APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 18-3298

UNITED STATES OF AMERICA AND STATE OF NEW JERSEY EX REL. VICTORIA DRUDING; BARBARA BAIN; LINDA COLEMAN; RONNI O'BRIEN,

Appellants,

v.

CARE ALTERNATIVES,

Appellee.

Argued: Sept. 10, 2019
Filed: Mar. 4, 2020

Before: HARDIMAN, GREENAWAY, JR. and BIBAS, *Circuit Judges*.

OPINION

GREENAWAY, JR., *Circuit Judge*.

This case requires us to consider whether and when clinical judgments can be considered "false" in the context of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733 (2009). It is a matter of first impression in this Court.

Victoria Druding, Linda Coleman, Barbara Bain, and Ronni O'Brien (collectively, "Appellants"), each of whom is a former employee of Appellee Care Alternatives, brought this FCA action alleging that Care Alternatives admitted patients who were ineligible for hospice care and directed its employees to improperly alter those patients' Medicare certifications to reflect eligibility. In support of their position, Appellants retained an expert. The expert opined in his report that, based on the records of the forty-seven patients he examined, the patients were inappropriately certified for hospice care thirty-five percent of the time.

Care Alternatives' expert disagreed and testified that a reasonable physician would have found all of the patients reviewed by Appellants' expert hospice-eligible on each occasion that Appellants' expert had deemed certification inappropriate. In considering Care Alternatives' summary judgment motion, the District Court determined that a mere difference of opinion between experts regarding the accuracy of the prognosis was insufficient to create a triable dispute of fact as to the element of falsity. In fact, the District Court required Appellants to instead provide evidence of an objective falsehood. Upon finding Appellants had not adduced such evidence, the District Court granted summary judgment in favor of Care Alternatives.

Today, we reject the District Court's objective-falsehood requirement for FCA falsity. Since we find that Appellants' expert testimony created a genuine dispute of material fact as to falsity, we will vacate the judgment and remand to the District Court for further proceedings consistent with this opinion.

I. BACKGROUND

Care Alternatives provides hospice care to patients throughout New Jersey. It employs a team of clinicians known as "interdisciplinary teams," ("IDTs") consisting of registered nurses, chaplains, social workers, home health aides, and therapists working alongside independent physicians who serve as hospice medical directors. The IDTs meet twice a month to review patient care plans and to identify any particular needs as well as discuss patients who are up for recertification of their need for hospice care.

Appellants are former employees of Care Alternatives, many of whom were clinicians that participated in IDTs. They brought this action under the FCA alleging, among other things, that Care Alternatives admitted ineligible patients and directed its employees to alter Medicare certifications to increase the number of eligible patients.

Before reaching the essential question of whether expert testimony may suffice to generate a genuine dispute as to a Medicare claim's falsity, we will review the requirements that hospice care providers must meet to qualify for Medicare reimbursement and the circumstances leading to this appeal.

A. Medicare Hospice Benefit

In 1983, Congress established the Medicare Hospice Benefit ("MHB"). *See* 48 Fed. Reg. 56,008 (Dec. 16, 1983) (codified at 42 C.F.R. pts. 400, 405, 408, 409, 418, 420, 421, 489). This regulation expanded the Health and Human Services Secretary's statutory authority to reimburse contractors that provide hospice care to eligible persons. 42 U.S.C. §§ 1395h (2006), 1395kk-1 (2015). Hospice care is considered

palliative care, meaning it is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering." 42 C.F.R. § 418.3 (2019). It aims to "mak[e a terminally ill] individual as physically and emotionally comfortable as possible." 48 Fed. Reg. at 56,008. A patient who has been certified as eligible for hospice care and elects to receive the MHB waives the right to Medicare payment for "curative" care that is designed to help improve the individual's condition. *See* 42 U.S.C. § 1395d(d)(2)(A) (2005); 42 C.F.R. § 418.24(e) (2019); 72 Fed. Reg. 50,452, 50,452 (Aug. 22, 2014).

The Medicare provisions that set forth the conditions for payment of the MHB require that an individual be certified within a ninety-day period by one or more physicians as terminally ill. 42 U.S.C. § 1395f(a)(7)(A)(i). The patient must also be recertified in a similar manner for each additional sixty- or ninety-day period during which he or she remains in hospice care.[1] *Id.* § 1395f(a)(7)(A)(ii). An individual is

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[1] In relevant part, the statute states that:

> payment for services furnished an individual may be made . . . only if . . . in the case of hospice care provided an individual—
>
> (A)(i) in the first 90-day period—
>
> (I) the individual's attending physician . . . , and
>
> (II) the medical director . . . of the hospice care program providing (or arranging for) the care, each certify in writing at the beginning of the period, that the individual is terminally ill . . . based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness, and
>
> (ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the

considered "terminally ill" when the individual has a medical prognosis that the individual's life expectancy is six months or less, if the illness runs its normal course. *Id.* § 1395x(dd)(3)(A) (2018); 42 C.F.R. § 418.3.

Regulations promulgated by the Secretary add another requirement. *See* 42 C.F.R. § 418.20. The regulations provide that, "[i]n order to be eligible to elect hospice care under Medicare, an individual must be . . . (b) Certified as being terminally ill in accordance with § 418.22." *Id.* Section 418.22, in turn, imposes certain obligations on hospices regarding the timing, content, and source of a certification, in addition to a maintenance-of-records requirement. Among these is the requirement that

> [c]linical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

§ 418.22(b)(2) (2011).

Therefore, in order for a patient to be eligible to receive the MHB and for a hospice provider to be entitled to bill for such benefits, an individual's

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> beginning of the period that the individual is terminally ill based on such clinical judgment . . .

§ 1395f(a)(7)(A); *see also* § 1395f(a)(7)(B)-(E) (providing the other statutory prerequisites).

certification of terminal illness must be signed by at least one physician, and be accompanied by "[c]linical information and other documentation that support the medical prognosis" of terminal illness in the medical record. *Id.* Indeed, while the Center for Medicare & Medicaid Services, the agency responsible for administering health benefits, has recognized that "making a prognosis is not an exact science," it has explained that this inexactitude "does not negate the fact that there must be a clinical basis for a certification[:] [a] hospice is *required* to make certain that the physician's clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course." 79 Fed. Reg. at 50,470 (emphasis added); *see also* 70 Fed. Reg. 70,532, 70,534-35 (Nov. 22, 2005) ("A hospice needs to be certain that the physician's clinical judgment can be supported by clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course. A signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare.").

B. Factual and Procedural Background

Appellants brought this suit under the *qui tam* provision of the FCA, which encourages actions by private individuals, called relators, who are entitled to a portion of the amount recovered, subject to certain limitations. *See* 31 U.S.C. § 3730(b), (d). Pursuant to the *qui tam* provision, Appellants filed their complaint under seal and provided the Government with the

information upon which they intended to rely so that the Government could make an informed decision as to whether it should intervene and take over the case. *Id.* § 3730(b)(2). Appellants alleged that Care Alternatives submitted false hospice-reimbursement claims to Medicare and Medicaid between 2006 and 2007, in violation of the FCA, which finds liable any person who knowingly submits to the United States a false claim for payment or approval. 31 U.S.C. §§ 3729(a)(1)(A), 3730(b)(1).

Seven years after the complaint was filed, the Government notified the District Court of its decision not to intervene in this action. Appellants opted to proceed independently and served the First Amended Qui Tam Complaint upon Care Alternatives.

During discovery, the parties produced extensive evidence addressing whether Care Alternatives admitted ineligible patients. This included dueling expert opinions. Appellants' expert, Dr. Jayes, prepared a report as to whether patient certifications were accompanied by supporting documentation. He examined the records of forty-seven patients and opined that the documents did not support a certification of need for hospice in thirty-five percent of these patients' hospice certification periods. In his view, for those periods, any reasonable physician would have reached the conclusion he reached. He also found that the medical records were incomplete for at least three patients.

Care Alternatives' expert, Dr. Hughes, disagreed. For each certification that Dr. Jayes reviewed, Dr. Hughes opined that a physician could have reasonably

determined that the prognosis for each patient was six months or less.

Care Alternatives moved for summary judgment arguing that Appellants could not make out the four prima facie elements of a claim under the FCA: falsity, causation, knowledge, and materiality.[2] *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). Most relevant to this appeal were Care Alternative's arguments that Appellants had not produced sufficient evidence of falsity. The Government submitted a statement of interest urging the District Court to reject the argument that the FCA requires evidence of an "objective falsehood."

The District Court granted summary judgment to Care Alternatives based solely on failure to show falsity. Relying on two district court decisions from Alabama and Texas, it rejected the Government's assertions and held that a "mere difference of opinion between physicians, *without more*, is not enough to show falsity." *Druding v. Care Alternatives, Inc.*, 346 F. Supp. 3d 669, 685 (D.N.J. 2018) (emphasis in original) (internal citation omitted). In doing so, it relied on the premise that medical opinions are subjective and cannot be false. *Id.* (quoting *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355

[2] Care Alternatives had also moved to dismiss the amended complaint for failure to comply with the statutory requirements of 31 U.S.C. § 3730(b)(2), which, among other things, requires a relator to submit a "written disclosure of substantially all material evidence and information the person possesses" in order for the Government to decide whether it will intervene in an action or move to dismiss the complaint. 31 U.S.C. § 3730(b)(2), (c)(2)(A). The District Court denied the motion. *Druding v. Care Alternatives, Inc.*, 346 F. Supp. 3d 669, 683-84 (D.N.J. 2018).

F.3d 370, 376 (5th Cir. 2004) (finding that "scientific judgments about which reasonable minds may differ cannot be 'false'" (internal citation omitted))).

Regarding the element of falsity, the District Court adopted a standard not previously embraced or established by this Court, which required Appellants to show evidence of "an objective falsehood," that the physician's prognosis of terminal illness was incorrect, in order to prevail on the element of falsity. *Id.*

Appellants appealed, and the Government submitted an amicus brief advancing substantially the same argument as it had before the District Court.

II. JURISDICTION & STANDARD OF REVIEW

The District Court had jurisdiction pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, and we have jurisdiction pursuant to 28 U.S.C. § 1291. "Our review of a district court's decision at summary judgment is plenary," so, viewing "all facts in the light most favorable to the non-moving party and draw[ing] all inferences in that party's favor," "[w]e determine whether the moving party has established that there is no genuine dispute of material fact . . . ." *Forrest v. Parry*, 930 F.3d 93, 105 (3d Cir. 2019) (citations omitted).

III. DISCUSSION

The central question on appeal is whether a hospice-care provider's claim for reimbursement can be considered "false" under the FCA on the basis of medical-expert testimony that opines that accompanying patient certifications did not support patients' prognoses of terminal illness. The answer is a straightforward yes. In coming to this conclusion, we

decline to adopt the District Court's "objective" falsity standard, as the test is inconsistent with the statute and contrary to this Court's interpretations of what is required for legal falsity. The District Court also erred in its determination that clinical judgments cannot be "false" for the purposes of FCA liability. In light of this analysis, we find Appellants' medical testimony creates a genuine dispute of material fact as to the element of falsity.

A.

In analyzing the statute's text, we find the premise of the District Court's holding—that a "mere difference of opinion" is insufficient to show FCA falsity—is at odds with the meaning of "false" under the statute. *Druding*, 346 F. Supp. 3d at 685. We also conclude that the District Court's "objective" falsity standard improperly conflates the elements of falsity and scienter, inconsistent with the application of the FCA.

As with any statutory interpretation question, our analysis begins with the text. *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). The FCA provides that any person who "knowingly presents, or causes to be presented, a *false or fraudulent* claim for payment or approval" is liable to the United States for a civil penalty between $5,000 and $10,000 as well as treble damages. 31 U.S.C. § 3729(a)(1)(A) (emphasis added). It also imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a *false or fraudulent* claim." *Id.* § 3729(a)(1)(B) (emphasis added).

Since Congress did not define what makes a claim "false" or "fraudulent" under the FCA, the Supreme Court has looked to common law to fill the definitional gap. *Escobar*, 136 S. Ct. at 1999-2000 ("[A]bsent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." (citation omitted)). Under the common law, an opinion can be considered "false" for purposes of liability. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 183-86 (2015) (finding that an opinion may be a "false statement" in determining liability under the securities laws); *Herskowitz v. Nutri/Sys., Inc.*, 857 F.2d 179, 184 (3d Cir. 1988) ("An opinion or projection . . . will be deemed untrue for purposes of the federal securities laws if it is issued without reasonable genuine belief or if it has no basis."); *see also* Restatement (Second) of Torts §§ 525 cmt. c, 539 cmt. a (1977) (instructing that an opinion may be false when the speaker makes an express statement contrary to the opinion he or she actually holds). Since there are circumstances in which an opinion may be considered "false" under common law, we find that the District Court's premise—an opinion is subjective and a difference of opinion is not enough to show falsity—is inconsistent with the meaning of "false" under the FCA.

Moreover, the District Court's "objective" falsity standard conflates the elements of scienter and falsity. Although the common law cases involving false opinions are often accompanied by a finding related to scienter, the plain language of the FCA denotes scienter as an element independent of falsity. 31 U.S.C. § 3729(a)(1)(A) (requiring "knowledge" separate from a "false or fraudulent claim"); *see*

Petratos, 855 F.3d at 487 (stating an FCA violation has four elements: falsity, causation, knowledge, materiality). Combining the two elements into "falsity" reads the scienter element out of the text of the statute.

That scienter serves a distinct purpose under the FCA further supports separating the falsity and scienter analyses. Scienter helps to limit the possibility that hospice providers would be exposed to liability under the FCA any time the Government could find an expert who disagreed with the certifying physician's medical prognosis. *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018) (noting scienter requirements are "rigorous" and can be used to address excessive liability concerns). Indeed, the Supreme Court has instructed as much. *Escobar*, 136 S. Ct. at 2002 ("[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the [FCA]'s materiality and scienter requirements." (internal quotations and citations omitted)).

By requiring "factual evidence that Defendant's certifying doctor was making a *knowingly* false determination," the District Court's "objective" falsity standard conflates scienter and falsity. *Druding*, 346 F. Supp. 3d at 688 (emphases added). In finding that Appellants could not prove falsity because they had not produced evidence that any physician lied and "received a kickback to certify any patient as hospice eligible" or "certif[ied] any patient whom that physician believed was not hospice eligible," the

District Court incorporated a scienter element into its analysis regarding falsity that was inconsistent with the text and application of the statute. *Id.* at 687.

B.

The District Court's "objective" falsity standard is also at odds with this Court's cases that have interpreted falsity to encompass a theory of liability based on non-compliance with regulatory instructions and not just objectively verifiable facts.

As the District Court itself recognized, a claim can be proven "false" in two ways: factually, when the facts contained within the claim are untrue, and legally, "when the claimant . . . falsely certifies that it has complied with *a statute or regulation* the compliance with which is a *condition* for Government payment." *Druding*, 346 F. Supp. 3d at 682 (quoting *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)) (emphasis added) (internal quotation marks omitted); *see also Petratos*, 855 F.3d at 487 ("[A] claim can be false if it does not comply with statutory conditions for payment . . . ."); *Polukoff*, 895 F.3d at 741 (noting legal falsity can be express, such as a false affirmative statement of compliance with a statutory, regulatory, or contractual prerequisite, or it can be implied—for instance, the absence of a material disclosure that would have prevented compliance with a statutory, regulatory, or contractual prerequisite). Although legal falsity necessarily encompasses situations of factual falsity, for instance, where a physician's lies about medical test results would render certifications for reimbursement inaccurate and non-compliant with regulations, *cf. United States v. Paulus*, 894 F.3d 267,

273 (6th Cir. 2018), the District Court nevertheless limited its analysis to factual falsity.

According to the District Court, a medical expert's opinion is false for purposes of FCA liability only when there is evidence of factual inaccuracy. In other words, opinions being subjective, a differing medical conclusion regarding a patient's prognosis alone is not enough to show the certifying physician's determination of terminal illness was factually incorrect.

We disagree with the District Court's decision to circumscribe FCA falsity to findings of factual falsity. This runs contrary to the cases in this Court, which have recognized falsity to include legal falsity. *See, e.g.*, *Petratos*, 855 F.3d at 486; *Wilkins*, 659 F.3d at 305; *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 441 (3d Cir. 2004); *see also United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (observing that the FCA "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government"). In other words, our cases instruct that FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government. *See Wilkins*, 659 F.3d at 305 (explaining that "[a] legally false FCA claim is based on a 'false certification' theory of liability" (citations omitted)); *see also United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005) ("Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed.").

Under legal falsity, Appellants must show that Care Alternatives failed to meet at least one of the two regulatory requirements: (1) that a physician certified the patient is terminally ill and (2) that the certification is in accordance with section 418.22, which requires that "[c]linical information and other documentation that support the medical prognosis [] accompany the certification . . . ." 42 C.F.R. §§ 418.20, 418.22(b)(2). Based on this theory, we find that disagreement between experts as to a patient's prognosis may be evidence of the latter; its relevance need not be limited to evidence of the accuracy of another physician's judgment.

This interpretation is also supported by the Tenth Circuit, which recently reversed a similar district court decision that had adopted an "objective" falsity requirement for FCA claims. *Polukoff*, 895 F.3d at 743, 745-46. In *Polukoff*, the Tenth Circuit considered whether a cardiologist falsely represented in his claims for Medicare reimbursement that the procedures he was performing were reasonable and necessary. *Id*. at 735, 738-39. In finding it "possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA," the Tenth Circuit emphasized that liability is not premised on factual falsity alone, but a certification is false simply "if the procedure was not reasonable and necessary under the government's definition of the phrase." *Id*. at 742-43. There, the Tenth Circuit adopted the view that FCA falsity is based on legal falsity—that falsity is simply a question of whether the claim is reimbursable, that is, compliant with the Medicare reimbursement instructions. *Id*. at 742-43. In so doing, it found that the plaintiff-physician's opinion that the defendant-

cardiologist's procedures were not "reasonable and necessary" was a cognizable allegation as to whether the cardiologist's reimbursement claims were "false" for failing to comply with Medicare procedures. *Id*. at 743-44.

So, based on our cases and the Tenth Circuit's rationale in *Polukoff*, we will not limit our inquiry to factual falsity and instead apply a theory of legal falsity.

C.

Moreover, we reject the District Court's bright-line rule that a doctor's clinical judgment cannot be "false." In *United States v. Paulus*, the Sixth Circuit reversed a cardiologist's acquittal for healthcare fraud based on expert testimony that he recorded severe arterial blockage in patients' medical records when the angiograms showed only mild or no blockage. 894 F.3d at 276-77, 280. In doing so, the Sixth Circuit stressed that medical "opinions are not, and have never been, completely insulated from scrutiny." *Id*. at 275. For example, "opinions may trigger liability for fraud when they are not honestly held by their maker. . . ." *Id.* Such was the case in *Paulus* where the defendant was charged with lying about the results of angiograms he conducted and billed taxpayers for procedures conducted based on those results. *Id.* at 272-73. As the Sixth Circuit explained, a good faith medical opinion is not punishable, but a bright-line rule that medical opinions can never be false fails to hold accountable a physician who "saw one thing on the angiogram and consciously wrote down another, and then used that misinformation to perform and bill unnecessary procedures." *Id*. at 276. The court

concluded that whether the defendant was acting in good faith or committing fraud by misrepresenting the angiogram results was an appropriate question for the jury. *Id.* at 276-77; *see also United States v. Rockwell*, 781 F.2d 985, 990 (3d Cir. 1986) ("The law will not countenance a usurpation by the court of the function of the jury to decide the facts and to assess the credibility of the witnesses."). In weighing that decision, the jury could consider evidence of different doctors who had interpreted the angiograms differently. *Paulus*, 894 F.3d at 276-77.

We can apply these same principles to our civil FCA case. The "reliability and believability of expert testimony . . . is exclusively for the jury to decide." *Id.* at 277 (citations omitted). Contrary to the District Court's reasoning, medical opinions may be "false" and an expert's testimony challenging a physician's medical opinion can be appropriate evidence for the jury to consider on the question of falsity.

D.

In adopting and applying an "objective" falsity standard, the District Court relied on *United States v. AseraCare Inc.*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015) ("*AseraCare I*") and *United States v. AseraCare Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. 2016) ("*AseraCare II*").[3] Since the Eleventh Circuit issued its opinion

[3] It also relied on *United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016) ("*Vista Hospice*"), an unreported case from the Northern District of Texas whose relevant facts and holding are nearly identical to those in *AseraCare I* and *AseraCare II*. Like Appellants here and the plaintiffs in *AseraCare*, the plaintiff-relator in *Vista Hospice* was also a former employee of the

affirming both *AseraCare I* and *AseraCare II*'s adoption of the "objective" falsity standard shortly before oral argument in this case, we briefly discuss our reasons for departing from our sister circuit. *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019) ("*AseraCare III*").

In *AseraCare*, former employees of the defendant hospice provider brought a *qui tam* suit alleging that AseraCare had a practice of knowingly submitting unsubstantiated Medicare claims in violation of the FCA. *Id.* at 1284. The Government chose to intervene. *Id.* In deciding AseraCare's first motion for summary judgment, the district court declined to adopt a "reasonable doctor" standard for the assessment of falsity, which would have required the Government to show that a reasonable physician could not have held the opinion that the patient was certifiably ill. *Id.* at 1285-86. The case proceeded to a bifurcated trial where the falsity element was tried first, followed by the remaining elements and the other common law claims in the second phase. *Id.* at 1286. During the first phase, the parties presented dueling expert

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defendants, which are hospice care providers in fourteen states. *Vista Hospice*, 2016 WL 3449833, at *1. The *qui tam* suit alleged that the defendants violated the FCA by "causing patients who were not eligible for the MHB to be certified as eligible, and then submitting claims for ineligible patients[.]"*Id.* As here, the district court granted summary judgment in favor of defendants, finding that a report by the relator's expert, a hospice physician, insufficient to create a genuine dispute of material fact regarding the element of falsity. *Id.* at *5, *17-18 (holding that "[a] testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity" (citing *AseraCare II*, 176 F. Supp. 3d at 1283)).

opinions from two doctors about whether, based on their own clinical judgment, the medical records of particular patients supported AseraCare's certifications that the patients were terminally ill. *Id.* at 1287. The question was then put to the jury to decide which expert's testimony was more persuasive. *Id.* at 1288-89. Following the partial verdict in which the jury found some of the medical records supported AseraCare's certifications and some did not, AseraCare moved for judgment as a matter of law, arguing that the court had articulated the wrong standard for falsity in its instructions to the jury. This time, the district court agreed that it had committed reversible error and that it should have advised the jury that the FCA's falsity element requires proof of an objective falsehood and that "a mere difference of opinion [between physicians] , *without more*, is not enough to show falsity." *AseraCare I*, 153 F. Supp. 3d at 1384.

The district court then took the extra step of considering summary judgment *sua sponte* and, after additional briefing from the parties, granted summary judgment in AseraCare's favor based on the district court's newly adopted "objective" falsity standard. *AseraCare II*, 176 F. Supp. 3d at 1284, 1286.

On appeal, the Eleventh Circuit affirmed the district court's adoption of the "objective" falsity test. *AseraCare III*, 938 F.3d at 1296-97. In setting up its discussion of FCA falsity, the Eleventh Circuit rejected the Government's framing of the falsity inquiry as a question of "whether the clinical information and other documentation accompanying a certification of terminal illness support[s] . . . the

physician's certification." *Id.* at 1294. Instead, it concluded that the supporting documentation requirement is only designed to address the mandate that there be a medical basis for certification. *Id.* at 1296-97. In deciding a claim's eligibility is therefore premised on the physician's clinical judgment and decision to certify a patient as terminally ill, the Eleventh Circuit limited the relevant inquiry to whether the Government had adduced sufficient evidence of "the accuracy of the physician's clinical judgment regarding terminality." *Id.* at 1294, 1296.

We depart from this framing of FCA falsity. As previously articulated, limiting falsity to factual falsity is inconsistent with our case law, which reads FCA falsity more broadly as legal falsity, encompassing circumstances where a claim for reimbursement is non-compliant with requirements under the statute and regulations. The MHB regulations state two requirements: (1) that a physician certifies the patient as terminally ill and (2) that clinical information and documentation supporting the prognosis accompany the certification. 42 C.F.R. §§ 418.20, 418.22(b)(2). Under a legal falsity theory, a medical opinion that differs from the certifying physician's opinion is therefore relevant evidence of the latter requirement, whether there was documentation accompanying the certification that supported the medical prognosis.

The Eleventh Circuit also determined that clinical judgments cannot be untrue. *AseraCare III*, 938 F.3d at 1297. ("[A] reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those

judgments . . . are false under the FCA."). We again disagree. In reaching the opposite determination, we invoke the principles previously articulated—that the common-law definition of fraud permits a finding that subjective opinions may be considered false and that medical opinions can be false and are not shielded from scrutiny. *Paulus*, 894 F.3d at 276-77. We therefore find that a difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity.

This does not mean that objectivity is never relevant for FCA liability. However, we find that objectivity speaks to the element of *scienter*, not *falsity*. As discussed above, the text and application of the FCA require that the elements of falsity and scienter be analyzed separately. In fact, *AseraCare III* supports this position. The Eleventh Circuit affirmed the adoption of the "objective" falsity test, but it reversed the District Court's *sua sponte* grant of summary judgment in favor of the defendants and remanded for further consideration of evidence the Government had intended to present to show "knowledge of the falsity of the claim." *AseraCare III*, 938 F.3d at 1302. Although the Eleventh Circuit instructions on remand were to consider all of the evidence "to determine whether a triable issue existed regarding *falsity*," *id.* at 1303 (emphasis added), we make clear that in our Court, findings of falsity and scienter must be independent from one another for purposes of FCA liability.[4] More than a formality, we

[4] We acknowledge that the Seventh Circuit's view differs somewhat from our instruction to keep falsity and scienter separate. *United States ex rel. Yannocopoulos v. Gen. Dynamics*,

seek to avoid the precise outcome in *AseraCare II*, where the district court folded the element of scienter into its "objective" falsity test, but failed to fully consider evidence of scienter and, as a result, prematurely granted summary judgment.

For these reasons, we are persuaded that the District Court's reliance on *AseraCare II* was misplaced.

E.

Since the District Court's decision to grant summary judgment in favor of Care Alternatives was based solely on its analysis of the falsity element, our decision is limited to the same. So, regarding FCA falsity, we reject the objective falsehood standard. Instead, we hold that for purposes of FCA falsity, a claim may be "false" under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements. We also find that a physician's judgment may be scrutinized and considered "false."

We therefore find that a physician's expert testimony challenging a hospice certification creates a triable issue of fact for the jury regarding falsity. Since Dr. Jayes's expert report has done just that, we conclude the report was sufficient evidence to create a genuine dispute of material fact. Having found that Appellants adduced enough evidence to overcome summary judgment as to the element of falsity, we need not address Appellants' other arguments

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652 F.3d 818, 836-37 (7th Cir. 2011) (citing *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (requiring an objective falsehood based on a test that conflates an analysis of the falsity and knowledge elements)).

regarding whether the evidence they submitted met the District Court's erroneous "objective" falsity test. Nor do we opine as to Appellants' odds of surviving summary judgment on the other prima facie elements, which the District Court did not reach.

IV. CONCLUSION

We therefore reverse the District Court's grant of summary judgment in favor of Defendant and remand for consideration of the other elements of FCA liability, consistent with this opinion.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 18-3298

UNITED STATES OF AMERICA AND STATE OF NEW JERSEY EX REL. VICTORIA DRUDING; BARBARA BAIN; LINDA COLEMAN; RONNI O'BRIEN,

Appellants,

v.

CARE ALTERNATIVES,

Appellee.

Filed: May 6, 2020

Present: SMITH, *Chief Judge*, McKEE, AMBRO, CHAGARES, JORDAN, HARDIMAN, GREENAWAY, JR., KRAUSE, RESTREPO, BIBAS, PORTER, MATEY, and PHIPPS, *Circuit Judges.*

ORDER

The petition for rehearing filed by Appellee in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing,

and a majority of the judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc is denied.

BY THE COURT,

s/Joseph A. Greenaway, Jr.

Circuit Judge

Dated: May 6, 2020

Appendix C

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

No. 08-2126

VICTORIA DRUDING; BARBARA BAIN; LINDA COLEMAN; and RONNI O'BRIEN,

Plaintiff-Relators,

v.

CARE ALTERNATIVES, INC.,

Defendant.

Filed: Sept. 26, 2018

OPINION

SIMANDLE, District Judge:

I. INTRODUCTION

Plaintiff-Relators in this *qui tam* action are former employees of Defendant Care Alternatives, Inc. ("Care Alternatives" or "Defendant"), a provider of end-of-life hospice care throughout New Jersey. They bring claims on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*., alleging that Defendant fraudulently billed Medicare and Medicaid by routinely admitting and recertifying inappropriate patients for hospice care. [Docket Item 12.] The United States investigated Plaintiff-Relators'

claims for more than seven years, but ultimately declined to intervene in this matter. [Docket Item 15.] The United States, however, remains an "interested party" pursuant to 28 U.S.C. § 517. [Docket Item 153.]

Currently pending before the Court are Defendant's motions to dismiss [Docket Item 126] and for summary judgment. [Docket Item 128.] The central issues in Defendant's motion to dismiss are whether Plaintiff-Relators failed to comply with 31 U.S.C. § 3730(b)(2), which requires that a relator must submit to the Government a "written disclosure of substantially all material evidence and information the person possesses," and, if so, whether dismissal of the Amended Complaint is warranted here. In the alternative, Defendant seeks summary judgment on several independent bases: (1) Plaintiff-Relators' allegations of falsity have insufficient evidentiary support; (2) there is insufficient evidence that Defendants submitted legally false claims; (3) Plaintiff-Relators have not satisfied the FCA element of "materiality;" and (4) Plaintiff-Relators have not adduced any evidence of scienter under the FCA. For the reasons discussed below, the motion to dismiss will be denied, while the motion for summary judgment will be granted.

II. FACTUAL AND PROCEDURAL BACKGROUND[1]

A. Background

Plaintiff-Relators bring this *qui tam* action on behalf of the United States for alleged violations of the

[1] Pursuant to Local Civil Rule 56.1, the Court distills this version of the facts from the First Amended *Qui Tam* Complaint

(hereinafter, "Am. Compl.") [Docket Item 12] when appropriate, Defendant's Statement of Undisputed Material Facts [Docket Item 131], Plaintiff-Relators' Response in Opposition to Defendant's Statement of Undisputed Material Facts [Docket Item 144-7], Defendant's Reply to Plaintiff-Relators' Response [Docket Item 160], and related exhibits and documents attached thereto.

The Court will, however, only consider properly documented citations in Plaintiff-Relators' "Counterstatement of Material Facts." [*See* Docket Item 144-8.] In addition to requiring the opponent of summary judgment to "furnish, with its opposition papers, a responsive statement of material facts," which Plaintiff-Relators filed [*see* Docket Item 144-7] and the Court will consider as stated above, Local Civil Rule 56.1 permits the opponent of summary judgment to "furnish a supplemental statement of disputed material facts, in separately numbered paragraphs citing to the affidavits and other documents submitted in connection with the motion, if necessary to substantiate the factual basis for opposition." *See* L. Civ. R. 56.1 (emphasis added). Plaintiff-Relators' Counterstatement does not comply with this rule. The Counterstatement reads like argument, either untethered to specific cites to the record or citing to material in the factual record that does not support the generalized arguments in the Counterstatement.

While Plaintiff-Relators' Counterstatement is technically separated by numbered paragraphs and cites record evidence at the end of each paragraph, many paragraphs contain numerous sentences, including up to nine sentences in at least two instances (*see, e.g.*, ¶¶ 91, 93), and fails to identify in any meaningful way which sentence in each paragraph is purportedly substantiated by which affidavit and/or other document submitted in connection with the motion. The Court is unable to easily discern whether each sentence (*i.e.*, statement) in the Counterstatement is, in fact, supported by the voluminous record, which stands nearly three feet high, and will not endeavor to do so here. *See Decree v. United Parcel Serv., Inc.*, 2009 WL 3055382, at *5 (D.N.J. Sept. 18, 2009) ("The Court further agrees with UPS that Plaintiff's 'Counterstatement of Material Fact' is unwieldy at best and violates Rule 56.1's insistence that facts be

FCA in connection with reimbursement claims that Defendant submitted to Medicare and Medicaid between 2006 and October 23, 2007. Plaintiff-Relators generally allege a concerted effort by Defendant to bring in patients to its residential facilities who were not actually eligible for hospice care coverage under Medicare, notwithstanding that each patient was certified as hospice eligible by an independent physician. (*See* generally Am. Compl.) Specifically, the Amended Complaint identifies 15 patients whose medical records allegedly did not support a finding of terminal prognosis. (*Id.* at ¶ 25.)

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set forth in separately numbered paragraphs and that factual allegations be supported with citation to the record.").

This Court has invested a great deal of time in examining the parties' submissions, but there are limits beyond which the Court must rely on the advocates' substantial compliance with their obligations in summary judgment practice in a complex factual case. "The purpose of the Rule 56.1 statement is for the parties to identify the facts relevant to the pending motion so the Court may determine whether a genuine dispute exists without having to first engage in a lengthy and timely review of the record." *Vibra-Tech Engineers, Inc. v. Kavalek*, 2011 WL 111417, at *2 (D.N.J. Jan. 13, 2011). "[S]trict compliance with Local Rule 56.1 helps the Court and the parties insure the proper application of summary judgment standards." *Fifth v. State Farm Ins. Co.*, 2014 WL 1253542, at *1 (D.N.J. Mar. 25, 2014). Again, the Counterstatement does not make the Court's job any easier because it seldom attempts to delineate which specific statement is supported by which piece of record evidence, nor does it comply with the Local Rules. Accordingly, because the Court is not equipped to search the volume of this record to seek support for Plaintiff's generalized Counterstatement, the Court will consider only those factual assertions for which direct record support is cited.

1. Defendant Care Alternatives

Defendant Care Alternatives provided hospice care to patients throughout New Jersey. (Veltri Dep. [Docket Item 128-6] at 25:1-4, 76:4-78:1; *see also* Spoltore Dep. [Docket Item 128-4] at 21-1-26:25, 46:12-47-8.) To that end, Defendant employed a variety of clinicians, including registered nurses, chaplains, social workers, home health aides, and therapists, and worked with independent physicians who served as hospice medical directors.[2] (Spoltore Dep. at 75:1-8; *see also* Care Alternative's Polices regarding Hospice Services [Docket Item 128-5] at 7, 10-17, 26-29, 38-39.) Together, these clinicians formed so-called "interdisciplinary teams" (hereinafter, "IDTs"), which met twice a month to review patient care plans, identify any particular patient needs, and discuss patients who were up for re-certification. (Spoltore Dep. at 149:25-150:15.) The IDTs also provided integrated care and services pursuant to individualized patient plans of care. (*Id.* at 21:15-26:26; *see also* Policies at 1.) The medical directors who

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[2] Defendant did not employ the physicians who certified its patients for the hospice benefit. (Spoltore Dep. at 59:8-60:2.) Rather, these physicians were either independent contractors or agents of contractors (in the case of hospice medical directors) or not affiliated with Care Alternatives at all (in the case of physicians who served only in an attending capacity). (*Id.* at 37:13-23; *see also* Veltri Decl. [Docket Item 128-6] at ¶ 4.) Compensation for medical directors was fixed, set in advance, and did not vary based on the number of patients a physician certified for hospice. (*Id.* at ¶ 5.) According to Plaintiff-Relator Druding, however, Care Alternatives kept score of each medical director's patient referrals and, if doctors did not provide enough referrals, Care Alternatives parted company with the doctors. (Druding Dep. at 224:21-225:5.)

were part of Defendant's Southwest Region IDT during the relevant period were Dr. Wadawa, Dr. Uwewemi, and Dr. Dignam. (Druding Dep. [Docket Item 144-3] at 23:13-25:1.)

According to Care Alternatives Hospice Administrator Loretta Spoltore ("Spoltore"),[3] Care Alternatives had well-established compliance, quality assurance, training, and auditing programs that were designed to ensure "continuous improvement" and "strove to make sure that what [the company was doing] was at or above national standards." (Spoltore Dep. at 94:16-24; *see also* Veltri Dep. [Docket Item 128-7] at 45:13-46:1.) Spoltore also testified that Care Alternatives devoted significant resources to ensuring that clinicians created thorough patient medical records. (Spoltore Dep. at 114:21-117:12.)

Care Alternatives' Susan Coppola ("Coppola")[4] led quarterly medical record audits to ensure that they were complete and contained documentation required by company policy. (Coppola Dep. [Docket Item 128-8] at 17:13-18:11, 56:19-58:4.) Nurses, full-time auditors, and regional managers assisted with these auditing efforts and, if deficiencies were identified, it was generally the regional manager's responsibility to develop and implement corrective action plans. (*Id.* at

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[3] Spoltore was the person responsible for overseeing the day-to-day operations of Care Alternatives' clinical program for New Jersey from November 2005 through January 2010. (Spoltore Dep. at 8:7-11:6.)

[4] From 2006 to 2011, Coppola worked in the compliance department at Care Alternatives, ultimately reaching the level of Chief Compliance Officer. (Coppola Dep. at 12:3-23.)

78:13-80:12; Spoltore Dep. at 74:8-75:12, 114:21-117:12.)

It was Care Alternatives' practice to provide education to staff members of "every policy and procedure, every audit form, every paper" in use by Care Alternatives. (Coppola Dep. at 96:21-97:3.) Care Alternatives employees generally received compliance training on an annual basis. (Spoltore Dep. at 95:25-96:14.) Moreover, newly-hired nurses were provided compliance orientation and then educated by their individual teams, other nurses, social workers, and chaplains so that they understood the standards of care and practice for Care Alternatives. (*Id.* at 34:13-35:22; *see also* Coppola Dep. at 97:4-97:19.) Care Alternatives' compliance training was "an ongoing educational process." (Coleman Dep. [Docket Item 130-2] at 30:17-31:2.)

In addition to its internal compliance efforts, Care Alternatives was audited by (and conferred accreditation by) Community Health Accreditation Partner ("CHAP") a non-profit, third-party accreditation agency that conducted on-site surveys of Care Alternatives. (Coppola Dep. at 14:1-7.) To that end, Care Alternatives required that all patient medical records be timely delivered and stored in its headquarter offices in Cranford, New Jersey in the event CHAP visited for an on-site review of Care Alternatives' program on short notice. [Docket Item 144-5 at 2.] Care Alternatives hired a consultant, Toni Swick, to review the medical preparation of any possible State audit or CHAP review. (Veltri Dep. at 145:1-146:6.)

2. Plaintiff-Relators

Plaintiff-Relators Victoria Druding, Linda Coleman, Barbara Bain, and Ronni O'Brien are former Care Alternatives employees. (Am. Compl at ¶ 1.)

a. Victoria Druding

Victoria Druding ("Druding") was employed by Care Alternatives as a Regional Manager of the Southwest Region for almost six months, from April 17, 2007 through September 6, 2007, when she quit without giving notice. (Druding HR File [Docket Item 128-11] at 1-2; Druding Dep. at 23:1-23:18.) As Regional Director, Druding was responsible for management of the clinical team, which included nurses, social workers, chaplains, and directors. (*Id.* at 23:13-25:1.) She was also responsible for ensuring that IDT meetings were scheduled and held in a timely manner. (*Id.*)

b. Linda Coleman

Linda Coleman ("Coleman") was employed by Care Alternatives as a Registered Nurse ("RN") Case Manager in the Southwest Region of New Jersey from April 2004 to September 2007. (Coleman Dep. at 9:18-10:1, 12:20-14-8.) As RN Case Manager, Coleman's duties were to "visit patients wherever they were . . . [and] trying to develop relationships for more referrals." (*Id.* at 8:15-21.) According to Coleman, her job "was to be the coordinator for patient care, . . . [which] involved making sure the patient was in a safe environment, had a caregiver, had a physician that was willing to work with hospice, medications necessary, pulling in the rest of the team . . . . It was my responsibility to make sure that

that all happened in a timely fashion for the care and comfort of the patient." (*Id.* at 14:18-15:6.)

c. Barbara Bain

Barbara Bain ("Bain") was employed by Care Alternatives as a Chaplain in the Southwest Region of New Jersey from December 28, 2003 to 2007. (Bain Dep. [Docket Item 130-3] at 8:15-9:4, 10:20-11:11, 12:4-6.) According to Bain, her job was more spiritual than religious, and she was responsible for helping patients feel good with themselves and repair their relationships with a church, their family, or themselves. (*Id.* at 15:8-17.) Bain testified that, as a member of the IDT, she always participated in the IDT meetings where patient care and hospice eligibility were discussed. (*Id.* at 25:19-26:18, 32:10-33:17.)

d. Ronni O'Brien

Ronni O'Brien ("O'Brien") was employed as a Community Education Liaison for the Southwest Region of Care Alternatives New Jersey. (O'Brien Dep. [Docket Item 128-15] at 11:17-12:21.) O'Brien's job was to bring in patient referrals and admissions, and she reported to marketing director Colleen Swick, (*id.* at 10:16-24), and she regularly participated in weekly marketing phone calls with Colleen Swick and Care Alternatives CEO Sam Vetri. (*Id.* at 73:4-74:15.) O'Brien was not a clinician and had no training or responsibility for evaluating patients for hospice eligibility. (*Id.* at 39:7-15.)

B. Hospice Care and the Medicare Hospice Benefit

Congress established the Medicare Hospice Benefit ("MHB") in 1983. *See* 48 Fed. Reg. 56008 (Dec.

16, 1983). Under federal regulations, hospice[5] care is considered palliative care, meaning it is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering," *see* 42 C.F.R. § 418.3, and it is designed around "an interdisciplinary approach to provide a variety of services, including medical, social, psychological, emotional, and spiritual, with the goal of making a terminally ill person as physically and emotionally comfortable as possible," *see* 48 Fed. Reg. 56008.

A patient who has been certified as eligible for hospice and who elects to receive hospice care voluntarily waives the right to Medicare payment for curative treatment, and instead receives only palliative care to manage pain or other symptoms of their terminal prognosis. *See* 42. U.S.C. § 1395d(2)(A). A Medicare beneficiary is eligible for the MHB if his or her attending physician and a hospice medical director certify that the individual is terminally ill.[6] 42 U.S.C. § 1395f(a)(7)(A)(i) (eff. Jan. 1, 2005). That certification should be "based on the physician's or medical director's clinical judgment" and must include "clinical

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[5] Between January 23, 2006 and 2011, Medicare Hospice regulations specifically defined "hospice" as "a comprehensive set of services described in 1861(dd)(1) of the [Social Security] Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care." [Docket Item 144-1 at 2-35.]

[6] "An individual is considered to be 'terminally ill' if the individual has a medical prognosis that the individual's life expectancy is 6 months or less." 42 U.S.C. § 1395x(dd)(3)(A) (eff. Dec. 29, 2007); *see also* 42 C.F.R. § 418.3.

information and other documentation that support the medical prognosis" and "a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms." 42 C.F.R. § 418.22(b).

The MHB provides two 90-day benefit periods for eligible patients, followed by an unlimited number of 60-day benefit periods. 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.21(a). After a patient is initially certified by hospice by an attending physician **and** a hospice medical director, the patient need only be recertified for subsequent benefit periods by an attending physician **or** hospice medical director. 42 U.S.C. § 1395f(a)(7)(A)(ii); 42 C.F.R. § 418.22.

The Centers for Medicare & Medicaid Services ("CMS"), which is responsible for administering the MHB, has stated that:

> Recognizing that prognoses can be uncertain and may change, Medicare's benefit is not limited in terms of time. Hospice care is available as long as the patient's prognosis meets the law's six month test. This test is a general one. As the governing statute says: 'The certification of terminal illness of an individual who elects hospice shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness.' CMS recognizes that making medical prognostication of life expectancy is not always an exact science. Thus, physicians need not be concerned. There is no risk to a physician about certifying an individual for

> hospice care that he or she believes to be terminally ill.

CMS's Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article: "Hospice Care Enhances Dignity and Peace as Life Nears Its End," CMS-Pub. 60AB, Transmittal AB-03-040 (Mar. 28, 2003).

CMS has not created clinical benchmarks that must be satisfied to certify a patient as terminally ill. *See* 73 Fed. Reg. 32088, 32138 (June 5, 2008) ("We have removed the term 'criteria' in order to remove any implication that there are specific CMS clinical benchmarks in this [proposed] rule that must be met in order to certify terminal illness.") Instead, CMS has been clear that a patient who stabilizes or improves may nevertheless remain eligible for hospice care. *See* 75 Fed. Reg. 70372, 70488 (Nov. 17, 2010) ("A patient's condition may temporarily improve with hospice care."); 74 Fed. Reg. 39384, 39399 (Aug. 6, 2009) ("We also acknowledge that at recertification, not all patients may show measurable decline.").

C. Procedural History

On April 29, 2008, Plaintiff-Relators filed the original *Qui Tam* Complaint on behalf of the United States in camera and under seal in accordance with 31 U.S.C. § 3730(b). [Docket Item 1.] On September 15, 2009, the Court ordered the United States to advise if it intended to intervene or decline to intervene. [Docket Item 8.] The United States subsequently filed an application for an order staying and administratively terminating the action to provide the United States with sufficient time to investigate the matter and decide whether to intervene, which the

Court granted. [Docket Item 11.] The Complaint was amended in 2013 to add state law claims under New Jersey's FCA. [Docket Item 12.] On July 21, 2015 (more than five years after the case was stayed and seven years after the Complaint was filed), the United States finally notified the Court of its decision to not intervene in this action. [Docket Item 15.] A redacted copy of the First Amended Qui Tam Complaint was thereafter served upon Defendant on July 29, 2015. [Docket Item 16.]

On September 25, 2015, Defendant filed its first motion to dismiss [Docket Item 27], which the Court granted in part and denied in part in an Opinion and Order dated February 22, 2016. [*See* Docket Items 47 & 48.] The Court dismissed without prejudice and with leave to amend Plaintiff-Relators' claims regarding altered documentation and violations of the Anti-Kickback Statute arising under an implied legally false theory under the FCA and the NJFCA, and dismissed with prejudice Plaintiff-Relators' claims alleging violations of the Stark Act and noncompliance with the IDT requirement. *Druding v. Care Alternatives*, 164 F. Supp. 3d 621, 632-35 (D.N.J. 2016). The Court permitted Plaintiff-Relators' to proceed only with their FCA allegations regarding inappropriate patient admissions and recertifications for hospice care. *Id.* at 630-32.

On March 8, 2016, Plaintiff-Relators notified the Court they were electing not to file a motion for leave to file a Second Amended Complaint, but instead "will proceed in the matter regarding inappropriate patient admission and recertifications for hospice care as set

forth in the [February 2016] Order." [Docket Item 49 at 1.]

Currently pending before the Court are two motions filed concurrently by Defendant: a motion to dismiss pursuant to 31 U.S.C. § 3730(b)(2) [Docket Item 126], and a motion for summary judgment. [Docket Item 128.] Plaintiff submitted opposition to both motions [Docket Items 143 & 144] and Defendant filed reply briefs in further support of each motion. [Docket Items 155 & 158.] With leave of Court [Docket Item 180], Plaintiff filed a sur-reply brief in opposition to Defendant's motion for summary judgment. [Docket Item 169] The United States also filed a "statement of interest" in response to Defendant's motion for summary judgment [Docket Item 153], pursuant to 28 U.S.C. § 517. With leave of the Court [Docket Item 179], Defendant filed a response to the Government's statement of interest. [Docket Items 168.] The Court convened oral argument on May 10, 2018. [Docket Item 191.] The pending motions are now fully briefed and ripe for disposition.

D. The Evidence

The evidence consists of: (1) deposition testimony and documents regarding whether Defendant improperly admitted ineligible patients; (2) deposition testimony alleged to establish that Defendant directed its employees to alter certifications; (3) a report by Plaintiff-Relators' expert, Dr. Jayes, in which he reviewed patient records for 48 Care Alternatives patients to evaluate the patients' eligibility for hospice care; and (4) a report by Defendant's expert, Dr. Hughes, in which he addressed Dr. Jayes' findings.

1. Testimony And Documents About Defendants Allegedly Admitting Ineligible Patients

During discovery, Care Alternatives produced almost 50,000 pages of documents. [Docket Item 128-17.] Plaintiff-Relators were also deposed, as were several other Care Alternatives employees. The documents and testimony addressing whether Defendant admitted ineligible patients are summarized as follows:

a. Druding's Testimony

Plaintiff-Relator Druding testified that patient A.P. could "walk without limitations, without assistance," "could talk as well as you and I are talking right now," was "always . . . able to [string together multiple sentences in a conversation," "was gaining weight," and "her weight was going up instead of down." (Druding Dep. at 198:3-5, 198:17-18, 199:5-11.) According to contemporaneous nursing assessments which Druding herself authenticated (*id.* at 214:21-215:3; 218:11-20), however, Druding documented that the same patient was "wheelchair restricted [which] means they're restricted to the wheelchair, they're not going anywhere without the wheelchair," had lost 43 pounds while on hospice, and that the "Undersigned [Druding] has deterimined patient remains hospice appropriate as evidenced by . . . weight loss despite a rigorous feeding program . . . [increased] lethargy, increase sleeping, decreased communication, increase in need for assistance, decrease [in] socialization." (*See* Nursing Assessment [Docket Item 130-5] at 2-7.) Notwithstanding these discrepancies, as discussed *infra*, Druding insists that she never falsified

documentation in patient medical records. (*See* Druding Dep. at 53:20-54:13; 63:18-64:1; *see also* Pl.'s Response to Def.'s Second Request for Admission [Docket Item 126-3] at ¶ 2.)

Druding testified that she knew of a Care Alternatives physician certifying a patient as terminally ill when the physician did not believe it to be true, but could not provide any supporting information. (Druding Dep. at 144:20-149:22.) She also testified that she did not know if any physician was pressured by Care Alternatives employees to certify a patient for hospice at all, let alone to certify a patient who was not appropriate for hospice care. (*Id.* at 109:20-23.)

b. Coleman's Testimony

Plaintiff-Relator Coleman identified two patients, W.B. and H.J., as not appropriate or eligible for hospice. With respect to W.B., Coleman testified that she was instructed by Druding to check off the box for W.B. indicating he was only able to speak six intelligible words or fewer (which would qualify him for hospice care), even though the patient was, in fact, able to speak more than six words (which would not qualify him for hospice care). (Coleman Dep. at 156:14-158:3.) As Coleman explained, "This man did not, was not able, if I understand or reading my notes correctly . . . this was a patient that the facility wanted us to admit because he was above and beyond what they were capable of handling. So this was one of those that was pressed on us to admit this patient, to find a diagnosis and to put him on, okay to keep our census up and to be accommodating the facility." (*Id.* at 157:6-16.) With respect to H.J., Coleman testified

that he was schizophrenic (which would not qualify him for hospice care), but she was still pressured by Druding to admit the patient for "dementia with depression" (which would qualify him for hospice care) when he did not actually meet the criteria for such a diagnosis. (*Id.* at 171:19-173:23.) Nevertheless, as discussed *infra*, Coleman maintains she never altered or falsified any patient's medical records.

Coleman testified that she recalled one instance "where our medical director felt that the patient was questionable [and] . . . maybe a diagnosis needed to be different or whatever." (*Id.* at 34:1-7.) But Coleman could not recall whether the medical director was Dr. Uwewemi or Dr. Dignam and she could not remember the name of the individual patient. (*Id.* at 34:9-12.) When asked about any other specific recollections she might have, Coleman testified "I can't give you any names of patients or whatever, but just concerns with, you know, length of stay, type of diagnosis, what the patient is actually able to do." (*Id.* at 51:1-4.)

Coleman never reported any hospice eligibility concerns to Care Alternative's compliance department (*id.* at 48:18-49:3), but testified that she complained to her coworkers, including Druding, regarding the working conditions at Care Alternatives, and voiced her concerns about inappropriate patient admissions, certifications, and recertifications during IDT meetings. (*Id.* at 50:23-51:4, 53:21-55:4, 65:6-14.)

Coleman recalled that when she raised any concerns at IDT meetings, the physicians' reactions were "[a]ttentive and checking information in the record that they had before them, the copies, and discussing with the regional manager." (*Id.* at 52:1-5.)

Coleman also testified that, in her experience the hospice medical directors were "absolutely" engaged during discussions at IDT meetings about patients and were "[v]ery proactive" (*id.* at 35:20-25), and that, in her opinion, Dr. Uwemi and Dr. Dignam "absolutely" had the patient's best interest at heart. (*Id.* at 52:6-16.) Furthermore, Coleman testified that she did not believe that any medical directors or other physicians affiliated with Care Alternatives were certifying patients for hospice when they did not believe that the patients were terminally ill. (*See* Coleman Dep. at 43:5-19.) ("Q: Did you ever have a belief that either of the physicians you remember, Dr. Dignam or Dr. Uwewemi, were certifying patients for hospice when they didn't believe the patient to be terminally ill? A: No. I really don't think that they did. . . . Q: Did either of the medical directors ever tell you that they didn't think a patient was appropriate for hospice? A: No."). When asked: "Do you have firsthand knowledge of a physician certifying a patient as terminally ill when the physician did not believe the certification to be true?" Coleman responded, "No." (*Id.* at 67:8-12.)

c. Bain's Testimony

Plaintiff-Relator Bain testified that, while she is not a clinician and does not have any formal training on hospice eligibility (Bain Dep. at 16:4-23), in her estimation, 90 percent of patients at Care Alternatives were appropriate for hospice. (*Id.* at 86:11-87:2.) Bain never reported any concerns about patient eligibility to Care Alternative's compliance department (*id.* at 81:1-82:18), but she testified that she reported concerns about patient eligibility at IDT meetings. (*Id.*

at 34:14-35-17.) Bain also testified that she had no firsthand knowledge of any physician having certified a patient as terminally ill at Care Alternatives when the physician did not believe the patient to be terminally ill. (*Id.* at 101:18-102:1.)

d. O'Brien's Testimony

Plaintiff-Relator O'Brien never reported any concerns about patient eligibility to Care Alternatives' compliance department (*id.* at 43:6-54:7), but testified that she complained about her concerns regarding hospice eligibility to her supervisor, Colleen Swick. (*Id.* at 43:3-44:24.) According to O'Brien, Colleen Swick responded that the issue of hospice eligibility was "not her concern" because she was not a nurse and "could not make diagnoses." (*Id.*) O'Brien also testified that, on weekly calls, Colleen Swick and Vetri instructed employees to "build the census no matter how they did it" and "bring me bodies." (*Id.* at 73:4-74:15.) O'Brien testified that she discussed inappropriate hospice admissions with other Care Alternatives regional marketing personnel from other regions of the company. (*Id.* at 42:22-43:2.)

e. Kelton's Testimony

In August 2007, Care Alternatives' Lauren Kelton ("Kelton")[7] conducted an internal compliance investigation into complaints that nurses in the Southwest Region of New Jersey felt pressured to

[7] Kelton was the Clinical Director of Care Alternatives New Jersey from 2007 to early 2009 and, in this role, she oversaw clinical operations in New Jersey, which included oversight of and involvement with clinical documentation practices, corrective action plans, and issues relating to hospice admissions and elevated levels of care. (Kelton Aff. at ¶¶ 2-4.)

admit patients whom the nurses believed were not appropriate for hospice. (Kelton Aff. [Docket Item 128-13] at ¶ 5.) During this investigation, Kelton interviewed several nurses in the Southwest Region who told her that "Druding was the person who was pressuring nurses to admit patients who the nurses did not believe were appropriate for hospice and to maintain patients on elevated levels of care whom the nurses did not believe were appropriate for that level of care." (*Id.* at ¶ 6.) Specifically, Kelton stated that "[t]wo nurses informed [her] that they felt from Druding an unwritten, unspoken pressure to maintain patients on elevated levels of care and this was in one case because the nurse was informed by . . . Druding that part of her bonus structure was contingent on the number of patients on elevated levels of care." (*Id.*) Kelton testified that when she informed Druding about the reports of perceived pressure and asked Druding if she knew by whom these nurses felt pressured, Druding responded "Well I guess by me." (*Id.* at ¶ 7.) According to Kelton, Druding "resigned before Care Alternatives had the opportunity to terminate her." (*Id.* at ¶ 9.) Kelton contemporaneously documented these findings in a memorandum dated August 27, 2017. (*Id.* at ¶ 8; *see also* Exhibit A to Kelton Aff. [Docket Item 128-13] at 6-7.)

Kelton further testified that, during her entire tenure at Care Alternatives, she never heard or received any report or allegation that any employee or contractor of Care Alternatives, other than Druding, had ever pressured any person to admit a patient who was not appropriate for hospice. (Kelton Aff. at ¶ 10.) According to Kelton, Care Alternatives "was dedicated to abiding by applicable rules and regulations and

always endeavored to 'do the right thing.'" (*Id.* at ¶ 11.) Throughout her time as an employee of Care Alternatives, Kelton "never had any concerns that Care Alternatives was engaging in a practice of admitting patients who were inappropriate for hospice or keeping patients on elevated levels of care who did not warrant that level of care." (*Id.* at ¶ 12.)

f. Coppola's Testimony

Coppola, Care Alteratives' Chief Compliance Officer, testified that she never heard or received any report that any nurse had been pressured to document improper hospice diagnoses, and that if she had received such a report, she would have addressed it immediately and supported the nurse who reported it. (Coppola Dep. at 99:1-18.)

g. Spoltore's Testimony

Care Alternatives Hospice Administrator Spoltire testified that she never received reports from nurses or case managers questioning a patient's appropriateness for hospice or the length of the stay, nor did she ever hear of pressure to admit patients who were not appropriate for hospice. (Spoltore Dep. at 158:12-160:9.)

h. Veltri's Testimony

Care Alternatives CEO Sam Veltri ("Veltri") testified that he never received any reports that Care Alternatives was maintaining patients who were inappropriate for hospice and that if he had received such a report, he would "have taken immediate steps to get to the bottom of that." (Veltri Dep. at 157:10-158:2.)

2. Plaintiff-Relators' Testimony Involving Allegations of Alteration

Druding testified that Toni Swick instructed her "in a group with regional managers and individually in discussion" to falsify, alter, or otherwise change medical documentation. (Druding Dep. at 53:16-18; 63:5-11.) According to Druding, "[w]hen we audited charts, if we found something that . . . did not promote compliance, whether it was fact or not, we were to change it." (*Id.* at 53:20-24.) Druding testified, however, that she **never** made these changes herself, including in the case of A.P. discussed above, because she could have sacrificed her nursing license if she had. (*Id.* at 54:9-13.) Instead, Druding testified, various unnamed "members of the staff," including nurses, chaplains, and social workers falsified, altered, or otherwise changed documents "upon instruction." (*Id.* at 54:17-20.) Druding could not identify any specific individuals who falsified, altered, or otherwise changed documents. (*Id.* at 54:21-55:12; *see also id.* at 56:7-15.)

Coleman testified that in August 2007 **Druding** directed her to "make the chart complete," which meant "[w]hatever it required. If notes were missing, which there were many missing, they wanted them regenerated you know. . . ." (Coleman Dep. at 80:16-22; 77:1-17; 80:12-14; *see also id.* at 181:8-14) ("Q: Do you ever recall being instructed to backdate paperwork? A: Yes. By who? A. Regional manager. Q: Victoria? A: By Victoria. Sorry.") Coleman testified that, notwithstanding these instructions, she **never** entered documentation in medical records that she

knew was not true, nor did she know of anyone who did. (*Id.* at 89:16-90:16.)

O'Brien testified that she was generally aware of Care Alternatives employees, including Druding and two unnamed social workers, going up to "change records" and "write whatever needed to be written in the charts." (O'Brien Dep. at 62:15-20; 64:5-24; 65:11-12.) However, O'Brien clarified, "Nobody had said that they falsified." (*Id.* at 65:3-6.) O'Brien also testified "I don't know exactly what they did. I was not there. I was not privy to see." (*Id.* at 65:13-14.)

3. Dr. Jayes' Expert Report

On August 20, 2017, Plaintiff-Relators' expert, Dr. Robert Jayes, M.D., prepared a report summarizing a review he conducted of the medical records for 47 patients whose records Care Alternatives produced during discovery, including the 15 patients identified in paragraph 25 of the Amended Complaint. (*See* Jayes Report [Docket Items 130-6 & 130-7].) In his report, Dr. Jayes explained that "[d]etermining the prognosis of patients with a serious terminal illness referred to hospice is a difficult task that depends on the judgment and experience of clinicians and the consideration of survival evidence from the literature." (*Id.* at 1.) "Recognizing this difficulty," Dr. Jayes looked to guidelines provided with the assistance of clinical experts from the National Hospice and Palliative Care Organization in the mid 1990's, as well as "several other criteria typically employed by hospice professionals," to determine whether documentation supported certification and/or

recertification of the 47 patients he reviewed for hospice. (*Id.* at 1-3.)[8]

According to Dr. Jayes, 214 out of 603 (or 35%) of the periods of hospice certification periods he reviewed lacked documentation supporting hospice care. (*Id.* at 1.) Dr. Jayes further opined that of the 47 patients whose records he reviewed, 26 were appropriate for hospice at all times and 16 more were appropriate for at least a part of their stay in hospice. (*Id.* at Appendix A.) Of the 15 patients identified in the Amended Complaint, Dr. Jayes opined that 8 were appropriate for hospice care for the entirety of their time in hospice while 4 more were appropriate for the majority of the time they were in hospice. (*Id.* at 19.) Dr. Jayes also found that at least 3 medical records appeared to be incomplete because those records were cut off at December 31, 2009 even though the patient apparently remained in hospice. (*Id.* at 7.)

4. Dr. Hughes' Expert Report

For each benefit period where Dr. Jayes determined that a patient was inappropriate for hospice based on his review of the medical records, Defendant's expert, Dr. Christopher Hughes, M.D., reviewed Dr. Jayes' findings. (Dr. Hughes Report [Docket Item 130-1].) In each instance, Dr. Hughes, based on his experience and clinical judgment, found it to be reasonable that a physician would have certified each patient Dr. Jayes reviewed for hospice during the benefit period in question. (*Id.* at 31-50.)

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[8] Defendant indicated that a motion to exclude the testimony of Dr. Jayes based on unreliable methodology is "forthcoming." [Docket Item 129 at 26 n. 12.]

III. STANDARD OF REVIEW

At summary judgment, the moving party bears the initial burden of demonstrating 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); *accord Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once a properly supported motion for summary judgment is made, the burden shifts to the non-moving party, who must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). In reviewing a motion for summary judgment, the court is required to examine the evidence in light most favorable to the non-moving party, and resolve all reasonable inferences in that party's favor. *Hunt v. Cromartie*, 526 U.S. 541, 552 (1999); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007).

A factual dispute is material when it "might affect the outcome of the suit under the governing law," and genuine when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. The non-moving party "need not match, item for item, each piece of evidence proffered by the movant," but must present more than a "mere scintilla" of evidence on which a jury could reasonably find for the non-moving party. *Boyle v. Cty. of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998) (quoting *Anderson*, 477 U.S. at 252).

IV. THE FALSE CLAIMS ACT

Under the FCA, private individuals can bring *qui tam* actions on behalf of the government in exchange for their right to retain some portion of any resulting

damages award. *United States ex rel. Wilkins v. United Health Care Group, Inc.*, 659 F.3d 295, 298 & n.1 (3d Cir. 2011) (citing 31 U.S.C. § 3729 *et seq.*). To establish a prima facie violation of the FCA, a plaintiff-relator must prove: (1) falsity; (2) causation; (3) knowledge; and (4) materiality. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017); *see also Wilkins*, 659 F.3d at 305 ("A plaintiff, in order to establish a prima facie FCA violation under section 3729(a)(1), must prove that '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'") (quoting *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004)).

Liability may attach under the FCA on two different theories: the presentment of factually false claims and the presentment of legally false claims. *Wilkins*, 659 F.3d at 305 (citing *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Wilkins*, 659 F.3d at 305. Legally false claims may be either express, where the claimant falsely certifies that it is in compliance with regulations, or implied, where the claimant "seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Id.* Under the so-

called "implied false certification theory," which Plaintiff-Relators invoke here, a plaintiff must demonstrate that the defendant submited a claim that includes "specific representations about goods or services provided" which are rendered "misleading half-truths" through "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements." *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

V. DEFENDANT'S MOTION TO DISMISS

Defendant first argues that the Amended Complaint should be dismissed because Plaintiff-Relators failed to comply with the statutory requirements of 31 U.S.C. § 3730(b)(2). [*See generally* Docket Item 127.] Among other requirements, Section 3730(b)(2) requires a relator to submit to the Government a "written disclosure of substantially all material evidence and information the person possesses." Such information allows the Government to decide whether it will intervene in an action, decline to intervene but permit the relator to proceed, or move to dismiss the complaint. *See* 31 U.S.C. §§ 3730(b)(2),(c)(2)(A).

According to Defendant, Plaintiff-Relators deliberately withheld material information in its "Written Disclosure of Substantially all Material Evidence and Information with Respect to Alleged False Claims" (the "Written Disclosure Statement"), which was served to the Government around the time the Complaint was filed in April 2008. [Docket Item 127 at 5-6.] Specifically, Defendant maintains that Druding's own deposition testimony revealed that

"Druding was the person who directed the conduct falsely attributed to Care Alternatives in the Complaint and that she was the subject of an internal compliance investigation where she admitted to this activity before immediately resigning." [*Id.* at 5.] According to Defendant, Druding testified at her deposition that she falsified medical records in connection with services provided to one patient, A.P., and this information was not included in the Written Disclosure Statement to the Government. [*Id.* at 7.] By "deliberately omitting" and "improperly with[holding]" this "material" information from the Written Disclosure Statement, Defendant argues, Plaintiff-Relators failed to comply with their pre-suit disclosure requirements under 31 U.S.C. § 3730(b)(2). [*Id.* at 6.] In support of its motion to dismiss, Defendant primarily relies on a novel interpretation of the recently-decided Supreme Court case, *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436 (2016), as discussed below.

In response, Plaintiff-Relators argue: (1) Defendant lacks "statutory" standing to seek dismissal for a purported violation of 31 U.S.C. § 3730(b)(2) because any injury from a violation of the statute would flow to the Government; (2) the Written Disclosure Statement was not deficient because Plaintiff-Relators gave the Government "substantially all material evidence and information" that they had, which was sufficient for the Government to decide whether or not to intervene; and (3) even if the Written Disclosure Statement was deficient, dismissal is not an appropriate remedy. [Docket Item 143.]

In *Rigsby*, the Supreme Court held that a district court **may** (but is not required to) dismiss a qui tam complaint for failure to comply with 31 U.S.C. § 3730(b)(2)'s requirement that an FCA complaint must be filed under seal. *Rigsby*, 137 S. Ct. at 444 ("In general, the question whether dismissal is appropriate should be left to the sound discretion of the district court.") Notably, the Supreme Court did not discuss the Section 3730(b)(2) requirement that a relator provide the government with "substantially all material evidence and information the person possesses." The *Rigsby* Court further observed, but did not hold, that the factors outlined in *United States ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242 (1995), "appear to be appropriate" for evaluating the consequences of a relator's violation of the § 3730(b)(2) deficiency at issue in that case. *Rigsby*, 137 S. Ct. at 444.

The Court assumes for purposes of deciding this motion to dismiss that *Lujan* articulated the proper test for dismissal due to a deficient Section 3730(b)(2) written disclosure statement.[9] Those factors are: (1) the actual harm to the Government; (2) the severity of the violations; and (3) evidence of bad faith. *Lujan*, 67 F.3d at 245-47. None of these three factors weigh in Defendant's favor.

First, Defendant has failed to show that the Government was actually harmed by the supposedly

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[9] Plaintiff-Relators argue, unpersuasively, that the Court should look to the six-factor test outlined in *Poulis v. State Farm Fire & Cas. Co.*, 747 F.2d 863, 867-68 (3d Cir. 1984), rather than the three-factor test outlined in *Lujan*. [*See* Docket Item 143 at 22-27.]

deficient Written Disclosure Statement, and "[t]he mere possibility that the Government **might** have been harmed by disclosure is not alone enough reason to justify dismissal of the entire action." *Lujan*, 67 F.3d at 245 (emphasis in original). This is especially so where, as here, the Government actively investigated the alleged misconduct for seven years, amassed tens of thousands of records, and ultimately declined to intervene.

Second, to the extent the Written Disclosure Statement was deficient, Plaintiff-Relators' alleged violation (*i.e.*, failure to disclose that Druding had, herself, apparently falsified the records of one patient, A.P.) was not necessarily "severe" in the context of a FCA action where Plaintiff-Relators had also identified 14 other patients in the Amended Complaint who allegedly received inappropriate hospice care.

Third, despite Defendant's hyperbolic rhetoric, there is no evidence that any omissions in the Written Disclosure Statement were the result of deliberate bad faith or willfulness on Plaintiff-Relators' part.

It also appears there have been no cases in which a defendant won dismissal of an FCA complaint where the purported 31 U.S.C. § 3730(b)(2) violation is a deficient Written Disclosure Statement presented to the Government. According to Plaintiff-Relators, "research reveals **no cases** in which a defendant has successfully sought dismissal for a violation of § 3730(b)(2)'s disclosure requirement." [Docket Item 143 at 16-17] (emphasis in original). The Court's own research efforts have produced similar results.

For these reasons, the motion to dismiss will be denied.

VI. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

In its motion for summary judgment, Defendant argues that: (1) Plaintiff-Relators' allegations of falsity have insufficient evidentiary support; (2) there is insufficient evidence that Defendants submitted legally false claims; (3) Plaintiff-Relators have not satisfied the element of "materiality;" and (4) Plaintiff-Relators have not adduced any evidence of scienter under the FCA. Because the Court finds that summary judgment is warranted on the first basis for the reasons described below, the Court need not address Defendant's other arguments.

1. Plaintiff-Relators Must Put Forth Evidence of "Objective Falsity"

As an initial matter, the Court finds persuasive the district courts' analyses in *United States v. AsercaCare, Inc.* ("*AseraCare I*"), 153 F. Supp. 3d 1372 (N.D. Ala. 2016), *United States v. AsercaCare, Inc.* ("*AseraCare II*"), 176 F. Supp. 3d 1282 (N.D. Ala. 2016), and *United States ex rel. Wall v. Vista Hospice Care, Inc.* ("*Vista Hospice*"), 2016 WL 3449833 (N.D. Tex.), wherein the trial courts held that, to survive a motion for summary judgment, evidence of "an objective falsehood" is required. *See also United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 383 (4th Cir. 2015) ("[F]or a claim to be considered false under the FCA, the statement or conduct alleged must represent an objective falsehood.") (internal citation omitted); *United States ex rel. Yannacopoulos v. General Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011)

("A statement may be deemed 'false' for purposes of the False Claims Act only if the statement represents an 'objective falsehood.'") (internal citation omitted); *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 982 (10th Cir. 2005) ("Falsity under the FCA does not mean 'scientifically untrue'; it means 'a lie.' At a minimum the FCA requires proof of an objective falsehood."); *United States ex rel. Riley v. St. Luke's Episcopal Hosp*, 355 F.3d 370, 376 (5th Cir. 2004) ("The district court concluded, however, that expressions of opinion or scientific judgments about which reasonable minds may differ cannot be 'false.' We agree in principle with the district court and accept that the FCA requires a statement known to be false, which means a lie is actionable but not an error.").

In *AseraCare*, the United States intervened in a *qui tam* action alleging that the medical records of 123 patients at issue in the case did not contain "clinical information and other documentation that support [this] medical prognosis," and thus, the defendant hospice provider's reimbursement claims for those patients were "false." *AseraCare II*, 176 F. Supp. 3d at 1283. Notably, the government did "not challenge that each claim for each patient at issue had an accompanying [certification of terminal illness] with the valid signature of the certifying physician. Nor [did] the Government point the court to any evidence that any of the documents in the patients' medical records were false; that any information on which the certifying physician relied was incorrect or false; or that the clinicians withheld information from the certifying physicians." *Id.* at 1285. Instead, the only evidence the government offered to prove falsity of the

claims came from the medical records of the patients at issue in the case and through the "testimony of [an expert] who offered **his opinion**, **based on his clinical judgment** after a review of those medical records, about the hospice eligibility of those patients." *Id.* at 1285-86 (emphasis in original).

After hearing evidence at a jury trial and then granting a new trial based on improper instructions the court gave to the jury regarding "false claims," *see AseraCare I*, 153 F. Supp. 3d at 1382-85, the Northern District of Alabama held that the government's theory failed as a matter of law because a "mere difference of opinion between physicians, **without more**, is not enough to show falsity." *AseraCare II*, 176 F. Supp. 3d at 1283 (emphasis in original) (citing *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1360 (S.D. Fla. 2015)) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false."). "Further, practices that may be improper, standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare." *AseraCare II*, 176 F. Supp. 3d at 1283-84 (internal citation and quotations omitted). In other words, the court explained, "[w]hen hospice certifying physicians and medical experts look at the very **same** medical records and disagree about whether the medical records support hospice eligibility, the opinion of one medical expert **alone** cannot prove falsity without further evidence of an objective falsehood." *Id.* at 1283 (emphasis in original).

The court then granted summary judgment in favor of the defendant hospice provider. *Id.* at 1286.[10]

Similarly, in *Vista Hospice*, the Northern District of Texas granted summary judgment in favor of a defendant hospice provider as to false claims allegations alleged by a *qui tam* relator who sought to prove that the hospice provider had submitted false reimbursement claims for inappropriate patients. There, the evidence consisted of two expert reports, as well as documents and testimony alleged to establish "a culture of admitting and maintaining patients who were ineligible for hospice," including deposition testimony of the relator and other employees who "describe[d] pressure allegedly imposed on them and others to falsify information in patient charts, which allegedly resulted in such information being falsified, and physicians certifying patients without reviewing patient files." *Vista Hospice*, 2016 WL 3449833, at *5; *see also id.* at *5-11 (summarizing the evidence and expert reports in detail).

First, the court explained that, "[b]ecause a physician must use his or her clinical judgment to determine hospice eligibility, an FCA claim about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis." *Id.* at *17 (citing *Morton*, 139 F. App'x at 982-83) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ

[10] The Court notes that *AceraCare* is currently pending on appeal. *See USA v. AseraCare, Inc.*, App. No. 16-13004 (11th Cir., filed on May 26, 2016).

cannot be false."). The court further observed, "[a] testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity." *Vista Hospice*, 2016 WL 3449833, at *17 (citing *AseraCare II* and *United States ex rel. Fowler v. Evercare Hospice, Inc.*, 2015 WL 5568614, at *9 (D. Colo. Sept. 21, 2015)). Accordingly, the court held that an expert's opinion that "certain of Defendants' patients were ineligible for hospice is insufficient to create a fact issue as to whether physician certifications and resulting claims were false." *Vista Hospice*, 2016 WL 3449833, at *18.

Next, the court considered relator's proffered evidence regarding the defendant hospice provider's corporate culture and allegations of altered medical documents. As the court observed, the relator produced "some evidence of the Defendants' pressure on their employees to admit large numbers of hospice patients, and that a few employees falsified data on a few specified patient charts. . . ," but failed to adequately "tie[] that evidence to the patients whose charts [the expert] evaluated, nor to the submission of a single false claim." *Id.* Without evidence of any such connection, the court found "there is no evidence of the falsity required to establish liability." *Id.* at 19.

Finally, the court determined that, "[n]o reliable evidence is presented by Relator that any patient was not terminally ill." *Id.* Although the relator and other non-physician employees "claim that they were involved in or observed the certification of patients who were medically ineligible, . . . eligibility depends on **physician** judgment, and thus, their allegations about patient health cannot support a conclusion that

any patient for whom a claim was submitted had a medical prognosis of more than six months." *Id.* (emphasis in original) (citing *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703) ("[T]hat Relator Janus, a social worker, and a nurse agreed that the patient was not appropriate for hospice because she could walk, eat, and talk does not suffice to allege that the doctor's certification that A.W. was appropriate for hospice was fraudulent; it merely alleges that Relator Janus and others disagreed with the doctor's assessment. Relators have not alleged facts demonstrating that the certifying physician did not or could not have believed, based on his or other clinical judgment, that the patient was eligible for hospice care."). The court then granted summary judgment in favor of the defendant hospice relator as to the false claims allegations. *Vista Hospice*, 2016 WL 3449833, at *21.

Again, the Court finds the reasoning in *AseraCare* and *Vista Hospice* persuasive. The logic of these cases is also supported by the Third Circuit's FCA caselaw. *See United States ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014) ("A statement is 'false' when it is objectively untrue."); *United States ex rel. Hill v. Univ. of Med. & Dentistry of N.J.*, 448 F. App'x 314, 316 (3d Cir. 2011) ("[E]xpressions of opinion, scientific judgments or statements as to conclusions which reasonable minds may differ cannot be false."). And Plaintiff-Relators cite to no binding authority that directly contradicts the analysis in either *AseraCare* and *Vista Hospice*. Accordingly, the Court adopts the reasoning of the district courts in these two well-reasoned and directly on-point cases with respect

to "objective falsity" for purposes of deciding Defendant's motion for summary judgment.

2. Plaintiff-Relators Have Not Adduced Sufficient Evidence of Objective Falsity

As in *AseraCare* and *Vista Hospice*, Plaintiff-Relators identified patients in the Amended Complaint who were allegedly inappropriate for hospice care. (*See* Am. Compl. at 25.) As in *AseraCare* and *Vista Hospice*, Plaintiff-Relators conceded that every patient identified in the Amended Complaint was certified by appropriate physicians for the hospice benefit, as required by 42 U.S.C. § 1395f(a)(7). *Druding*, 164 F. Supp. 3d at 631. As in *AseraCare* and *Vista Hospice*, Plaintiff-Relators have adduced no evidence that any physician received a kickback to certify any patient as hospice eligible, nor have Plaintiff-Relators accused a single physician of certifying any patient whom that physician believed was not hospice eligible. As in *AseraCare* and *Vista Hospice*, Plaintiff-Relators instead argue (primarily through an expert witness) that Defendant submitted false claims to the government simply because Defendant is missing adequate medical record documentation to support hospice certification. And as in *AseraCare* and *Vista Home*, the Court now finds that Plaintiff-Relators have not adduced evidence of objective falsity from which a reasonable fact finder could conclude that Defendant submitted any false claims for MHB reimbursement as to any of the identified hospice patients identified in the Amended Complaint.

As detailed in Section II.D.1, *supra*, Plaintiff-Relators' deposition testimony mostly reveals that, contrary to the allegations in the Amended Complaint, the only person who put any direct pressure on nurses or other Care Alternatives employees to admit ineligible patients for hospice was *Druding* herself. (*See, e.g.*, Coleman Dep. at 156:14-158:3; 171:19-173:23.) This is corroborated by Kelton's August 2007 internal investigation, which revealed that nurses reported feeling pressured by *Druding*, and only Druding, to admit patients whom the nurses believed were inappropriate for hospice (*see* Kelton Aff.), as well as the deposition testimony of several Care Alternatives Employees, including Coppola, Spoltore, and Veltri.

Nor is there evidence of alteration or falsification of any identified patient's record. As noted above, the Court previously dismissed without prejudice Plaintiff-Relators' allegations that Care Alternatives "submitted false claims for reimbursement by presenting to the Government claims based on altered medical records." *Druding*, 164 F. Supp. 3d at 632-33. Plaintiff-Relators did not seek leave to amend these allegations, instead choosing to "proceed in the matter regarding inappropriate patient admissions and re-certifications for hospice care." [Docket Item 49 at 1.] Nonetheless, Plaintiff-Relators still seek to advance the theory that medical documents were altered or falsified through their deposition testimony. But even then, there is simply no evidence to support Plaintiff-Realtors' theory. Bain and O'Brien testified that they never altered or falsified documents. Coleman testified that she was pressured to alter or falsify documents **by Druding**, but that she nonetheless

never altered or falsified any documents. And, most importantly, Druding adamantly maintains that, notwithstanding her contradictory remarks regarding A.P., she never altered or falsified any medical documents. In sum, no Plaintiff-Relator has identified a single document that was actually altered or falsified by any Care Alternatives employee.

The only remaining evidence of falsity that Plaintiff-Relators have put forth is the expert report of Dr. Jayes. But, as Third Circuit precedent makes clear, the difference of opinion of an expert cannot be false. *Hill*, 448 F. App'x at 316 ("[E]xpressions of opinion, scientific judgments or statements as to conclusions which reasonable minds may differ cannot be false."). Thus, while the respective expert witness for Plaintiff-Relators (Dr. Jayes) and for Defendant (Dr. Hughes) disagree as to whether they find a reasonable basis for admitting several identified patients into hospice, their diverging opinions do not create a genuine issue of material fact about the falsity of a physician's determinations that the patient meets hospice eligibility where, as here, there is no factual evidence that Defendant's certifying doctor was making a knowingly false determination. This is because the ultimate issue is not whether the certification of hospice eligibility was correct or incorrect, but rather whether it was knowingly false. Moreover, even if Plaintiff-Relators were entitled to rely exclusively on Dr. Jayes' expert report to establish falsity, which they are not, Dr. Jayes opined, in fact, that 12 of the 15 patients identified in the Amended Complaint were actually appropriate for hospice for at least part of their stay (Jayes Report at Appendix A), and testified that reasonable physicians could differ

with his assessment. (*See* Jayes Dep. [Docket Item 128-23] at 92:6-17; 94:1-5; 282:13-283:1; 283:12-19.) Thus, Dr. Jayes' expert report is plainly insufficient to establish a genuine dispute of material fact as to falsity.

In sum, Plaintiff-Relators have not adduced sufficient evidence of falsity sufficient to raise a genuine dispute of material fact. Accordingly, summary judgment must be granted in favor of Care Alternatives.

VII. CONCLUSION

In light of the foregoing, the Court will deny Defendant's motion to dismiss and grant Defendant's motion for summary judgment. An accompanying Order will be entered.

September 26, 2018	s/ Jerome B. Simandle
Date	JEROME B. SIMANDLE U.S. District Judge

Appendix D

RELEVANT STATUTORY AND REGULATORY PROVISIONS

31 U.S.C. § 3729(a)(1)(A)-(B)

(1) In general.–Subject to paragraph (2), any person who–

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

* * *

42 U.S.C. § 1395f(a)(7)(A) (2005)

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if—

* * *

(7) in the case of hospice care provided an individual—

(A)(i) in the first 90-day period and

(I) the individual's attending physician (as defined in section 1395x(dd)(3)(B) of this title)(which for purposes of this subparagraph does not include a nurse practitioner), and

(II) the medical director (or physician member of the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program providing (or arranging for) the care,

each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1395x(dd)(3)(A) of this title) based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness,

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment;

* * *

42 C.F.R. § 418.22(b) (2006)

* * *

(b) Content of certification. Certification will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The certification must conform to the following requirements:

(1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(2) Clinical information and other documentation that support the medical

prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

(3) The physician must include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms.

(i) If the narrative is part of the certification or recertification form, then the narrative must be located immediately prior to the physician's signature.

(ii) If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum.

(iii) The narrative shall include a statement under the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his or her examination of the patient.

(iv) The narrative must reflect the patient's individual clinical circumstances and cannot

contain check boxes or standard language used for all patients.

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