact as to Humana's scienter regarding retention of overpayments due to erroneous code submissions. The Court should deny Humana's motion for summary judgment on the reverse false claims count.

RECOMMENDATION

Based on the foregoing, the undersigned respectfully **RECOMMENDS** that the Defendant Humana Inc.'s Motion for Summary Judgment and Memorandum of Law in Support Thereof (DE# 630, 10/72/16) be DENIED.

The parties will have fourteen (14) days from the date of being served with a copy of this Report and Recommendation within which to file written objections, if any, with the Honorable Federico A. Moreno, United States District Judge. Failure to file objections timely shall bar the parties from a *de novo* determination by the District Judge of an issue covered in the Report and shall bar the parties from attacking on appeal unobjected-to factual and legal conclusions contained in this Report except upon grounds of plain error if necessary in the interest of justice. See 28 U.S.C. § 636(b)(1); *Thomas v. Arn*, 474 U.S. 140, 149 (1985); *Henley v. Johnson*, 885 F.2d 790, 794 (1989); 11th Cir. R. 3-1 (2016).

RESPECTFULLY SUBMITTED in Chambers at Miami, Florida, this **27th** day of February, 2017.



JOHN J. O'SULLIVAN
UNITED STATES MAGISTRATE JUDGE

Copies provided:
United States District Judge Moreno
All Counsel of Record