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I. INTRODUCTION

This Article serves as a review of significant healthcare developments in the United States Court of Appeals for the Eleventh Circuit during this past survey period and builds upon Mercer Law Review's past two Healthcare Articles[1] in Volumes 69 and 70. Specifically, this Article will cover cases and trends involving Healthcare Fraud.

II. NEW FALSITY STANDARD IN HOSPICE ELIGIBILITY CERTIFICATION CASES

On September 9, 2019, the Eleventh Circuit issued its long-awaited opinion, *United States v. AseraCare, Inc.*[2] As previously reported, the decision was much anticipated as the case dealt with the legal standard for the "falsity" element under the False Claims Act (FCA)[3] with regard to hospice eligibility certifications, which has been "[o]ne of the undecided areas of law in the Eleventh Circuit."[4]

A. Underlying Litigation

At the district court level, the Government brought an action under the FCA against AseraCare, Inc. (AseraCare), alleging that AseraCare submitted false claims to Medicare on behalf of 123 hospice patients.[5] The Federal Regulation governing hospice Medicare eligibility requires

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1. Kathryn S. Dunnam, *Healthcare Law, Eleventh Circuit Survey,* 69 MERCER L. REV. 1209 (2018); Kathryn Dunnam Harden, *Healthcare Law, Eleventh Circuit Survey,* 70 MERCER L. REV. 1053 (2019).

2. 938 F.3d 1278 (11th Cir. 2019).

3. 31 U.S.C. § 3729(a)(1)–(2) (2020).

4. United States v. AseraCare, Inc., 153 F. Supp. 3d 1372, 1375 (N.D. Ala. 2015).

5. United States v. AseraCare, Inc., 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016).

certification of the patient's terminal illness.[6] "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."[7] The FCA provides, in relevant part, that if a person:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) 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 [for civil penalties].[8]

In 2015, the United States District Court for the Northern District of Alabama bifurcated the trial into two phases, with the "falsity element" to be tried first.[9] Upon AseraCare's motion, the court subsequently granted a new trial because the court did not instruct the jury that "a mere difference of opinion, *without more*, is not enough to show falsity."[10]

In 2016, the district court granted, *sua sponte*, summary judgment in favor of AseraCare.[11] The court explained that the Government must provide "proof of an objective falsehood" in prosecuting a FCA violation.[12] In making this "falsity" determination, the court disagreed with the Government's argument that the lack of "clinical information" in the patients' medical records supporting their hospice eligibility warranted the claims for those patients as "false."[13] "When 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."[14] Indeed, the district court cautioned that if:

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6. 42 C.F.R. § 418.22 (2020).

7. 42 C.F.R. § 418.22(b)(1) (2020).

8. 31 U.S.C. § 3729(a)(1) (2020). The FCA provides that "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 reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b).

9. *AseraCare, Inc.*, 153 F. Supp. 3d at 1377.

10. *Id.* at 1385.

11. *AseraCare, Inc.*, 176 F. Supp. 3d at 1286.

12. *Id.* at 1283 (quoting United States *ex rel.* Parato v. Unadilla Health Care Ctr. Inc., 787 F. Supp. 2d 1329, 1339 (M.D. Ga. 2011)).

13. *Id.*

14. *Id.*

> [A]ll the Government needed to prove falsity in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician, hospice providers would be subject to potential FCA liability any time the Government could find a medical expert who disagreed with the certifying physician's clinical judgment. The court refuses to go down that road.[15]

Therefore, the district court held that the Government failed to prove falsity as a matter of law and granted, *sua sponte*, summary judgment for AseraCare.[16]

B. Eleventh Circuit

On appeal, as the Eleventh Circuit aptly synopsized: "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."[17] In its opinion, the Eleventh Circuit first provided a practical and thorough background of hospice care in the United States and the availability of the federal government's Medicare benefits in this regard.[18] The Eleventh Circuit then structured its discussion and legal analysis by "defining the contours of the hospice-eligibility framework and clarifying the circumstances under which a claim violates the requirements for reimbursement."[19] Then, it "consider[ed] the ways in which a hospice claim might be deemed 'false' for purposes of the FCA."[20]

1. The Hospice-Eligibility Determination Centers on Clinical Judgment

With regard to the first prong of its analysis, the Eleventh Circuit explained that "[t]he language of the statute and implementing regulations makes plain that the clinical judgment of the patient's [physician or medical director] lies at the center of the eligibility

15. *Id.* at 1285.

16. *Id.* at 1286. In its 2015 Memorandum Opinion, the court suggested that the outcome may be different if the United States "offered [] evidence that AseraCare billed for phantom patients, that it submitted Certificates of Terminal Illness [] with forged signatures, or that any AseraCare employees lied to or withheld critical information from the certifying doctors about any specific patients." *AseraCare, Inc.*, 153 F. Supp. 3d at 1375.

17. *AseraCare, Inc.*, 938 F.3d at 1291.

18. *Id.* at 1282–84.

19. *Id.* at 1292.

20. *Id.*

inquiry."[21] The pertinent regulation states in relevant part: "clinical information and other documentation that support the medical prognosis . . . *accompany the certification*" and are "*filed in the medical record*."[22] In addition, "[t]his 'medical prognosis' is, itself, 'based on the physician's . . . clinical judgment.'"[23] "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."[24] "Rather, the framework asks a physician responsible for the patient's care to exercise his or her judgment as to the proper interpretation of the patient's medical records."[25]

> 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.[26]

Thus, the Eleventh Circuit rejected the Government's argument on appeal that "supporting documentation must, standing alone, prove the validity of the physician's initial clinical judgment."[27]

2. Objective Falsity: More Than a Reasonable Difference in Clinical Judgment

With regard to the second prong of its analysis, the Eleventh Circuit agreed with the district court's decision 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."[28] As long as "the underlying clinical judgment does not reflect an objective falsehood," then the claim will not be false "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

21. *Id.* at 1293.

22. *Id.* at 1294 (emphasis in original) (quoting 42 C.F.R. § 418.22(b)(2)).

23. *Id.* (quoting 42 C.F.R. § 418.22(b)(2)).

24. *Id.* at 1293.

25. *Id.* at 1294.

26. *Id.* at 1295.

27. *Id.* at 1294.

28. *Id.* at 1297. While acknowledging that this issue is a matter of first impression, the Eleventh Circuit relied upon holdings from the United States Courts of Appeals for the First, Fourth, Seventh, Ninth, Tenth, and D.C. Circuits with regard to the "objective falsity" requirement. *Id.* at 1298.

normal course of the individual's illness.'"[29] Indeed, "[a]ll the legal framework asks is that physicians exercise their best judgment in light of the facts at hand and that they document their rationale."[30]

The Eleventh Circuit unequivocally held, in hospice reimbursement cases, that

> in order to properly state a claim under the FCA . . . 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.[31]

Thus, where there is no other factual allegation of falsity, the Eleventh Circuit's decision eliminates the opportunity for a jury to decide "in [a] battle of experts . . . which expert it [thinks] to be more persuasive, with the less persuasive opinion being deemed to be false."[32] The Eleventh Circuit ultimately affirmed the district court's grant of a new trial, vacated the grant of summary judgment in favor of AseraCare after the verdict had been reached, and remanded[33] for the district court to reconsider the matter based on the entirety of the evidence.[34]

3. Practical Guidance

While the Eleventh Circuit was critical of the Government framing its FCA case around the notion that a physician's *clinical judgment* as to a patient prognosis can be "false,"[35] it did provide guidance by way of hypothetical situations where objective falsity may occur:

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29. *Id.* at 1296–97.

30. *Id.* at 1296.

31. *Id.* at 1297.

32. *Id.* at 1288–89.

33. The Eleventh Circuit cautioned that, on remand, the Government must be able to link the allegations regarding AseraCare's business practices to the specific Medicare claims brought forth in the case. *Id.* at 1305. This link is necessary to establish "falsehood" and "knowledge." *Id.* Specifically, the Government must link the allegedly flawed certification practices to the claims identified from the sample size of the total patients AseraCare billed Medicare for hospice care. *Id.* at 1285, 1305.

34. *Id.* at 1305. While the Eleventh Circuit commended the district court for vacating the original verdict in order to apply the appropriate falsity standard, the Eleventh Circuit disagreed with the district court's limitation of evidence for consideration in its *sua sponte* grant of summary judgment. *Id.* at 1301–05.

35. *Id.* at 1296.

> 1. "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."
>
> 2. "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."[36]
>
> 3. "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."[37]

Notably, with the foregoing examples, "the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts."[38]

In sum, the Eleventh Circuit ultimately agreed with the Northern District of Alabama's falsity standard.[39] It is insufficient for the Government to use a "mere difference of reasonable opinion" by way of expert testimony to establish "proof of an objective falsehood" in hospice eligibility certification cases.[40] With the *AseraCare* decision, the Eleventh Circuit has provided clarity "in the often clinically murky area

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36. In contrast, in *AseraCare, Inc.*:

> 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.

Id. at 1288.

37. *Id.* at 1297. The Eleventh Circuit repeatedly emphasized that, not only did the Government's own expert fail to conclude that the AseraCare physicians lied, the expert also failed to conclude that the AseraCare physicians' clinical judgments were unreasonable or wrong. *Id.* at 1300. The expert "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." *Id.* at 1287. While not legally operative, the Eleventh Circuit also found it worth noting that the expert changed his opinion regarding the hospice eligibility of certain patients during the proceedings. *Id.* at 1287–88. In addition, another Government witness testified that "two doctors using their clinical judgment could come to different conclusions about a patient's prognosis and neither be right or wrong." *Id.* at 1305 n.18.

38. *Id.*

39. *See AseraCare, Inc.*, 153 F. Supp. 3d at 1377.

40. *Id.*

of complex medical practice."[41] Moving forward, "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."[42]

III. STATUTE OF LIMITATIONS CLARITY IN FCA *QUI TAM* ACTIONS

As reported last year, the Supreme Court of the United States decided to resolve a circuit split involving the proper interpretation of the FCA's statute of limitations provisions.[43] On November 16, 2018, the Supreme Court granted Cochise Consultancy Inc.'s Petition for Writ of Certiorari in *Cochise Consultancy Inc. v. United States ex rel. Hunt*.[44] In the underlying case, *U.S. ex rel. Hunt v. Cochise Consultancy, Inc., et al.*,[45] the Eleventh Circuit held, as a matter of first impression, that the FCA's tolling provision applies to a relator's claim even when the government has not intervened.[46] In so holding, the Eleventh Circuit reversed the district court's determination otherwise, reasoning that the critical consideration is the government's knowledge of the material facts, not the relator's. This decision aligned with the Ninth Circuit, but only to the extent that relators may take advantage of the tolling provision.[47] In contrast, the Fourth Circuit and Tenth Circuit previously determined that the tolling provision is only available in *qui tam* actions when the government actually intervened and is a party to the suit.[48]

On May 13, 2019, the Supreme Court issued its opinion ultimately affirming the Eleventh Circuit's more generous interpretation of 31

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41. Zack Buck, *Keeping an Eye on the Eleventh*, HARV. L. BLOG: BILL OF HEALTH (June 29, 2017), http://blogs.harvard.edu/billofhealth/2017/06/29/keeping-an-eye-on-the-eleventh#more-22892.

42. *AseraCare, Inc.*, 938 F.3d at 1301.

43. Cochise Consultancy, Inc. v. United States *ex rel.* Hunt, 139 S. Ct. 1507 (2019); 31 U.S.C. § 3731(b).

44. 139 S. Ct. 566 (2018).

45. 887 F.3d 1081 (11th Cir. 2018).

46. *Id.* at 1083.

47. *Id.* at 1096; *see, e.g.*, U.S. *ex rel.* Hyatt v. Northrop Corp., 91 F.3d 1211 (9th Cir. 1996).

48. *See, e.g.*, U.S. *ex rel.* Sanders v. N. Am. Bus Indus., Inc., 546 F.3d 288, 294 (4th Cir. 2008) (explaining that "[t]he government's knowledge of 'facts material to the right of action' does not notify the relator of anything, so that knowledge cannot reasonably begin the limitations period for a relator's claims"); U.S. *ex rel.* Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702, 724–25 (10th Cir. 2006) (holding that legislative history supports the interpretation that the tolling provision does not apply to private *qui tam* suits).

U.S.C. § 3731(b).[49] The tolling provision will be available to a relator regardless of whether or not the government intervenes in the action.[50] In addition, the statute of limitations does not commence until the United States official knew or should have known the relevant facts and not when the *qui tam* relator knew or should have known such knowledge.[51]

IV. CONCLUSION

This past survey has seen significant developments in the field of healthcare law. In *AseraCare*, the Eleventh Circuit provided clarity in FCA hospice eligibility certification cases and raised the requisite standard for the Government to establish "falsity."[52] In *Cochise*, the Supreme Court expanded the statute of limitations for FCA *qui tam* actions where the Government does not intervene, providing more leeway for *qui tam* relators.[53]

49. *Cochise Consultancy, Inc.*, 139 S. Ct. at 1514.
50. *Id.* at 1511–12.
51. *Id.* at 1514.
52. *AseraCare, Inc.*, 938 F.3d 1278.
53. *Cochise Consultancy, Inc.*, 139 S. Ct. 1507.