[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 16-13004

D.C. Docket No. 2:12-cv-00245-KOB

UNITED STATES OF AMERICA,

Plaintiff - Appellant,

versus

ASERACARE, INC.,
GGNSC ADMINISTRATIVE SERVICES,
d.b.a. Golden Living,
f.k.a. Beverly Enterprises, Inc.,
HOSPICE PREFERRED CHOICE, INC.,
HOSPICE OF EASTERN CAROLINA, INC.,

Defendants - Appellees.

Appeal from the United States District Court
for the Northern District of Alabama

(September 9, 2019)

Before ROSENBAUM and JULIE CARNES, Circuit Judges, and SCHLESINGER,* District Judge.

JULIE CARNES, Circuit Judge:

This case requires us to consider the circumstances under which a claim for hospice treatment under Medicare may be deemed "false" for purposes of the federal False Claims Act. Defendants comprise a network of hospice facilities that routinely bill Medicare for end-of-life care provided to elderly patients. In the underlying civil suit, the Government alleged that Defendants had certified patients as eligible for Medicare's hospice benefit, and billed Medicare accordingly, on the basis of erroneous clinical judgments that those patients were terminally ill. Based on the opinion of its expert witness, the Government contends that the patients at issue were not, in fact, terminally ill at the time of certification, meaning that AseraCare's claims to the contrary were false under the False Claims Act.

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* The Honorable Harvey E. Schlesinger, United States District Judge for the Middle District of Florida, sitting by designation.

As the case proceeded through discovery and a partial trial on the merits, the district court confronted the following question: Can a medical provider's clinical judgment that a patient is terminally ill be deemed false based merely on the existence of a reasonable difference of opinion between experts as to the accuracy of that prognosis? The district court ultimately answered this question in the negative and therefore granted summary judgment to AseraCare on the issue of falsity.

Upon careful review of the record and the relevant law, and with the benefit of oral argument, we concur with the district court's ultimate determination that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment. We do, however, think that the Government should have been allowed to rely on the entire record, not just the trial record, in making its case that disputed issues of fact, beyond just the difference of opinion between experts, existed sufficient to warrant denial of the district court's post-verdict *sua sponte* reconsideration of summary judgment on the falsity question. We therefore affirm in part and remand in part.

I. BACKGROUND[1]

Each year, more than a million Americans make the difficult decision to forgo curative care and turn instead to end-of-life hospice care, which is designed to relieve the pain and symptoms associated with terminal illness. *See* 79 Fed. Reg. 50452, 50454–55 (Aug. 22, 2014). The federal government's Medicare program makes such care affordable for a significant number of terminally ill individuals. Defendants, collectively referred to as AseraCare, operate approximately sixty hospice facilities across nineteen states and admit around 10,000 patients each year. Most of AseraCare's patients are enrolled in Medicare. In fact, from 2007 to 2012, Medicare payments composed approximately ninety-five percent of AseraCare's revenues. As such, AseraCare routinely prepares and submits claims for reimbursement under Medicare.

This case began when three former AseraCare employees alleged that AseraCare had a practice of knowingly submitting unsubstantiated Medicare claims in violation of the federal False Claims Act. We begin by setting out the requirements hospice providers like AseraCare must meet in order to be entitled to

[1] We derive the pertinent facts from the parties' submissions, the summary judgment record, and the trial testimony presented in the proceeding below.

hospice reimbursement and identifying the tools the Government uses to police compliance with these requirements.

A. The Medicare Hospice Benefit

In order for a hospice claim to be eligible for Medicare reimbursement, the patient's attending physician, if there is one, and the medical director of the hospice provider must "each certify in writing at the beginning of [each] 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." 42 U.S.C. § 1395f(7)(A). "Terminally ill" means that 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). Under the statute's implementing regulations, a claim for hospice reimbursement must conform to several requirements in order to be payable. Most notably for purposes of this appeal, the certification must be accompanied by "[c]linical information and other documentation that support the medical prognosis," and such support "must be filed in the medical record with the written certification." 42 C.F.R. § 418.22(b)(2).

An initial certification conforming to these requirements is valid for a period of ninety days. 42 U.S.C. § 1395f(7)(A). The patient must be recertified in a similar manner for each additional sixty- or ninety-day period during which he or she remains in hospice. *Id.* While a life-expectancy prognosis of six months or

less is a necessary condition for reimbursement, regulators recognize that "[p]redicting life expectancy is not an exact science." 75 Fed. Reg. 70372, 70488 (Nov. 17, 2010). Accordingly, the Medicare framework does not preclude reimbursement for periods of hospice care that extend beyond six months, as long as the patient's eligibility is continually recertified. This framework also recognizes that, in some cases, patients with an initial prognosis of terminality can improve over time, and it allows such patients to exit hospice without losing their right to Medicare coverage to treat illness. *Id*. Thus, there is no statutory limit to the number of periods for which a patient may be properly certified. 42 U.S.C. § 1395d(d)(1) (establishing that hospice providers may collect reimbursement for an unlimited number of recertification periods).

The Medicare program is overseen by the Centers for Medicare and Medicaid Services ("CMS"), a division of the Department of Health and Human Services. CMS operates locally through so-called Medicare Administrative Contractors ("MACs"), which process claims from healthcare providers and make payment for eligible services. A majority of AseraCare's Medicare claims are processed by a MAC called Palmetto GBA ("Palmetto"), which operates in the southeast United States.

In preparing its claims for hospice reimbursement, AseraCare employs interdisciplinary teams of skilled staff—including physicians, nurses,

psychologists, social workers, and chaplains—that render services directly to patients and collectively make eligibility determinations. To guide this review, AseraCare professionals rely in part on documents called Local Coverage Determinations ("LCDs"), which are issued by Palmetto's medical directors. LCDs provide detailed lists of diagnostic guidance and clinical information that, if documented in a patient's medical record, suggest that the patient has a life expectancy of six months or less. LCDs are not clinical benchmarks or mandatory requirements for hospice eligibility, however. Rather, they are designed to help clinical staff understand the type of information that should be considered prior to concluding that a patient is terminally ill. The LCDs themselves explicitly state that they are non-binding.

Once AseraCare physicians reach a clinical judgment that a patient is eligible for hospice care, AseraCare may begin providing treatment. It submits claims to Palmetto for reimbursement only after care has been rendered. The trial testimony of Mary Jane Schultz, a registered nurse and former director of Palmetto's medical review team, clarified at trial the process by which Palmetto reviewed and paid claims for hospice coverage during the relevant time period of 2007 to 2012. As Ms. Schultz described, the first round of claim review was conducted by an automated claim-processing system designed to ensure that no critical information, such as a patient's Medicare identification number, was

missing or invalid. If no critical information was missing, the system would then check for any "red flags" that might require further review of the claim—such as the involvement of a particular provider, patient, or type of care that Palmetto staff believed may pose heightened eligibility risks. For instance, if Palmetto wished to conduct a targeted audit of claims submitted by a particular provider, it could program the automated system to pull all or a portion of those claims for additional review before payment.

If automated review uncovered no missing information or red flags, the system would process the claim directly for payment. As a result, Palmetto paid many claims without directly reviewing the medical documentation underpinning them. Where, on the other hand, a claim was flagged for heightened medical review, Palmetto would immediately issue a request to the provider for medical documentation substantiating the patient's terminal prognosis, such as notes from physicians, nurses, and social workers and records of medications and treatments prescribed. A trained medical review team would then review the supporting documentation before determining whether the claim should be paid in full, paid in part, or denied. Like AseraCare's medical staff, the medical review team commonly uses the LCDs as guidelines in its assessment, but it is not required to rigidly apply their criteria. Instead, the review team also looks at the "whole picture" of information submitted with the claim.

B. The False Claims Act

The False Claims Act ("FCA") serves as a mechanism by which the Government may police noncompliance with Medicare reimbursement standards after payment has been made. The Act imposes civil liability—including treble damages—on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). To prevail on an FCA claim, the plaintiff must prove that the defendant (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the Government to make a payment. *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015).

Private citizens, called *qui tam* relators, are authorized to bring FCA suits on behalf of the United States. 31 U.S.C. § 3730(b). The United States can, and frequently does, intervene in *qui tam* suits to develop the civil case itself. Thus, to the extent the Government concludes that it has reimbursed a hospice provider that knowingly submitted deficient claims, the Government can use the FCA cause of action to recoup payments and to penalize the provider.

II. PROCEDURAL HISTORY

A. Suit Against AseraCare Under the FCA

The underlying case began in 2008, when three former AseraCare employees, acting as *qui tam* relators, filed a complaint against AseraCare alleging submission of unsubstantiated hospice claims. Following a transfer of venue from the Eastern District of Wisconsin to the Northern District of Alabama, the Government intervened and filed the operative complaint. In its complaint, the Government alleged that AseraCare knowingly employed reckless business practices that enabled it to admit, and receive reimbursement for, patients who were not eligible for the Medicare hospice benefit "because it was financially lucrative," thus "misspending" millions of Medicare dollars. The Government's complaint described a corporate climate that pressured sales and clinical staff to meet aggressive monthly quotas for patient intake and, in so doing, discouraged meaningful physician involvement in eligibility determinations. More specifically, the Government alleged that AseraCare "submitted documentation that falsely represented that certain Medicare recipients were 'terminally ill'" when, in the Government's view, they were not.

In light of these allegations, the Government's case falls under the "false certification" theory of FCA liability. Under this theory, FCA liability may arise where a defendant falsely asserts or implies that it has complied with a statutory or regulatory requirement when, in actuality, it has not so complied. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016).

In developing its case, the Government began by identifying a universe of approximately 2,180 patients for whom AseraCare had billed Medicare for at least 365 continuous days of hospice care. The Government then focused its attention on a sample of 223 patients from within that universe. Through direct review of these patients' medical records and clinical histories, the Government's primary expert witness, Dr. Solomon Liao, identified 123 patients from the sample pool who were, in Dr. Liao's view, ineligible for the hospice benefit at the time AseraCare received reimbursement for their care. Should it prevail as to this group, the Government intended to extrapolate from the sample to impose further liability on AseraCare for a statistically valid set of additional claims within the broader universe of hospice patients for whom AseraCare received Medicare payments.

To supplement the testimony of Dr. Liao, the Government also sought to develop evidence that AseraCare's broader business practices fostered and promoted improper certification procedures while deemphasizing clinical training on terminal-illness prognostication. Several former AseraCare employees, including the *qui tam* relators, supported the Government's narrative by describing a process in which physicians merely rubber-stamped terminal-illness certifications without thoroughly examining the relevant medical records underlying them.

Importantly, though, the Government's false-claims allegations in this case

were narrowly circumscribed. There were no allegations that AseraCare billed for phantom patients, that certifications or medical documentation were forged, or that AseraCare employees lied to certifying physicians or withheld critical information regarding patient conditions. Indeed, there was no doubt in the proceeding below that AseraCare possessed accurate and comprehensive documentation of each patient's medical condition and that its certifications of terminal illness were signed by the appropriate medical personnel. Rather, the Government asserted that its expert testimony—contextualized by broad evidence of AseraCare's improper business practices—would demonstrate that the patients in the sample pool were not, as a medical fact, terminally ill at the time AseraCare collected reimbursement for their hospice care. The sole question related to the sufficiency of the clinical judgments on which the claims were based.

On this theory, the Government sought to recover damages under two subsections of the FCA, 31 U.S.C. § 3729(a)(1)(A)[2] and 31 U.S.C. § 3729(a)(1)(B),[3] and on claims of common-law unjust enrichment and mistaken

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[2] "[A]ny person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government . . . ." 31 U.S.C. § 3729(a)(1)(A).

[3] "[A]ny person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . is liable to the United States Government . . . ." 31 U.S.C. § 3729(a)(1)(B).

payment.

B. First Motion for Summary Judgment

Following extensive discovery and expert analysis of relevant patient records, AseraCare moved for summary judgment on the ground that the Government failed to adduce evidence of the falsity of any disputed claims and failed to show that AseraCare had any knowledge of the alleged falsity. Most notably for purposes of this appeal, AseraCare put squarely before the district court the question whether the Government's medical-opinion evidence was sufficient to establish the threshold element of falsity. To that point, AseraCare urged the district court to embrace a "reasonable doctor" standard for the assessment of falsity, which would state that, to avoid summary judgment in an action involving false claims for hospice reimbursement, the Government must show that a reasonable physician applying his or her clinical judgment could not have held the opinion that the patient at issue was terminally ill at the time of certification.[4]

The district court found the "reasonable doctor" standard "appealing and logical," but noted that it had not been adopted by the Eleventh Circuit and

[4] AseraCare asked the district court to adopt the standard for falsity established by the Northern District of Illinois in a case with a similar fact pattern and posture. The court in that case dismissed FCA claims against a for-profit hospice facility because relators failed to allege facts "demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care." *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012).

declined to apply it. The court ultimately denied AseraCare's motion for summary judgment, concluding that fact questions remained regarding whether clinical information and other documentation in the relevant medical records supported the certifications of terminal illness on which AseraCare's claims were based.

Following the denial of its motion for summary judgment, AseraCare moved to certify the following question for interlocutory appeal before this Court under 28 U.S.C. § 1292(b):

> In a False Claims Act case against a hospice provider relating to the eligibility of a patient for the Medicare hospice benefit, for the Government to establish the falsity element under 31 U.S.C. § 3729(a)(1), must it show that, in light of the patient's clinical information and other documentation, no reasonable physician could have believed, based on his or her clinical judgment, that the patient was eligible for the Medicare hospice benefit?

The district court certified the question for interlocutory appeal. We considered AseraCare's motion for review but declined to consider the question at that stage of the proceeding.

C. Bifurcation of Trial

Subsequent to the denial of summary judgment, AseraCare moved the district court to bifurcate trial under Federal Rule of Civil Procedure 42(b) into two phases: one phase on the falsity element of the FCA and a second phase on the FCA's remaining elements and the Government's common-law claims. The Government vehemently opposed the motion. It argued that the proposed

bifurcation was "extraordinary," requiring the Government "to jump over an arbitrary hurdle that is without precedent" because "the elements of 'falsity' and 'knowledge of falsity' are not so distinct and separable that they may be tried separately without injustice." Indeed, the Government noted, the elements of FCA liability had "never before been bifurcated by a federal district court." The Government further argued that bifurcation was unworkable because documentary and testimonial evidence that was probative in the falsity phase—"because it undermines the reliability of the [certifications of terminal illness]"—was "also probative in the 'knowledge of falsity' phase because it shows AseraCare knew or should have known that it was submitting false claims for non-terminally [*sic*] patients."

Nonetheless, the district court granted the motion in light of its concern that evidence pertinent to the knowledge element of the FCA would confuse the jury's analysis of the threshold question of whether the claims at issue were "false" in the first instance. The court noted that, while "pattern and practice" evidence showing deficiencies in AseraCare's admission and certification procedures could help establish AseraCare's *knowledge* of the alleged scheme to submit false claims—the second element of the Government's case—the *falsity* of the claims "cannot be inferred by reference to AseraCare's general corporate practices unrelated to specific patients." In the court's view, allowing the Government to present

knowledge evidence before falsity was determined would be unduly prejudicial to AseraCare, thus warranting separation of the knowledge and falsity elements.

In accordance with this rationale, the district court "drew the line of admissibility" in Phase One of trial "at anecdotal evidence about a specific, but unidentified, patient or event that would be impossible for the Defense to rebut." The court did, however, allow in Phase One anecdotal testimony regarding improper clinical or corporate practices that "had a time and place nexus with the 123 allegedly ineligible patients at issue." Such testimony, in the court's view, would have been "highly probative and admissible in Phase One." Indeed, in bifurcating trial, the court presumed—based on the Government's own representations—that the Government possessed and would present such evidence in Phase One. The court did allow in Phase One general testimony regarding AseraCare's business practices and claim-submission process during the relevant time period, but only to contextualize the falsity analysis and "afford[] the jury an opportunity to more fully understand the hospice process within AseraCare." Such evidence was not, however, admissible to prove the falsity of the claims at issue.[5]

[5] The Government continues to complain on appeal that bifurcation of the trial was "fundamentally unfair" and confused the issues, albeit it does not expressly challenge on appeal the district court's decision.

D. Phase One of Trial

The first phase of the trial lasted approximately eight weeks and proceeded to a jury verdict largely against AseraCare on the question of falsity. During its case in chief, the Government presented several days of testimony from Dr. Liao, who explained that, in his expert opinion, the medical records of the patients at issue did not support AseraCare's "terminal illness" certifications because they did not reveal a life expectancy of six months or less. Dr. Liao made clear that his testimony was a reflection of only his own clinical judgment based on his after-the-fact review of the supporting documentation he had reviewed. He conceded that he was "not in a position to discuss whether another physician [was] wrong about a particular patient's eligibility. Nor could he say that AseraCare's medical expert, who disagreed with him concerning the accuracy of the prognoses at issue, was necessarily "wrong." Notably, Dr. Liao never testified that, in his opinion, no reasonable doctor could have concluded that the identified patients were terminally ill at the time of certification. Instead, he only testified that, in his opinion, the patients were not terminally ill. Even more notable is the fact that Dr. Liao himself changed his opinion concerning the eligibility of certain patients over the course of the proceeding—deciding that some of the patients he had earlier concluded were not terminally ill were in fact terminally ill. Nevertheless, he testified at trial that both sets of contradictory opinions remained "accurate to a reasonable degree of

certainty." To explain these reversals, Dr. Liao stated that he "was not the same physician in 2013 as [he] was in 2010."

The Government also presented testimony of the relators and other AseraCare employees regarding AseraCare's certification procedures, but, as discussed *supra*, this testimony was characterized as being offered solely to show context, not falsity. In rebuttal, AseraCare offered expert testimony that directly contradicted Dr. Liao's opinions.

The parties' expert witnesses disagreed along two lines. First and foremost, they fundamentally differed as to how a doctor should analyze a patient's life expectancy for Medicare reimbursement purposes. The Government's Dr. Liao applied what might be called a "checkbox approach" to assessing terminal illness: He examined the patients' records and compared them against Palmetto's LCDs (and other, similar medical guidelines) for specific diagnoses, including Alzheimer's, heart disease, cardiopulmonary disease, and "adult failure to thrive." By contrast, AseraCare's experts considered but did not formulaically apply the LCD guidance in making their assessments. Instead, they took a "whole patient" approach, making prognoses based on the entirety of the patient's history, the confluence of ailments from which a patient may be suffering, and their own experience with end-of-life care. AseraCare's experts did not discount the LCD "criteria," but—as the latter instruct— these experts did not consider themselves

compelled to conclude that a patient was ineligible merely because the patient had failed to meet one of those indicia.

The district court correctly stated in its instructions to the jury that the LCDs are "eligibility guidelines" that are not binding and should not be considered "the exact criteria used for determining" terminal illness. As such, the jury was not permitted to conclude that Dr. Liao's testimony was more credible because he made reference to the LCD criteria, or that AseraCare's claims were false if they failed to conform to those criteria. Nonetheless, the experts' disagreement as to the proper analytical approach impacted their ultimate judgments as to each patient's terminality.

Because neither the checkbox approach nor the holistic approach to making terminal-illness prognoses is contrary to the law, the jury's sole job at trial was to review the medical records of each patient and decide which experts' testimony seemed more persuasive on the question whether a particular patient should be characterized as "terminally ill" at the time of certification. To be clear, the Government never alleged that AseraCare's doctors relied on medical documentation that was too thin, vague, or lacking in detail to reasonably substantiate their "clinical judgments" of terminal illness. Indeed, there is no dispute that each patient certification was supported by a meaningful set of medical records evidencing various serious and chronic ailments for which the patient was

entitled to some level of treatment. The question before the jury was instead which doctor's interpretation of those medical records sounded more correct. In other words, in this battle of experts, the jury was to decide which expert it thought to be more persuasive, with the less persuasive opinion being deemed to be false. To guide that assessment, the district court provided the following instruction on falsity: "A claim is 'false' if it is an assertion that is untrue when made or used. Claims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable."

Ultimately, the expert testimony in this case revealed a fundamental difference of professional opinion regarding the manner in which each patient's complete medical picture contributed to his or her life expectancy at the time he or she received hospice care. Both sets of experts looked at the same medical documentation, considered the same medical standards for the terminal-illness determination (even while differing as to the weight such standards should be given), and relied on their own experience as seasoned physicians specializing in end-of-life care. Dr. Liao testified that, in his professional opinion, the patients at issue were not likely to die within six months of the date on which they were certified for hospice care. AseraCare's experts arrived at opposite conclusions.

As an illustration of this disagreement, consider the testimony of the Government's Dr. Liao and AseraCare's Dr. Gail Cooney regarding the patient

Elsin K., who was an AseraCare hospice patient for over a year and who ultimately died in an AseraCare facility. Elsin was first admitted to hospice upon her physician's diagnosis of "debility," also called "adult failure to thrive," in which a patient experiences a general decline in health due to old age. Elsin experienced subsequent periods of improvement and decline; she left hospice care and was recertified on at least two occasions before her death.

As with each patient at issue in this case, Dr. Liao's assessment of Elsin's hospice eligibility contrasted starkly with Dr. Cooney's, even though there was no dispute as to Elsin's underlying diagnoses. Dr. Liao noted that many of Elsin's ailments, including severe infections arising from a joint replacement, were chronic and had recurred for many years. He also noted that she did not demonstrate the level of physical debility that published medical criteria typically associate with terminal patients. On the basis of his medical review, he described Elsin as struggling with chronic illness but "overall rather stable, if not improving," and thus lacking a prognosis of six months or less to live at the time of her certifications and recertifications. Dr. Cooney, the defense expert, also recognized that Elsin "had been sick for a long time," but she saw in the medical records a trend of steady physical and mental decline, decreased mobility, and increasing pain. Elsin's physical and psychological ailments, viewed in combination with one another, complicated the picture of Elsin's overall health and

contributed to Dr. Cooney's judgment that Elsin was terminally ill during each relevant time period. In the Government's view, it was properly within the purview of the jury to decide which doctor's judgment was correct and, to the extent the jury found Dr. Liao's prognosis to be more persuasive, to find that AseraCare had thereby submitted a false statement when it filed a claim based on a prognosis that differed from Dr. Liao's.

At the conclusion of the parties' cases, the court instructed the jury to answer special interrogatories regarding the prognoses of each of the 123 patients at issue. The jury ultimately found that AseraCare had submitted false claims for 104 patients of the 123 patients at issue during the relevant time periods.

E. Grant of New Trial and Second Motion for Summary Judgment

Following the partial verdict in this first phase of trial, AseraCare moved for judgment as a matter of law, arguing that the court had articulated the wrong legal standard in its instructions to the jury. The district court agreed. In the court's own words, "[a]s the court worked through AseraCare's challenges," it "became convinced that it had committed reversible error in the instructions it provided to the jury." It ultimately concluded that proper jury instructions would have advised the jury of two "key points of law" that the court had not previously acknowledged: (1) that the FCA's falsity element requires proof of an objective falsehood; and (2) that a mere difference of opinion between physicians, *without*

more, is not enough to show falsity. AseraCare had advocated for this legal standard since the start of trial, but only after hearing all the evidence had the court become "convinced" that "a difference of opinion is not enough." The court ultimately concluded that the failure to instruct the jury on these points was reversible error and that the only way to cure the prejudice caused thereby was to order a new trial.

The court then went one step further, deciding to consider summary judgment *sua sponte* under Federal Rule of Civil Procedure 56(f)(3). Specifically, it informed the parties that it intended to consider "whether the Government, under the correct legal standard, has sufficient admissible evidence of more than just a difference of opinion to show that the claims at issue are objectively false as a matter of law." The court gave the parties an opportunity to brief the issue, advising that:

> The Government's proof under the FCA for the falsity element would fail as a matter of law if all the Government has as evidence of falsity in the second trial is Dr. Liao's opinion based on his *clinical judgment* and the medical records that he contends do not support the prognoses for the 123 patients at issue in Phase One.

In its summary-judgment briefing, the Government argued that it was procedurally improper for the court to raise summary judgment *sua sponte* after already deciding to grant a new trial. The district court rejected this argument, and the Government does not revive the challenge on appeal.

Following briefing and a hearing, the court granted summary judgment in AseraCare's favor on the basis of the court's newly adopted legal standard. The court concluded, "[a]fter careful review of all [the parties'] submissions and the Phase One [trial] record, . . . that the Government has failed to point the court to any admissible evidence to prove falsity other than Dr. Liao's opinion that the medical records for the 123 patients at issue did not support the Certifications of Terminal Illness" that were submitted for Medicare reimbursement. Because "[t]he Government [ ] presented no evidence of an objective falsehood for any of the patients at issue," it could not prove the falsity element of its FCA claim as a matter of law. The court thus granted summary judgment in AseraCare's favor.

The Government appeals the district court's summary judgment order and its grant of a new trial, contending that the legal standard the court ultimately adopted reflected a "deeply flawed" understanding of the falsity element of an FCA claim. The Government thus asks this Court to reject the legal standard for falsity that the district court adopted, reverse the district court's grant of summary judgment and order of a new trial, and reinstate the jury's Phase One findings: namely, that the Government successfully proved falsity as to several of the claims at issue.

III. STANDARD OF REVIEW

This Court reviews the district court's grant of summary judgment *de novo*, viewing all the evidence and drawing all reasonable inferences in favor of the non-

moving party. *Vessels v. Atlanta Indep. Sch. Sys.*, 408 F.3d 763, 767 (11th Cir. 2005). By contrast, we review a district court's ruling on a motion for a new trial for abuse of discretion. *Hewitt v. B.F. Goodrich Co.*, 732 F.2d 1554, 1556 (11th Cir. 1984).

IV. DISCUSSION

This appeal requires us to consider how Medicare's requirements for hospice eligibility—which are centered on the subjective "clinical judgment" of a physician as to a patient's life expectancy—intersect with the FCA's falsity element. Under this Court's precedent, "Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005). There is no allegation that the hospice services AseraCare provided were not rendered as claimed. Thus, the sole question is whether the claims AseraCare submitted were reimbursable under the Medicare framework for hospice care—that is, whether AseraCare's certifications that patients were terminally ill satisfied Medicare's statutory and regulatory requirements for reimbursement. If not, the claims are capable of being "false" for FCA purposes.

Thus framed, our primary task on appeal is to clarify the scope of the hospice eligibility requirements, which are set out in the federal Medicare statute,

42 U.S.C. § 1395f, and its implementing regulation, 42 C.F.R. § 418.22. Our secondary task is to determine whether the district court's formulation of the falsity standard was consistent with the law and properly applied. Neither this Court nor any of our sister circuits has considered the standard for falsity in the context of the Medicare hospice benefit, where the controlling condition of reimbursement is a matter of clinical judgment. After careful review of the relevant law, the underlying record, and the considerations raised by the parties and the amici curiae, we agree that the instruction given to the jury was inadequate and agree with the general sense of the legal standard embraced by the district court after the verdict.

A. Legal Standard for Falsity of Hospice Claims

The Government argues that the district court's initial jury instructions—that "[a] claim is 'false' if it is an assertion that is untrue when made or used" and that "[c]laims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable"—comprised a complete and correct statement of the legal standard for falsity. As applied to this case, the Government argues that it can show falsity by producing expert testimony that a patient's medical records do not support a terminal-illness prognosis as a factual matter. Where the parties present competing expert views on a patient's prognosis, the "falsity" of the defendant's prognosis is put to a jury.

AseraCare contests the Government's characterization of the statutory and regulatory framework, arguing that the determinative inquiry in an eligibility analysis is whether the certifying physician exercised genuine clinical judgment regarding a patient's prognosis and further arguing that the accuracy of such judgment is not susceptible to being proven true or false as a factual matter.

Given the dearth of controlling case law regarding the intersection of the FCA and the Medicare hospice benefit and the parties' vigorous disagreement on the fundamental points of law, we begin by defining the contours of the hospice-eligibility framework and clarifying the circumstances under which a claim violates the requirements for reimbursement. We then consider the ways in which a hospice claim might be deemed "false" for purposes of the FCA.

1. Hospice Eligibility Framework

Our analysis begins with the language of the relevant statute and regulations. *See United States v. Aldrich*, 566 F.3d 976, 978 (11th Cir. 2009) ("[T]he 'starting point' of statutory interpretation is 'the language of the statute itself.'") (citing *Randall v. Loftsgaarden*, 478 U.S. 647, 656 (1986)). "To determine the plain meaning of a statute or regulation, we do not look at one word or term in isolation, but rather look to the entire statutory or regulatory context." *Sec. & Exch. Comm'n v. Levin*, 849 F.3d 995, 1003 (11th Cir. 2017).

In relevant part, the statute states that payment for hospice care provided to an individual may be made only if:

> (i) in the first 90-day period . . . (I) the individual's attending physician . . . and (II) the medical director (or physician member of the interdisciplinary group described in [42 U.S.C. § 1395x(dd)(2)(B)]) of the hospice program providing . . . the care, *each certify in writing at the beginning of the period, that the individual is terminally ill* (as defined in [42 U.S.C. § 1395x(dd)(3)(A)]) *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 . . . recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment.

42 U.S.C. § 1395f(a)(7)(A) (emphasis added).[6] "Terminally ill" means that the individual "has a medical prognosis that the individual's life expectancy is 6

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[6] The statute contains three additional requirements, each of which was in place during the relevant time period of 2007 through 2012:

> (B) a written plan for providing hospice care with respect to such individual has been established . . . and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in 42 U.S.C. § 1395x(dd)(2)(B)]) of the hospice program;
>
> (C) such care is being or was provided pursuant to such plan of care; [and]
>
> (D) on and after January 1, 2011 . . . a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility . . . prior to the 180th-day recertification and each subsequent recertification . . . and attests that such visit took place . . . .

42 U.S.C. § 1395f(a)(7). The Government does not allege that AseraCare failed to meet any of these additional requirements.

months or less." 42 U.S.C. § 1395x(dd)(3)(A). In any case, "no payment may be made . . . for any expenses incurred . . . which are not reasonable and necessary for the palliation or management of terminal illness." 42 U.S.C. § 1395y(a)(1)(C).

The implementing regulations echo the language of the statute, reiterating that each written certification of terminal illness "will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." 42 C.F.R. § 418.22(b). *See also* 42 C.F.R. § 418.22(a)(1) (stating "general rule" that hospice provider "must obtain written certification of terminal illness" for each claimed period of care).

The regulations go on to identify several requirements for the submission of claims. First, and most significant to this appeal, "[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." 42 C.F.R. § 418.22(b)(2). Second, the certifying physician must include with the certification "a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less." 42 C.F.R. § 418.22(b)(3). This narrative explanation "must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients." 42 C.F.R.

§ 418.22(b)(3)(iv).[7] And third, in deciding whether to certify a patient as terminally ill, a physician is obligated to consider several factors: the patient's primary terminal condition and related diagnoses; current subjective and objective medical findings; current medication and treatment orders; and information about the medical management of any conditions unrelated to the terminal illness. 42 C.F.R. § 418.102(b); 42 C.F.R. § 418.25(b) (establishing that, "[i]n reaching a decision to certify that the patient is terminally ill, the hospice medical direct must consider at least" the diagnosis of the patient, other health conditions, and "[c]urrent clinically relevant information supporting all diagnoses"). *See also* 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) ("[T]he certification of terminal illness is based in the unique clinical picture of the individual that is reflected in the comprehensive assessment and other clinical records and documentation . . . ."); 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014) (noting that, in deciding whether to recertify a patient who has not shown measurable decline, the physician "must assess and evaluate the full clinical picture" of the patient).

The language of the statute and implementing regulations makes plain that the clinical judgment of the patient's attending physician (or the provider's medical

[7] The requirement of a brief narrative explanation accompanying the certification was added to the regulations on October 1, 2009. *See* 74 Fed. Reg. 39384, 39398–400, 39413 (Aug. 6, 2009).

director, as the case may be) lies at the center of the eligibility inquiry. Under this language, a patient is eligible for the Medicare hospice benefit if the appropriate physician makes a clinical judgment that the patient is terminally ill in light of the patient's complete medical picture, as evidenced by the patient's medical records.

Importantly, none of the relevant language states that the documentary record underpinning a physician's clinical judgment must prove the prognosis as a matter of medical fact. Indeed, CMS has recognized in crafting the implementing regulations that "[p]redicting life expectancy is not an exact science." 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010). *See also* 79 Fed. Reg. at 50470 ("[W]e also have recognized the challenges in prognostication" and therefore expect "that the certifying physicians will use their best clinical judgment.").[8] Nor does this framework state or imply that the patient's medical records must unequivocally demonstrate to an unaffiliated physician, reviewing the records after the fact, that the patient was likely to die within six months of the time the certifying physician's clinical judgment was made. Rather, the framework asks a physician

[8] We have held in the context of FCA proceedings that "guidance issued by the governmental agency charged with administrating the regulatory scheme," including the Medicare regulatory scheme, "can be consulted to understand the meaning of that regulation." *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1357 (11th Cir. 2005).

responsible for the patient's care to exercise his or her judgment as to the proper interpretation of the patient's medical records.

The Government seeks to elevate the significance of the regulation's supporting-documentation requirement, asserting that eligibility "turns on" whether the clinical information and other documentation accompanying a certification of terminal illness support, as a factual matter, the physician's certification. Specifically, the Government maintains that the testimony of Dr. Liao, which "was designed to assist the jury in understanding the medical records" for each patient, created "a factual dispute as to whether '[c]linical information and other documentation' in the medical record 'support[ed] the medical prognosis' of a life expectancy of six months or less." (Citing 42 C.F.R. § 418.22(b)(2).)

We conclude that the Government's framing of the eligibility inquiry is not consistent with the text or design of the law. The relevant regulation requires only that "clinical information and other documentation that support the medical prognosis . . . *accompany the certification*" and "*be filed in the medical record*." 42 C.F.R. § 418.22(b)(2) (emphases added). This "medical prognosis" is, itself, "based on the physician's . . . clinical judgment." 42 C.F.R. § 418.22(b). To conclude that the supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment would read more into the legal framework than its language allows. Read in the context of the statute and

regulations, the requirement that supporting documentation "accompany" the claim is designed to address CMS's mandate that "there must be a clinical basis for a certification." 79 Fed. Reg. at 50470 (noting that, although "certification is based on a clinical judgment," this "does not negate the fact that there must be a clinical basis for a certification"). That is, the physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records.

We also note that, had Congress or CMS intended the patient's medical records to objectively demonstrate terminal illness, it could have said so. Yet, Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS's own choice of the word "support"—instead of, for example, "demonstrate" or "prove"—does not imply the level of certitude the Government wishes to attribute to it. *Cf. Davidson v. Capital One Bank (USA), N.A.*, 797 F.3d 1309, 1316 (11th Cir. 2015) (We "presume that Congress said what it meant and meant what it said.") (quotation marks omitted).

More broadly, CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference. As noted *supra*, CMS has repeatedly emphasized that "[p]redicting life expectancy is not an exact science." 75 Fed. Reg. at 70448. *See also* 79 Fed. Reg. at 50470 (same). And in clarifying

the process for reporting a patient's "principal hospice diagnosis" on a hospice claim, CMS stated: "We believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill." 78 Fed. Reg. at 48247. Furthermore, in response to public comment, CMS removed the term "criteria" from a proposed regulation defining the certification requirements, wishing "to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness." 73 Fed. Reg. 32088, 32138 (June 5, 2008). While there is no question that clinical judgments must be tethered to a patient's valid medical records, it is equally clear that the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.

The Government cautions that a narrow reading of the eligibility framework "would entitle hospice providers to reimbursement for services provided to *any* individual, regardless of medical condition, assuming the provider could find a physician willing to sign the certification." This point again ignores that the physician's clinical judgment, informed by the patient's medical records, is the threshold requirement for eligibility. A physician cannot, as the Government suggests, hold a clinical judgment under the eligibility framework that disregards the patient's underlying medical condition. *See, e.g.*, 42 C.F.R. § 418.102(b)

(identifying factors physicians must consider when arriving at clinical judgments regarding terminal illness, including "subjective and objective medical findings" regarding the patient's condition). Such a clinical judgment would clearly be illegitimate under the law.

The Government further warns that, under our reading of the framework, "if a physician certifies a patient as terminally ill, CMS is *required* to reimburse the hospice care provider unless it can determine that *no* other reviewer of the patient's medical records could possibly conclude the patient was terminally ill." But, as the Government elsewhere notes, CMS is statutorily prohibited from reimbursing providers for services "which are not reasonable and necessary for the palliation or management of terminal illness." 42 U.S.C. § 1395y(a)(1)(C). *See also* 79 Fed Reg. 50452, 50470 (Aug. 22, 2014) (explaining that CMS retains a well-established right to review claims for hospice reimbursement and to deny claims that it does not consider to be "reasonable and necessary" under the statutory standard). The Government's argument that our reading of the eligibility framework would "tie CMS's hands" and "requir[e] improper reimbursements" is contrary to the plain design of the law.

2. Falsity in this case under the FCA

Having identified the contours of the Medicare framework, it becomes clear that there are two separate representations embedded in each claim for hospice

reimbursement: a representation by a physician to AseraCare that the patient is terminally ill in the physician's clinical judgment and a representation by AseraCare to Medicare that such clinical judgment has been obtained and that the patient is therefore eligible. As such, this case requires us to distinguish between two possible species of "falsity." The first relates to the legitimacy of a physician's clinical judgment. The second relates to the legitimacy of AseraCare's statement that a clinical judgment has been properly made.

Under the Government's false-certification theory in this case, AseraCare "submitted documentation that falsely represented that certain Medicare recipients were 'terminally ill'" when, in the Government's view, they were not. There is no allegation that AseraCare submitted claims that were not, in fact, based on a physician's properly formed clinical judgment, nor is there an allegation that AseraCare failed to abide by each component of the claim requirements.[9] The Government's allegations focus solely on the accuracy of the physician's clinical judgment regarding terminality. If, the theory goes, AseraCare represented to Medicare that a patient was "terminally ill" based on a physician's clinical

[9] We might, for instance, envision a viable FCA suit alleging that a hospice provider failed to obtain any clinical judgment at all, or obtained a clinical judgment from someone other than the patient's attending physician or the provider's medical director, or fabricated the certification itself. No such facts are alleged here.

judgment, and the Government later persuades a jury that this clinical judgment was wrong, then AseraCare's representation was, in turn, "false." This "falsity" opens the door to FCA liability. Thus, the Government's FCA case hangs entirely on the following question: When can a physician's clinical judgment regarding a patient's prognosis be deemed "false"?

In light of our foregoing discussion, we concur with the district court's post-verdict conclusion that "physicians applying their clinical judgment about a patient's projected life expectancy could disagree, and neither physician [ ] be wrong." Indeed, the Government's own witness—Mary Jane Schultz, the former head of Palmetto's medical review department—conceded at trial that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong." Nothing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment. Nor does the law suggest that a hospice provider has failed to comply with Medicare's requirements for hospice reimbursement if the only flaw in its claim is an absence of certitude that, in light of the relevant medical records, the patient will die within six months. The legal framework signals, and CMS itself has acknowledged, that no such certitude can be expected of physicians in the practice of treating end-of-

life illness. All the legal framework asks is that physicians exercise their best judgment in light of the facts at hand and that they document their rationale.

It follows that when a hospice provider submits a claim that certifies that a patient is terminally ill "based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness," 42 U.S.C. § 1395f(7), 42 C.F.R. § 418.22(b), the claim cannot be "false"—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood.

Objective falsehood can be shown in a variety of ways. Where, for instance, a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting that the patient is terminal, his ill-formed "clinical judgment" reflects an objective falsehood. The same is true where a plaintiff proves that a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification. A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records. In each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts.

By contrast, a reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those

judgments—or any claims based on them—are false under the FCA. A properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong. *Cf. Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015) (holding that "a sincere statement of pure opinion is not an 'untrue statement of material fact'" under the Securities Act of 1933, "regardless whether an investor can ultimately prove the belief wrong").

Accordingly, in order to properly state a claim under the FCA in the context of hospice reimbursement, a plaintiff alleging that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment. Where no such facts or circumstances are shown, the FCA claim fails as a matter of law.

In so holding, we agree with the district court's conclusion that, in order to show objective falsity as to a claim for hospice benefits, the Government must show something more than the mere difference of reasonable opinion concerning the prognosis of a patient's likely longevity.[10] And although we appear to be the

[10] Several district courts within and outside the Eleventh Circuit have embraced comparable reasoning in cases alleging FCA liability on the basis of clinical judgments of terminal illness. *See, e.g., United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *17 (N.D.

first circuit court to consider the precise question at issue here, a number of opinions from our sister circuits lends support to our conclusion that the Government must show an objective falsity.[11]

Tex. June 20, 2016) ("Because 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."); *United States ex rel. Fowler v. Evercare Hospice, Inc.*, 2015 WL 5568614, at *9 (D. Colo. Sept. 21, 2015) (observing that, if Government's complaint had been "based entirely on disagreements with [the provider's] certifying physicians," the complaint "would be insufficient to state a claim"); *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012) (dismissing FCA claims because "[r]elators have not alleged facts demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care"). *But see Druding v. Care Alternatives, Inc.*, 164 F. Supp. 3d 621, 623 (D.N.J. 2016) (holding that where plaintiffs alleged that patients were ineligible for hospice because they did not meet LCD criteria, claims were "legally false . . . because the claim[s] did not include sufficient clinical facts in the patient's medical records to justify a terminal prognosis").

[11] *See United States ex rel. Yannacopoulos v. General Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011) (stating that "[a] statement may be deemed 'false' for purposes of the False Claims Act only if the statement presents 'an objective falsehood'") (citing *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008)); *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 310 (1st Cir. 2010), (explaining that an opinion may qualify as a false statement for purposes of the FCA where the speaker "knows facts 'which would preclude such an opinion'") (quoting *United States ex rel. Siewick v. Jamieson Science and Engineering, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000)); *Wilson*, 525 F.3d at 376–77 (holding that "[t]o satisfy [the] first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood" and "imprecise statements or differences in interpretation growing out of a disputed legal question are [ ] not false under the FCA") (quotation omitted); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 959 (10th Cir. 2008) ("At a minimum the FCA requires proof of an objective falsehood."); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999) (noting that opinions or estimates can be "false" under the FCA if their speaker knows they are not supported by the facts); *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047–49 (9th Cir. 2012) (same). *Cf. Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1323, 1326–27 (2015) (holding in the context of securities fraud statutes that a statement of opinion can be "false" if the opinion did not reflect the speaker's actual belief at the time it was given).

The Government urges that the standard we adopt today improperly "usurp[s] the role of the jury" by precluding the jury from determining, based on expert testimony, the accuracy of the clinical judgments at issue. In support of this contention, the Government relies heavily on this Court's reasoning in *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349 (11th Cir. 2005). But *Walker* is clearly distinguishable and does not control our analysis.

In *Walker*, an FCA relator contended that her employer, a medical-clinic operator, billed Medicare for services rendered by non-physicians as if those services had been rendered "incident to the service of a physician," as the relevant statute required. *See id*. at 1353. In reality, the relator alleged, services had been provided by nurse practitioners or physician assistants without any physician involvement. *Id*. The defendant-clinic did not dispute that physicians were not present in the clinic when services were rendered. *Id*. at 1354. It argued instead that these claims could not have been false as a matter of law because the meaning of "incident to the service of a physician" was "vague and subject to reasonable interpretations other than that championed by Walker." *Id*. Specifically, the clinic argued that it interpreted "incident to the service of a physician" to cover services that were rendered by non-physicians as long as a physician was available by pager or telephone, even if not actually physically present in the office. *Id*. The district

court agreed, finding the statute ambiguous and defendant's interpretation of the statute reasonable. *Id.*

This Court reversed. *Walker*, 433 F.3d at 1356. The question presented was whether a claim based on a reasonable interpretation of an ambiguous statutory term could never be deemed "false," or whether instead the meaning of the ambiguous term—and the corresponding falsity of the claims made thereunder—could potentially pose factual questions that should be put to a factfinder. *Id.* Given the particular facts of the case before us, our Court adopted the latter approach. Specifically, the relator presented evidence from the Medicare Carrier's manual, Medicare bulletins, and seminar programs to "support a finding that, in the Medicare community, the language of the statute was understood to mean that a physician had to be physically present in the office suite" in order to justify reimbursement for the medical service provided by a non-physician. *Id.* at 1356–57. We concluded that this evidence created a jury question as to both whether the Medicare regulation required more physician involvement with a patient than the defendant clinic had provided and whether the defendant knew of this requirement. *Id.* at 1358.

In *Walker*, the eligibility criterion at issue was subject to multiple interpretations because its language was ambiguous, yet ultimately only one of the two possible interpretations could be deemed correct. By contrast, the key

eligibility criterion at issue here—"terminally ill"—presents, by design, a question of debatable clinical judgment that may not, in all circumstances, lend itself to just one determination as to the proper exercise of that judgment. As the district court noted below, asking the jury to decide whether medical records supported a finding of "terminal illness" put the jury in the position of evaluating, and second-guessing, the clinical judgment of the certifying physician. This is not the role the factfinder was playing in *Walker*; indeed, it is a role requiring medical knowledge and expertise that Congress has clearly reserved for physicians in the hospice-benefit context. *Walker* therefore does not compel the conclusion that eligibility requirements that hinge on clinical judgment present jury questions simply because they are susceptible to differing opinions, each of which could be reasonable.

The Government has also filed supplemental authority, citing to out-of-circuit appellate cases that it says establish that a mere difference of medical opinion can be sufficient to show that a statement is false. We find these cases distinguishable. In *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018), the physician-defendant had been convicted of healthcare fraud based on his performance of allegedly unnecessary coronary stent procedures. In arguing for reversal of his conviction, the defendant contended that he based his decision to perform the procedures on his interpretation of angiogram tests showing a high degree of blockage in the patients' arteries, and thus his medical judgment on this

point represented merely an opinion that could neither be truthful nor false. The Government contended that, to the contrary, the defendant had lied when he said that he interpreted the angiograms as showing a level of coronary blockage that would warrant inserting a stent into the heart, and it offered substantial expert testimony disputing that the level of blockage shown on the angiogram test was at the level the defendant asserted it was.

The Sixth Circuit[12] agreed with the defendant that "[o]rdinarily, facts are the only item that fits in [the false statement] category; opinions—when given honestly—are almost never false . . . .There is no such thing as a false idea." *Id*. at 275 (citations and internal quotation marks omitted). Nevertheless, the court continued, opinions have "never been completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion." *Id.* The court then cited with apparent approval the district court opinion in the present case for the proposition that "certain good-

[12] The *Paulus* court indicated its intention to clarify the standard underlying its earlier decision in *United States v. Persaud*, 866 F.3d 371 (6th Cir. 2017), which the Government has also cited in the present case. *Paulus*, 894 F.3d at 275.

faith medical diagnoses by a doctor cannot be false."[13] *Id*. In the case before it, however, the *Paulus* court noted that "coronary artery blockage actually exists as an aspect of reality," meaning that an assertion about the degree of blockage can be objectively true or false. *Id.* at 276 (quotation marks omitted). And it concluded that the Government's expert testimony was sufficient to support an inference that the defendant had lied when he reported readings of the angiograms that the experts said were simply not true: "[W]e think it is clear that Paulus was convicted for misrepresenting facts, not giving opinions." *Id.*

Moreover, whereas in the present case the Government's expert witness declined to conclude that Asercare's physicians had lied about their clinical judgment or even that their judgments were unreasonable or wrong[14]—as opposed to just different from what the Government's expert opined—in *Paulus*, it appears clear that the Government's experts there were not so charitable. The *Paulus* court noted that the Government had claimed that "Paulus repeatedly and systematically saw one thing on the angiogram and consciously wrote down another, and then

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[13] The court stated, "*see also United States v. AseraCare, Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. 2016) (holding that certain good-faith medical diagnoses by a doctor cannot be false.") *Paulus*, 894 F.3d at 275.

[14] As noted *supra*, the former head of the Palmetto medical review team, called as a Government witness, also conceded at trial that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong."

used that misinformation to perform and bill unnecessary procedures," and it explained that "[h]owever difficult it might be for a cardiology expert to prove that his colleague was lying about what he saw on a scan," it was up to the jury to decide the reliability of that testimony. *Id*. at 267–77. In short, the Government's expert testimony in *Paulus* appeared to suggest that no reasonable doctor could interpret the scan as had Paulus and that Paulus was actually lying. Thus, *Paulus* is not supportive of the Government's contentions here.[15]

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[15] The Government here also cites *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018), an FCA case in which the district court had granted the defendant's motion to dismiss on the ground that his medical judgment about the need for cardiac PFO closure procedures to prevent future strokes in his patients was an opinion that was not subject to being deemed true or false. The Tenth Circuit reversed, found a plausible allegation of falsity, and directed that the case proceed to discovery. The circuit court noted that the Government had alleged that the applicable Medicare statute authorized reimbursement only when the he PFO procedure was reasonable and necessary for the treatment of an illness; that there is agreement in the medical community that a PFO closure is not medically necessary except where there is a confirmed diagnosis of a recurrent stroke; that the applicable guidelines allow for consideration of the procedure only when the patient has had two or more strokes and that the guidelines do not "contemplate the potential for PFO closures" if the patient has not had a prior stroke; that the defendant claimed to believe that the procedure should be performed prophylactically to cure migraine headaches or to prevent strokes even if the patient had never before had a stroke; and, knowing that Medicare would not pay on that basis, the defendant falsely represented that the procedure was being performed based on the indications set forth in the guidelines. *Id.* at 736, 737. In addition, a fellow physician alleged that he had witnessed the defendant perform an unnecessary procedure and actually *create* the problem the surgery was intended to remedy by puncturing intact septa in the patients. *Id.* at 738.

Obviously, the above facts are quite different from those alleged in this case. It is true that the Tenth Circuit opinion held that regardless of the physician's opinion to the contrary, he will be deemed to have made a false statement when claiming reimbursement if the medical procedure is determined to have not been reasonable or necessary. "We thus hold that a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."

The Government expresses concern that a requirement of objective falsehood will produce a troubling under-inclusion problem: that is, by holding that an FCA claim fails as a matter of law if the plaintiff proves nothing more than a reasonable difference of opinion as to the patient's prognosis, hospice providers with sloppy or improper admission practices may evade FCA liability so long as they can argue after the fact that their physicians' clinical judgments were justifiable. That may well be. To be sure, it will likely prove more challenging for an FCA plaintiff to present evidence of an objective falsehood than to find an expert witness willing to testify to a contrasting clinical judgment regarding cold medical records.

But if this is a problem, it is one for Congress or CMS to solve. In deciding how to craft the hospice eligibility requirements, Congress and CMS could have imposed a more rigid set of criteria for eligibility determinations that would have minimized the role of clinical judgment. Instead, they were careful to place the physician's clinical judgment at the center of the inquiry. Indeed, CMS has considered and expressly declined to impose defined criteria that would govern the physician's exercise of judgment. *See* 73 Fed. Reg. 32088, 32138 (June 5, 2008).

Id. at 742. As set out in text, however, the hospice-benefit provision at issue here, by design, looks to whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion as to a patient's likely longevity.

In any event, absent a showing of an objective and knowing falsehood, the FCA is an inappropriate instrument to serve as the Government's primary line of defense against questionable claims for reimbursement of hospice benefits. For the above reasons, we agree that the district court's jury instruction concerning falsity was lacking and that a new trial was warranted to allow the giving of a more complete charge: specifically, a charge that would convey that the mere difference of reasonable opinion between physicians, without more,[16] as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood. We therefore AFFIRM the district court's grant of a new trial.

B. Grant of Summary Judgment

Deciding that the district court acted correctly in determining that a new trial was warranted—with a revised instruction to the jury concerning falsity—does not end our review of this case. Instead, as noted in the procedural discussion above, the district court went further and, after granting a new trial, it then *sua sponte* granted summary judgment to AseraCare. The court reasoned as follows. Given its new position on the standard for determining falsity—that falsity cannot be established based merely on a reasonable disagreement between experts as to

[16] Should there be another trial on this matter, we leave to the district court and the parties the task of fleshing out just what that "more" needs to include.

whether clinical records in a patient's file warranted a prognosis of a terminal illness that would likely result in the patient's death within six months—the district court indicated that it would hear from the Government whether the court record contained any other evidence sufficient to create a jury question as to whether AseraCare had made an objectively false representation when claiming reimbursement for hospice benefits it had provided. Following that response and concluding that the Government's evidence of falsity consisted only of Dr. Liao's testimony indicating his disagreement with the prognosis arrived at by AseraCare for most of the patient files he reviewed, the district court found that the Government's evidence of falsity was insufficient to allow it to proceed further. For that reason, the court granted summary judgment.

Leaving aside the question whether the substance of an opinion, by itself, can ever be deemed to constitute an objective falsity, the parties agree that an opinion can be considered objectively false if the speaker does not actually hold that opinion. *See Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1323, 1326–27 (2015) (holding in the context of securities fraud statutes that a statement of opinion can be "false" if the opinion did not reflect the speaker's actual belief at the time it was given). Further, in examining whether a physician's clinical judgment was truly communicated, the latter must first have actually exercised such judgment. If it can be shown that the physician

never considered the underlying records supporting the prognosis at issue, but instead rubber-stamped whatever file was put in front of him, then the physician has offered no clinical judgment. Moreover, an opinion can enter falsifiable territory when it is based on information that the physician knew, or had reason to know, was incorrect. Finally, if no reasonable physician would think that a patient had a terminal illness based on the evidence before that physician, then falsity can be inferred, as well as the existence of a knowing violation.

With the above thoughts in mind, the Government argues that the district court took too constricted a view of the evidence upon which a determination of falsity could be made by a jury when it refused to consider other evidence from the first phase of the trial that the Government asserts tended to show knowledge of the falsity of the claim, as well as evidence that the Government intended to present in the second phase of the trial to further show AseraCare's alleged awareness[17] that it was submitting claims that did not reflect a physician's good faith clinical judgment and prognosis for each patient. In its opposition to the *sua sponte* grant of summary judgment, the Government stated:

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[17] For purposes of the FCA, "the terms 'knowing' and 'knowingly' (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in in reckless disregard of the truth or falsity of the information, and (B) no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

> It is indefensible for the Court to grant summary judgment on the grounds that this case is just about a good faith disagreement between experts—and that the United States failed to present evidence that AseraCare knew or recklessly disregarded that its claims were false—when the Court bifurcated the trial and expressly excluded from Phase One any evidence of AseraCare's knowledge of falsity.

We agree with the Government that before granting summary judgment, the district court should have considered all the evidence, both in the trial record and the summary judgment record, to determine whether a triable issue existed regarding falsity. Here is why we reach that conclusion.

The Government had been prepared to introduce evidence to show AseraCare's knowledge at trial, but was prevented from doing so by the district court's decision, over the Government's strong objections, to bifurcate the trial and preclude introduction of any evidence showing knowledge of falsity in Phase I. The Government did, however, introduce evidence in that first phase that seems to offer some potential basis for inferring knowledge. Specifically, nine witnesses, whose testimony was purportedly connected in time and location to the patients at issue, testified that AseraCare had a deliberate practice of not giving physicians relevant, accurate, and complete information about patients whose certifications for hospice the doctors were being asked to sign. For example, one former director of clinical services in Decatur, Alabama, testified that when she declined to admit ineligible patients to hospice, she was instructed to go back and find whatever she

needed to admit the patient. Further, she typically did not provide the certifying physician with any clinical information, but usually just gave him a stack of papers to sign. Indeed, each of the nine former-employee witnesses reiterated these themes in their testimony. In large part, because the Government had not denominated this evidence as proof of falsity during this first phase—but instead as evidence of context—the district court refused to consider it as evidence of falsity in this post-verdict summary judgment phase.

The Government also intended to offer at the second phase evidence from AseraCare's internal and external auditors criticizing the company because the certifying medical directors were not adequately involved in making initial eligibility determinations and did not consistently receive medical information prior to the initial certification. In addition to the testimony of other former employees, the Government also planned to offer testimony from a former AseraCare physician that employees did not defer to his clinical judgment that certain patients were unentitled to hospice benefits, but instead proceeded to file the claims. The district court declined to factor the above evidence into its evaluation of whether a jury question still remained concerning AseraCare's knowledge that it was submitting claims that did not warrant the reimbursement of hospice benefits.

The district court's refusal to consider any of the above-described additional evidence on the question of falsity was largely based on the Government's response to AseraCare's discovery interrogatories inquiring what evidence the Government would offer on that issue. The district court emphasized that the Government had "painted itself into a corner by failing to disclose during discovery that it would use anything other than the testimony of Dr. Liao and medical records to prove the falsity of the claims."

It is true that the Government denominated only the Liao testimony as evidence of falsity during the discovery period. But, in fairness to the Government, it disclosed all the above evidence in question during discovery, including the evidence that the district court declined to consider for post-verdict summary judgment purposes. At the time of disclosure, the Government had no idea that the district court would later order the bifurcation of trial between falsity and knowledge phases, and it clearly assumed that all of its evidence would be heard by the jury in one proceeding, with no need to so starkly pigeon-hole the category into which a given piece of evidence might fit. As the Government noted in its opposition to bifurcation, with no contradiction by AseraCare, the elements of an FCA liability claim had "never been before been bifurcated by a federal district court." Nor had the Government ever anticipated such a decision, because, according to it, such an order was "extraordinary, requiring the United States to

jump over an arbitrary hurdle that is without precedent . . . [because] [t]he elements of 'falsity' and 'knowledge of falsity' are not so distinct and separable that they may be tried separately without injustice."

Moreover, the district court had rejected AseraCare's initial motion for summary judgment based on the latter's argument that the mere disagreement of experts is insufficient to imply falsity. At the time of trial, the court had already declined to apply this "reasonable physician" standard to the falsity analysis, despite granting AseraCare's § 1292(b) motion for review. As such, the Government's failure to present its case in a manner consistent with such a standard is understandable. Moreover, the court declined to give the instructions requested by AseraCare to that effect and instead gave only the charge requested by the Government: "Claims to Medicare may be false if the provider seeks payment, or reimbursement, for health care that is not reimbursable. For a hospice provider's claims to Medicare to be reimbursable, the patient must be eligible for the Medicare hospice benefit."

Accordingly, the Government, which had prepared and presented its case based on all the above information, was never alerted to the possibility that the conceptual underpinnings of its case would shift so dramatically once it had won a jury verdict on that theory. We emphasize that we do not criticize the district court for its post-verdict change of mind about the appropriate standard for proving

falsity. To the contrary, this district court judge was diligent, conscientious, and thoughtful throughout the long and complex pre-trial proceedings and the eight-week trial whose verdict she ultimately vacated. Given that expenditure of time and energy, it is commendable that the district court would consider starting over once she became convinced that she had made a legal error.

Nonetheless, under all these unusual circumstances, it is only fair that the Government be allowed to have summary judgment considered based on all the evidence presented at both the summary judgment and trial stages, and we direct that this occur. When the goalpost gets moved in the final seconds of a game, the team with the ball should, at the least, have one more opportunity to punch it into the endzone.

Having given the Government the green light to once again try to persuade the district court that a triable issue exists on both falsity and knowledge, we emphasize that we do not know that this effort will succeed. For sure, to the extent that a reasonable jury might credit the Government's proffered evidence regarding AseraCare's practices, that evidence suggests that AseraCare's certification procedures were seriously flawed. As noted, a former Director of Clinical Services testified that one physician she worked with was in the habit of signing certifications before reviewing any medical documentation whatsoever; clinical staff typically "just gave him . . . a stack of papers to sign, [and] he just signed the

papers." Another former employee testified that signing certifications had become so rote for one physician that he "would nod off" while signing. This testimony certainly raises questions regarding AseraCare's certification process writ large. But crucially, on remand the Government must be able to link this evidence of improper certification practices to the specific 123 claims at issue in its case. Such linkage is necessary to demonstrate both falsehood and knowledge.[18] *See Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015) ("disregard of government regulations or failure to maintain proper internal procedures" are not sufficient to demonstrate FCA violation); *Carrel v. AIDS Healthcare Foundation, Inc.*, 898 F.3d 1267, 1277–78 (11th Cir. 2018) (a relator cannot prove that an actual false claim was filed based only on a showing of general practices untethered to that claim).

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[18] Alternatively, the Government could meet its burden under the falsity standard now adopted by the district court, and endorsed by this Court, if it could establish through expert testimony that no reasonable physician reviewing the medical records at issue could have concluded that a particular patient was terminally ill. The Court, however, is unaware that any such evidence exists. Indeed, as noted, Mary Jane Schultz, the former head of Palmetto's medical review department, testified that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong." Also, as noted, Dr. Liao himself changed his opinion concerning the eligibility of certain patients over the course of the proceeding but testified at trial that both sets of opinions remained "accurate to a reasonable degree of certainty." To explain these reversals, Dr. Liao stated that he "was not the same physician in 2013 as [he] was in 2010." As the district court observed, if Dr. Liao can form contradictory opinions based on the same medical records and yet claim not to have been wrong on either occasion, then it is difficult to explain how his difference of opinion with AseraCare's physicians concerning other patients would demonstrate that no reasonable physician could agree with AseraCare, absent some additional evidence to warrant that inference.

For the above reasons, we VACATE the district court's post-verdict grant of summary judgment to AseraCare and REMAND for the court to reconsider that matter based on the entirety of the evidence, not just that evidence presented at trial nor just the evidence denominated as being offered to prove falsity.

V. CONCLUSION

For the reasons explained above, we **AFFIRM** the district court's grant of a new trial. We, however, **VACATE** the post-verdict grant of summary judgment to AseraCare and **REMAND** for the district court to reconsider that decision in light of all the relevant evidence proffered by the Government.