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## End of Life Uncertainty: Terminal Illness, Medicare Hospice Reimbursement, and the "Falsity" of Physicians' Clinical Judgments

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## END OF LIFE UNCERTAINTY: TERMINAL ILLNESS, MEDICARE HOSPICE REIMBURSEMENT, AND THE “FALSITY” OF PHYSICIANS’ CLINICAL JUDGMENTS

*Jameson Steffel*

### I. INTRODUCTION

If asked to visualize what “fraud” looks like, one might envision a theft, a computer hacker, or falsified signatures and documents. A doctor and an elderly man sitting in a hospice facility, on the other hand, seem like unlikely culprits. Although a hospice facility and fraud may not be an intuitive pairing, it is estimated that fraud and inaccurate billing cost the federal government’s Medicare program as much as \$60 billion dollars annually.<sup>1</sup> Studies have linked hospice facilities to enrolling patients who are not terminally ill and falsifying patient documentation, among other appalling behaviors.<sup>2</sup> Naturally, efforts to combat these types of behaviors have found their way into the United States federal courts.<sup>3</sup> Questions have arisen regarding the behavior of America’s most trusted profession<sup>4</sup>, medical professionals, within the hospice setting.

Relators and the Government have relied on the Federal False Claims Act (“FCA”) to bring actions against hospice facilities for billing Medicare for end-of-life care to allegedly ineligible patients.<sup>5</sup> To prevail on an FCA claim, plaintiffs must prove that a claim for reimbursement for Medicare Hospice Benefit (“MHB”) was “false” under the FCA. Often central to the “false” element of the claim is the sufficiency of a doctor’s “clinical judgment” in labeling a patient as terminally ill.<sup>6</sup> Recently, a budding circuit split has developed regarding what can deem a doctor’s

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1. Ashleigh Garrison, *Medicare’s Most Indefensible Fraud Hotspot: Hospice Care*, CNBC (Aug. 2018), <https://www.cnbc.com/2018/08/02/medicares-most-despicable-indefensible-fraud-hotspot-hospice-care.html>.

2. U.S. DEP’T OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., OEI-02-16-00570, VULNERABILITIES IN THE MEDICARE HOSPICE PROGRAM AFFECT QUALITY CARE AND PROGRAM INTEGRITY: AN OIG PORTFOLIO 1 (July 2018), available at [https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf?utm\\_source=STAT+Newsletters&utm\\_campaign=a14adc5bd9-MR\\_COPY\\_09&utm\\_medium=email&utm\\_term=0\\_8cab1d7961-a14adc5bd9-150483829](https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf?utm_source=STAT+Newsletters&utm_campaign=a14adc5bd9-MR_COPY_09&utm_medium=email&utm_term=0_8cab1d7961-a14adc5bd9-150483829).

3. See *infra* Parts II and III.

4. Megan Brennan, *Nurses Again Outpace Other Professions for Honesty, Ethics*, GALLUP (Dec. 2018), [https://news.gallup.com/poll/245597/nurses-again-outpace-professions-honesty-ethics.aspx?g\\_source=link\\_NEWSV9&g\\_medium=NEWSFEED&g\\_campaign=item\\_&g\\_content=Nurses%20Again%20Outpace%20Other%20Professions%20for%20Honesty%2c%20Ethics;%20see%20also%20https://www.pewresearch.org/science/2019/08/02/findings-at-a-glance-medical-doctors/](https://news.gallup.com/poll/245597/nurses-again-outpace-professions-honesty-ethics.aspx?g_source=link_NEWSV9&g_medium=NEWSFEED&g_campaign=item_&g_content=Nurses%20Again%20Outpace%20Other%20Professions%20for%20Honesty%2c%20Ethics;%20see%20also%20https://www.pewresearch.org/science/2019/08/02/findings-at-a-glance-medical-doctors/).

5. *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281 (11th Cir. 2019).

6. *Id.* at 1285.

clinical judgment as “false” for the purposes of FCA liability.<sup>7</sup> In the Eleventh Circuit’s *United States v. AseraCare, Inc.* opinion, the court held that a difference in two doctors’ clinical judgments, without more, was insufficient to show falsity under the FCA.<sup>8</sup> However, just six months later, the Third Circuit in *United States v. Care Alternatives* explicitly departed from the Eleventh Circuit’s rule, instead holding that a difference in expert opinion may create a triable, genuine dispute of material fact regarding the falsity of a doctor’s clinical judgment.<sup>9</sup>

This Article explores the aforementioned circuit split and focuses on how these two recent cases have interpreted both the language of the FCA as well as the standards required of medical professionals by Medicare and the MHB. Further, based on the plain language meaning of the statutes and guidance, along with general policy concerns, this Article argues that the approach taken by the Eleventh Circuit in *AseraCare* is not only the correct legal interpretation but also the better policy approach.

Part II of this Article provides a foundational understanding of the FCA, *qui tam* claims, and the current guidance provided to medical professionals who try to use the federal MHB for reimbursement of medical services provided to patients. Part II also discusses two background cases that initially ruled on the FCA’s “falsity” element and were later relied upon in the two most recent cases that split the circuits. Part III analyzes the two recent cases that have directly caused the split: *United States v. AseraCare, Inc.*,<sup>10</sup> and *United States ex rel. Druding v. Care Alternatives*.<sup>11</sup> Part IV argues that although there is a genuine need to combat fraud within the hospice medical arena, dueling expert opinions, without more, should always be considered insufficient to create a question of falsity under the FCA. Further, Part IV suggests that the appropriate avenue to combat subjective, yet questionable, clinical judgments of doctors is through legislation, not the courts.

Finally, Part V concludes by summarizing the above issues and sides with the Eleventh Circuit’s holding in *AseraCare, Inc.* Overall, due to the naturally uncertain and subjective nature of the elderly populations’ health in their waning months and years on earth, medical professionals should be granted the deference given to them by the plain language of

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7. Jessica E Joseph et al., *Third Circuit Creates Budding Circuit Split in United States v. Care Alternatives, Ruling That “Objective Falsity” Is Not Required Under FCA*, FOLEY & LARDNER LLP (Mar. 2020), <https://www.foley.com/en/insights/publications/2020/03/third-rules-objective-falsity-not-required-fca>.

8. *AseraCare*, 938 F.3d at 1281.

9. *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 91 (3d Cir. 2020). (“*Care Alternatives*”).

10. 938 F.3d 1278 (11th Cir. 2019).

11. 952 F.3d 89 (3d Cir. 2020).

the regulations when they make clinical judgments of terminal illness. Stricter scrutiny of medical professionals' clinical judgments of terminal illness could result in worse health outcomes for the same patients for whom the MHB was initially implemented to help.<sup>12</sup>

## II. BACKGROUND

### A. *The Federal False Claims Act (FCA)*<sup>13</sup>

Today, the FCA serves as a primary tool for the United States government to combat fraud against the government and to protect the federal treasury.<sup>14</sup> The FCA's origins are rooted in the United States Civil War.<sup>15</sup> During the war, Congress received disturbing reports that detailed contractors defrauding the Union military in their supply contracts.<sup>16</sup> The reports led to the FCA bill, which was generally well supported and designed to "prevent and punish frauds" upon the United States Government.<sup>17</sup>

The design of the FCA was to "deputize an army of insiders to uncover, inform, and pursue those government contractors who knowingly cheat in their agreements with the government."<sup>18</sup> The FCA allows private individuals to file suit on behalf of the government through its "*qui tam*" provision.<sup>19</sup> In this scenario, the individual bringing the suit on behalf of the government is referred to as a "relator."<sup>20</sup> A *qui tam* suit must be filed under seal and served to the U.S. Attorney General.<sup>21</sup> The government is required to investigate the allegation and then may decide whether to intervene or decline to intervene.<sup>22</sup> If the government chooses to intervene, then the government holds primary responsibility for prosecuting the action.<sup>23</sup>

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12. See *History of Hospice Care; Hospice: A Historical Perspective*, NAT'L HOSPICE & PALLIATIVE CARE ORG., <https://www.nhpco.org/hospice-care-overview/history-of-hospice/>.

13. 31 U.S.C. § 3729.

14. James B. Helmer Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1261 (2013), available at <https://scholarship.law.uc.edu/cgi/viewcontent.cgi?article=1153&context=uclr>.

15. *Id.* at 1264.

16. *Id.*

17. *Id.* at 1265. (citing CONG. GLOBE, 37TH CONG., 3D SESS. 955, 348 (1863) (statement of Sen. Wilson)).

18. *Id.* at 1262.

19. 31 U.S.C. § 3730(b).

20. *The False Claims Act: A Primer*, U.S. DEPARTMENT OF JUSTICE, [https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS\\_FCA\\_Primer.pdf](https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf).

21. 31 U.S.C. § 3730(b)(2)

22. 31 U.S.C. § 3730(a), (b)(4), (5).

23. 31 U.S.C. § 3730(e)(1).

The primary incentive for a relator to bring a claim under the FCA is money. Those found to be in violation of the act are liable to the federal government for a standard monetary civil penalty plus three times the amount of damages which the government sustained because of the act(s) of the violator.<sup>24</sup> If the government intervenes, then the relator is entitled to receive between fifteen and twenty-five percent of the amount ultimately recovered by the government.<sup>25</sup> If the government does not intervene, the individual is still entitled to receive between twenty-five and thirty percent of whatever is recovered through the action or settlement.<sup>26</sup> Successful FCA claims can often result in multimillion dollar payouts to the relators who originally brought the claim.<sup>27</sup>

Generally speaking, to be found liable under the FCA, a person must knowingly submit a false claim or cause another to submit a false record or statement material to a fraudulent claim, to the United States government.<sup>28</sup> The statute also encompasses conspiring to submit a false claim and knowingly avoiding due payments to the government.<sup>29</sup> Knowledge is defined by the statute to include (1) actual knowledge, (2) deliberate ignorance of the truth or falsity of the submitted information, and (3) reckless disregard of the truth or falsity of the information.<sup>30</sup> Importantly, the statute does not require proof of specific intent to defraud.<sup>31</sup> From the above requirements, an FCA claim is broken down into four elements: falsity, causation, knowledge, and materiality.<sup>32</sup> Central to the circuit split discussed in this Article is the element of falsity.

### *B. The Medicare Hospice Benefit*

Congress established the Medicare Hospice Benefit (“MHB”) in 1983.<sup>33</sup> The MHB shifts patient treatment from “curative” care to “palliative” care.<sup>34</sup> Curative care is designed to focus on improving an

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24. 31 U.S.C. § 3729(a).

25. 31 U.S.C. § 3730(d)(1).

26. 31 U.S.C. § 3730(d)(2).

27. Todd Yoder, *DOJ Announces Four New False Claims Act Settlements*, THE NAT’L L. REV. (Apr. 15, 2020), <https://www.natlawreview.com/article/doj-announces-four-new-false-claims-act-settlements>.

28. 31 U.S.C. § 3729(a).

29. 31 U.S.C. § 3729(a)(1)(C); 31 U.S.C. § 3729(a)(1)(G). However, this does not apply to tax claims under the Internal Revenue Code. (31 U.S.C. § 3729(d)).

30. 31 U.S.C. § 3729(b)(1).

31. 31 U.S.C. § 3729(b)(1)(B).

32. *Care Alternatives*, 952 F.3d 89, 94 (3d Cir. 2020).

33. 48 Fed. Reg. 56,008 (Dec. 16, 1983) (codified at 42 C.F.R. pts. 400, 405, 408, 409, 418, 420, 421, 489).

34. James F. Barger, Jr., *Symposium Article: Life, Death, and Medicare Fraud: The Corruption of Hospice and What the Private Public Partnership Under the Federal False Claims Act is Doing About It*,

individual patient's medical condition, where palliative care instead emphasizes "pain-relief, comfort, and emotional and spiritual support to patients with a terminal diagnosis."<sup>35</sup> Today, a growing number of individuals facing a terminal medical diagnosis choose to forgo traditional curative care for palliative hospice treatment. In 2016, the MHB provided hospice care to around 1.4 million beneficiaries, a fifty-three percent increase from a decade earlier.<sup>36</sup> In total, in 2016 Medicare reimbursed \$16.7 billion for hospice related care.<sup>37</sup>

Medicare and Medicaid programs may provide payment to hospice providers for healthcare service costs incurred under the Social Security Act.<sup>38</sup> However, to be eligible to elect hospice care, MBH requires written confirmation of an individual's diagnosis as terminally ill.<sup>39</sup> Certification must be done by the physician and medical director.<sup>40</sup> "Terminally ill" is defined as an individual whose medical prognosis is a life expectancy of six months or less.<sup>41</sup> Further, regulations also require that clinical information and other documentation supporting the medical prognosis be filed in the medical record with the written certification of terminal illness.<sup>42</sup> Therefore, a signed certification without a medically sound basis supporting the clinical judgment is insufficient to support the terminally ill clinical judgment for MHB reimbursement purposes.

However, recognizing the limitations on science's ability to predict when someone may die, the federal regulations admit that "[p]redicting life is not an exact science" and allow for continual recertification of patients who surpass their six-month timetable.<sup>43</sup> Regulations state that "the hospice medical director must assess and evaluate the full clinical picture" when determining if a patient is, or continues to be, terminally ill.<sup>44</sup> Further, the regulations note that "we have always acknowledged the uniqueness of every Medicare beneficiary" when determining if a patient meets the eligibility criteria for certification of terminally ill.<sup>45</sup> Clearly, the regulations recognize that subjectivity is natural and expected in

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53 AM. CRIM. L. REV. 1, 13 (2016).

35. *Id.* at 13.

36. U.S. DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN., *supra* note 2, at 3.

37. *Id.*

38. Michael W. Thomas et al., *False Claims Act Actions – The Developing Case Law Regarding If and When Opinions Of Medical Necessity Can Be Fraudulent*, 27 HEALTH LAW. 36, 37 (2015).

39. 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.22(a)

40. 41 U.S.C. § 1395f(a)(7)(A)(i).

41. 42 U.S.C. § 1395x(dd)(3)(A).

42. 42 C.F.R. § 418.22(b).

43. 75 Fed. Reg. 70488 (Nov. 17, 2010); 42 U.S.C. § 1395d(d)(1) (allowing providers to collect reimbursement for an unlimited number of recertification periods).

44. 79 Fed. Reg. 50452,50471. (Aug. 22, 2014).

45. *Id.*

doctors' clinical judgments of potentially terminally ill patients.

Local Center for Medicare and Medicaid Services ("CMS") contractors and Medicare Administrative Contractors ("MACs") help process claims from hospice providers and provide eligibility criteria.<sup>46</sup> Hospice professionals rely on Local Coverage Determinations ("LCDs") that are produced by local MACs as guidance for analyzing whether a patient's life expectancy is six months or less.<sup>47</sup> Notably, the LCDs themselves state that they are non-binding and are not a list of mandatory requirements.<sup>48</sup>

### *C. Cases at the Cross Section of FCA's Falsity Element and Doctors' Clinical Judgments*

#### 1. Two Types of Falsity: United States ex rel. Polukoff v. St. Mark's Hosp.<sup>49</sup>

The *Polukoff* claim came from a former doctor-colleague of the doctor-defendant.<sup>50</sup> The relator, a former co-worker of the defendant, brought a *qui tam* action against the doctor for allegedly performing thousands of unnecessary heart surgeries.<sup>51</sup> Under the Medicare Act, the medical provider received reimbursement for surgeries that were deemed medically "reasonable and necessary."<sup>52</sup> The act provided that medical providers must "certify the necessity of the services."<sup>53</sup> The complaint referenced industry guidelines that advised when certain heart surgeries were appropriate for patients who had experienced strokes, which contradicted the medical practices of the defendant-doctor.<sup>54</sup> The defendant had performed an abnormally high number of these heart surgeries and performed the surgeries in his "medically unsupported belief" that the surgery would cure medical issues not traditionally connected to the surgery.<sup>55</sup> The complaint alleged that the defendant knew Medicare would not pay for the surgery to treat the specific issues for

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46. United States v. AseraCare, Inc., 938 F.3d 1278, 1283 (11th Cir. 2019); 79 Fed. Reg. 50452,50471. (Aug. 22, 2014).

47. 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014).

48. *Id.*

49. 895 F.3d 730 (10th Cir. 2018).

50. *Id.* at 734.

51. *Id.*

52. *Id.* at 735.

53. *Id.* (quoting 42 C.F.R. 424.10(a) (Oct. 1, 2013)).

54. *Id.* at 736, 737. (The guidelines surround potential surgery for PFO closures.).

55. *Id.* at 737. (Normally, PFO closures were not performed until a patient had experienced at least one stroke. The Defendant performed these surgeries in an effort to (1) prevent strokes before they occurred or (2) to cure migraine headaches.). *Id.*

which he performed the surgery, so the defendant instead “represent[ed] that the procedures had been performed based upon [the industry] . . . guidelines.”<sup>56</sup> Further, the relator alleged the defendant-doctor had himself “create[d] . . . puncture[s]. . . in patients” hearts, who otherwise did not have the heart condition.<sup>57</sup>

The relator’s claim was based upon his contention that the defendant represented that the surgeries he performed “were medically reasonable and necessary and that this representation was false” under the FCA.<sup>58</sup> However, the district court ruled that “because opinions, medical judgments and conclusions about which reasonable minds may differ cannot be false for the purposes of the FCA,” the doctor’s representations “could not be false.”<sup>59</sup> Therefore, the relator’s FCA claims “failed as a matter of law” and the district court dismissed the case.<sup>60</sup>

On appeal, the Tenth Circuit disagreed with the district court’s holding that a “medical judgment concerning the necessity of a treatment could not be deemed false or fraudulent under the FCA.”<sup>61</sup> Instead, the court held that a doctor’s certification that a procedure is reasonable and necessary can be false under the FCA if the surgery does not fit within Medicare’s definition of “reasonable and necessary.”<sup>62</sup>

To support its holding, the Tenth Circuit relied on its previously developed understanding of what may be considered “false” under the FCA.<sup>63</sup> Previously, the Tenth Circuit had held that “false” may mean either factually false or legally false.<sup>64</sup> Factual falsity covered express claims that simply were false, such as a provider submitting incorrect information or requesting reimbursement for a service never performed.<sup>65</sup> Legal falsity generally covered situations when persons knowingly certified they were in compliance with regulations that were a “condition of payment” when, in fact, they were not.<sup>66</sup> Since the relator’s complaint alleged that the doctor did not comply with the “reasonable and necessary requirement” of the regulations, the relator alleged the doctor “submitted legally false requests for payment.”<sup>67</sup> Under legal falsity, the fact that the doctor misrepresented the reasoning for the surgery in order to meet the

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56. *Id.*

57. *Id.* at 738.

58. *Id.* at 739.

59. *Id.* (internal quotation marks omitted).

60. *Id.*

61. *Id.* at 740.

62. *Id.* at 742, 743.

63. *Id.* at 741.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*



guidelines for reimbursement meant that the doctor made a false statement under the FCA.<sup>68</sup> For that reason, the Tenth Circuit held that the relator had “pleaded enough to . . . survive dismissal” and reversed the district court and remanded the case for further proceedings.<sup>69</sup> Overall, the *Polukoff* case illustrates two theories of falsity, factual and legal, that may demonstrate that a defendant made a “false” statement to Medicare under the FCA.

## 2. Piercing the Opinion Shield: *United States v. Paulus*<sup>70</sup>

The *Paulus* case concerned a well-known cardiologist who was accused of defrauding Medicare by performing medically unnecessary surgeries and procedures for patients.<sup>71</sup> The complaint alleged that the cardiologist performed procedures to place stents in patients’ arteries when, according to the angiograms, stents were not needed.<sup>72</sup> The issue primarily concerned the reading of angiograms, which are performed to measure the severity of blockage in patients’ arteries.<sup>73</sup> The plaintiffs’ case was built largely on the testimony of nine doctors who testified that the angiograms did not show the level of blockage that the defendant had reported in order to justify the medical procedure.<sup>74</sup> The doctors further alleged the defendant “systematically exaggerated the amount of blockage he saw on the angiograms.”<sup>75</sup> On the other hand, the defendant contended he could not have made a false statement when interpreting the angiograms because (1) different doctors interpret angiograms differently and (2) multiple studies existed which illustrated large variability in the percent of blockage reported among doctors based on their readings of angiograms.<sup>76</sup> The defendant argued that since the studies showed large “inter-observer variability,” his allegedly false reporting of blockage could not be considered a false statement for FCA purposes.<sup>77</sup>

At the district court level, a jury convicted the cardiologist of committing healthcare fraud and making false statements based on the jury’s belief that he exaggerated the extent of the blockage in patients.<sup>78</sup>

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68. *Id.* at 743, 744.

69. *Id.* at 743.

70. 894 F.3d 267 (6th Cir. 2018).

71. *Id.* at 270.

72. *Id.* at 272.

73. *Id.* at 271.

74. *Id.* at 273, 274. Often times the defendant had reported as high as 80% blockage, when, according to the experts there was no blockage present in the angiograms. *Id.*

75. *Id.* at 274.

76. *Id.* at 272.

77. *Id.*

78. *Id.* at 270.

However, the district court set aside the guilty verdicts, holding that, as a matter of law, the plaintiffs “failed to prove falsity,” an essential element of the crime.<sup>79</sup> In the court’s view, the degree of blockage was a “subjective medical opinion” that, based on evidence presented at trial, was a “difficult task” that “cardiologists frequently disagreed” over.<sup>80</sup> Therefore, the defendant’s statement about the degree of blockage “could neither be false or fraudulent.”<sup>81</sup>

On appeal, the Sixth Circuit disagreed and overruled the district court, explicitly stating that the degree of blockage shown on an angiogram “is a fact capable of proof or disproof.”<sup>82</sup> Moreover, the court stated that a “doctor who deliberately inflates the blockage he sees on an angiogram has told a lie; if he does so to bill . . . more . . . then he has also committed fraud.”<sup>83</sup> The court’s decision rested on whether the plaintiffs could prove that the defendant did not honestly report what he saw on the angiogram.<sup>84</sup> It reasoned that if a statement was “capable of confirmation or contradiction” and demonstrated as untrue, this may show “that the defendant made a false statement” satisfying the “falsity” element of the offense.<sup>85</sup> The court also clarified that “[o]rdinarily, facts are the only item that fits in this category; opinion – when given honestly – are almost never false . . . but opinions are not, and have never been, completely insulated from scrutiny.”<sup>86</sup> Then, the court further deduced that “opinions may trigger liability for fraud when they are not honestly held.”<sup>87</sup> For this reason, the court opined the defendant was convicted “for misrepresenting facts, not giving opinions . . . [the defendant] was charged with lying about the results.”<sup>88</sup> Overall, the court suggested that medical opinions can be deemed false if not honestly held. Further, the way to demonstrate that opinions are not honestly held is to evidence underlying facts, upon which the opinion is based, that are capable of proof or disproof.

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79. *Id.* at 274, 275.

80. *Id.* at 275.

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.* at 276. (The defendant “repeatedly and systematically saw one thing on the angiogram and consciously wrote down another, and used that misinformation to perform and bill unnecessary procedures. The difficulty of interpreting angiograms has no bearing on the capacity of these statements to be false.”).

## III. THE SPLIT

The two cases central to the circuit split both rely on the statutory language of the FCA and the regulations surrounding the MHB to arrive at different conclusions as to what exactly determines “falsity” of medical professionals’ clinical judgments under the FCA in the hospice setting. First, this Part will discuss the Eleventh Circuit’s ruling in *United States v. AseraCare, Inc.*, which allows hospice providers to more easily prevail against FCA claims at the summary judgment stage.<sup>89</sup> Second, this Part will discuss the Third Circuit’s ruling in *United States v. Care Alternatives*, which explicitly departs from the holding in *United States v. AseraCare, Inc.* by rejecting the Eleventh Circuit’s “objective falsehood” standard.<sup>90</sup> The practical result of the *Care Alternatives* ruling is that relators and the government are more likely to survive the summary judgment stage and create a triable issue of fact simply by providing dueling expert opinions.<sup>91</sup>

A. *United States v. AseraCare, Inc.*

The *AseraCare* litigation arose from three former AseraCare employees who, acting as *qui tam* relators, alleged that AseraCare had practices of knowingly submitting unsubstantiated Medicare claims in violation of the FCA.<sup>92</sup> The Government chose to intervene in the suit.<sup>93</sup> The Government further alleged that AseraCare knowingly employed reckless business practices that enabled AseraCare to receive Medicare reimbursement for patients who were not eligible for MHB because it was “financially lucrative” and, thus, misspent millions of Medicare dollars.<sup>94</sup>

The Government’s case fell under the “false certification” theory of FCA liability.<sup>95</sup> Liability under this theory arises when a defendant falsely “implies that it has complied with a statutory or regulatory requirement” when, in fact, it has not.<sup>96</sup> The Government first found over 2,000 hospice patients that AseraCare billed Medicare for at least 365 continuous days of hospice care and, within that group, created a sample of 223 patients.<sup>97</sup>

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89. *Supra* Part III.A.

90. *Supra* Part III.B.

91. *Id.*

92. *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1282 (11th Cir. 2019).

93. *Id.* at 1284.

94. *Id.* (“The complaint described a corporate climate that pressured sales and clinical staff to meet aggressive monthly quotas for patient intake and . . . discouraged meaningful physician involvement in eligibility determinations”).

95. *Id.*

96. *Id.*

97. *Id.*

Then, the Government relied on the expert testimony of a doctor who identified 123 patients from that sample pool who, in his opinion, were ineligible for MHB when AseraCare filed for its Medicare reimbursement.<sup>98</sup> Centrally, the doctor, in his medical opinion, did not believe that the medical records of the identified patients supported AseraCare's certification of terminal illness, since the records did not support a life expectancy of six months or less.<sup>99</sup> The doctor made clear that his testimony was a reflection only of his own clinical judgment and that he did not think that a doctor who held a belief counter to his was "necessarily wrong."<sup>100</sup> AseraCare presented its own expert whose testimony "directly contradicted" the Government doctor's expert testimony.<sup>101</sup>

At the heart of the disagreement between the experts was how exactly medical professionals should analyze patient life expectancy.<sup>102</sup> According to the Government expert, physicians should use a "checkbox approach" that assesses terminal illness by comparing the patient's medical records to LCD and medical guidelines to determine a specific diagnosis that would deem the patient "terminally ill" under MHB guidelines.<sup>103</sup> On the other hand, AseraCare's experts "considered but did not formulaically apply the LCD guidance in making their assessment."<sup>104</sup> Overall, the approach presented by AseraCare was a more "holistic" approach compared to the more objective standard suggested by the Government's expert.<sup>105</sup>

It is important to understand the AseraCare case's nontraditional procedural posture to better comprehend the conclusions and rulings of the district court. After discovery, AseraCare initially moved for summary judgment based on the Government's failure to adduce evidence of the "falsity" element required for FCA claims.<sup>106</sup> AseraCare asked the district court to apply a "reasonable doctor" standard for the purposes of assessing falsity under the FCA.<sup>107</sup> The "reasonable doctor" standard would require the Government to show that any "reasonable physician applying his or her clinical judgment could not have held the opinion that the patient at issue was terminally ill."<sup>108</sup> Although the

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98. *Id.* at 1285.

99. *Id.* at 1287.

100. *Id.*

101. *Id.* at 1288.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.* at 1285.

107. *Id.* at 1286.

108. *Id.*

district court found this standard “appealing and logical,” it ultimately decided not to apply it and denied AseraCare’s motion.<sup>109</sup> In reasoning its denial, the court concluded that questions remained regarding whether clinical information and other documentation relied upon by AseraCare actually supported AseraCare’s “terminally ill” judgment.<sup>110</sup>

Against the opposition of the Government, the district court next decided to bifurcate the trial into two phases: phase one on the falsity element and phase two on the remaining FCA elements.<sup>111</sup> As a result, the Government’s witness testimony regarding AseraCare’s procedures and practices was allowed, but only to show context and not to rebut AseraCare’s own expert testimony.<sup>112</sup> After the dueling expert opinions were presented in phase one of the trial, the case was sent to the jury, whose “sole job . . . was to review the medical records of each patient and decide which expert’s testimony seemed more persuasive”—a classic battle of the experts.<sup>113</sup> The question presented to the jury was “whether a particular patient should [have been] characterized as ‘terminally ill’ at the time of certification.”<sup>114</sup> Ultimately the jury answered special interrogatories regarding each of the 123 patients at issue and found false claims for 104 of the patients.<sup>115</sup>

Unfortunately for the Government, the favorable partial jury verdict had a short lifespan. After the verdict, AseraCare moved for judgment as a matter of law, contending that the court applied the wrong legal standard in its jury instructions and again campaigned for the reasonable doctor standard.<sup>116</sup> The district court agreed and ordered a new trial.<sup>117</sup> The court concluded that proper jury instructions would have stated “(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.”<sup>118</sup> However, the district court did not stop there. It reconsidered AseraCare’s motion for summary judgment under its newly adopted legal standard that required the Government to show an “objective falsehood” to create an issue of fact regarding the falsity element.<sup>119</sup> Under this approach, the court granted summary judgment in

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109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* at 1288.

113. *Id.*

114. *Id.*

115. *Id.* at 1289.

116. *Id.* at 1289-90.

117. *Id.* at 1290.

118. *Id.*

119. *Id.* (The district court was able to reconsider summary judgment *sua sponte* under Federal Rule of Civil Procedure 56(f)(3)).

AseraCare’s favor because “the Government [had] failed to point the court to any admissible evidence to prove falsity other than [the doctor’s] opinion that medical records . . . did not support the Certification of Terminal Illness.”<sup>120</sup> Since the government lacked evidence of an objective falsehood, it “could not prove the falsity element of its FCA claim as a matter of law.”<sup>121</sup>

The Government appealed the decision. The Eleventh Circuit started its analysis by noting that the issue before the court was an issue of first impression.<sup>122</sup> Specifically, the court “considered that standard for falsity in the context of the [MHB], where the controlling condition of reimbursement is a matter of clinical judgment.”<sup>123</sup> The court summarized that the Government had essentially argued that dueling experts who disagree over whether a patient’s medical records support a prognosis of terminally ill was enough to raise a factual question that should be presented to a jury.<sup>124</sup> On the other hand, the defendants argued that “the determinative inquiry in an eligibility analysis is whether the certifying physician exercised [a] genuine clinical judgment.”<sup>125</sup> Further, as long as the clinical judgment was genuinely held, then the accuracy of the judgment was not a question of fact that a jury could decide was false.<sup>126</sup> Ultimately, the court concluded that it agreed with the “general sense” of the objectively false standard and agreed with the district court that the jury instructions were inadequate.<sup>127</sup>

The Eleventh Circuit started by determining how the claim before the court may fall under the FCA. The court believed there was two possible representations that could have been deemed false under the FCA: (1) the representation by the physician to AseraCare that a patient was terminally ill, and (2) the representation by AseraCare to Medicare that the physician’s clinical judgment was obtained and, therefore, that the patient qualified as eligible for reimbursement.<sup>128</sup> The focus of the case at hand was based on the first representation, the representation the physician made to AseraCare.<sup>129</sup> Under this theory, once the hospice provider presented to Medicare the physician’s allegedly false representation of a patient’s terminally ill prognosis, the hospice provider was then deemed

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120. *Id.*

121. *Id.*

122. *Id.* at 1291.

123. *Id.*

124. *Id.*

125. *Id.* at 1292.

126. *Id.*

127. *Id.* at 1291.

128. *Id.* at 1295, 1296.

129. *Id.* at 1296.

in violation of the FCA if the prognosis was, in fact, false.<sup>130</sup>

Naturally, the question before the court became what exactly may deem a physician's clinical judgment as "false." The court looked almost exclusively to the text of the MHB statute and its regulations to find its answer.<sup>131</sup> Overall, the court required that hospice providers must submit a claim that certifies a patient as terminally ill.<sup>132</sup> The certification must be in writing, be based on a clinical judgment, and the reimbursement must be for payments that were "reasonable and necessary" for the management of the terminal illness.<sup>133</sup> Further, the regulations required that "clinical information and other documentation . . . support the medical prognosis" and accompany the request for reimbursement.<sup>134</sup>

The court further noted that the regulations often made room for subjectivity. For example, the required narrative explanation of the physician's clinical judgment could not "contain check boxes or standard language" and must consider several factors including both "current subjective and objective medical findings."<sup>135</sup> Overall, the court emphasized that the regulations clearly made obtaining the physician's clinical judgment the centerpiece of the MHB eligibility.<sup>136</sup>

The main constraint on the clinical judgment was simply that the underlying medical documentation must support the judgment.<sup>137</sup> However, the regulations also emphasized that the nature of a clinical judgment is not a matter of medical fact.<sup>138</sup> Moreover, the court reasoned that "none of the relevant language state[d] that the documentary record underpinning . . . [the] judgment must prove the prognosis," and also cited where the regulations conceded that "predicting life expectancy is not an exact science" to explain why those who wrote the implementing regulations chose to show deference to the medical professional making the judgment.<sup>139</sup> The court disagreed with the Government's approach that underlying documentation must support the physician's certification "as a factual matter."<sup>140</sup> Instead, "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

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130. *Id.*

131. *Id.* at 1292-95.

132. *Id.* at 1292.

133. *Id.* at 1293.

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.* at 1294.

138. *Id.* at 1293.

139. *Id.* (quoting 75 Fed. Reg. 70372, 70448).

140. *Id.* at 1294.

record.”<sup>141</sup> Overall, as long as the clinical judgment represented a “reasonable interpretation of the relevant medical records, then the physician’s clinical judgment should dictate eligibility. “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.”<sup>142</sup>

The Government argued that the ruling essentially crippled the Government’s ability to bring FCA claims against hospice providers because all hospice providers would need to justify their request for reimbursement is a physician who was willing provide the hospice provider with a clinical judgment of their liking.<sup>143</sup> However, in response to this fear, the court reminded the Government that the clinical judgment of a physician must be informed by the patient’s medical records.<sup>144</sup> It also stated that if Congress had intended for a more rigid and objective standard for determining terminal illness, it would have used different language.<sup>145</sup> Instead of requiring that medical records “support” the clinical judgment, it could have instead used “demonstrate” or “prove.”<sup>146</sup> Simply put, it was not the role of the court to require more certitude than the plain language of the statute and regulations implied; such reading was not consistent with the text or design of the law.<sup>147</sup>

After holding that a “claim cannot be ‘false’—and thus not trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood,” the court also commented on how plaintiffs could prove an objective falsehood moving forward.<sup>148</sup> Evidence that a physician either failed to (1) review a patient’s medical records, (2) familiarize himself with the patient’s condition, or (3) subjectively believe the patient was terminally ill, could all prove an objective falsehood for FCA purposes.<sup>149</sup> The court also noted that evidence “that no reasonable physician could have concluded that a patient was terminally ill” would also suffice to show an objective falsity.<sup>150</sup> In contrast, however, the court stated that “a properly formed and sincerely held clinical judgment [was] not untrue even if a different physician later contends the judgment [was] wrong.”<sup>151</sup> Overall, under the Eleventh Circuit’s approach, if a plaintiff alleges false

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141. *Id.* (Internal quotes omitted. Emphasis omitted. Quoting 42 C.F.R. § 418.22(b)(2)).

142. *Id.*

143. *Id.* at 1295.

144. *Id.*

145. *Id.* at 1294.

146. *Id.*

147. *Id.* at 1294, 1295.

148. *Id.* at 1296, 1297.

149. *Id.* at 1297.

150. *Id.*

151. *Id.*



certification for hospice care, the plaintiff must identify “facts and circumstances surround[ing] the patient’s certification that are . . . [an] [im]proper exercise of a physician’s clinical judgment.”<sup>152</sup> Due to the subjectivity of the clinical judgment and the deference shown to the physician’s judgment by the statute and regulations, the court articulated that future plaintiffs best rely on outside facts and circumstances to show the clinical judgment was not a genuinely held belief.

*B. United States ex rel. Druding v. Care Alternatives*

As in the *AseraCare* case, the relators in the *Care Alternatives* case consisted of former employees of the hospice care provider, Care Alternatives.<sup>153</sup> The former employees similarly alleged that the company admitted patients for hospice care who should have been illegible for MHB.<sup>154</sup> Moreover, they alleged that Care Alternatives directed its employees to improperly alter patients’ Medicare certifications to reflect eligibility.<sup>155</sup> Unlike in *AseraCare*, the government declined to intervene, but the relators decided to proceed with the claim.<sup>156</sup>

At the district court level, the central question surrounded the falsity element of the FCA claim.<sup>157</sup> Discovery led to “dueling expert opinions” regarding whether the underlying medical documentation supported the clinical judgment of terminally ill.<sup>158</sup> The relators had a doctor examine the records of forty-seven past patients.<sup>159</sup> The doctor testified that the documentation was unresponsive of a terminally ill certification in thirty-five percent of the patient files he reviewed.<sup>160</sup> The expert also went a step further and testified that, in his view, “any reasonable physician would have reached the conclusion he reached.”<sup>161</sup> Care Alternatives also presented their own expert witness who testified that, in his opinion, “a physician could have reasonably determined” that each patient in question was, in fact, terminally ill.<sup>162</sup>

Care Alternatives then moved for summary judgment.<sup>163</sup> Relying on the objective falsehood standard, Care Alternatives argued that the

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152. *Id.*

153. *Care Alternatives*, 952 F.3d 89, 91 (3d Cir. 2020).

154. *Id.*

155. *Id.*

156. *Id.* at 93.

157. *Id.* at 91.

158. *Id.* at 94.

159. *Id.* at 91.

160. *Id.*

161. *Id.* at 94.

162. *Id.*

163. *Id.*

plaintiffs “could not make out the four prima facie elements of a claim under the FCA,” most importantly the element of falsity.<sup>164</sup> The district court granted Care Alternative’s motion and based its opinion entirely on the plaintiff’s failure to show falsity.<sup>165</sup> In reaching its conclusion, the court relied on the ruling in *AseraCare* and held that a “mere difference of opinion between physicians, *without more*, is not enough to show falsity.”<sup>166</sup> The crux of the court’s decision also relied on the premise that “medical opinions are subjective and cannot be false.”<sup>167</sup>

On appeal, the Third Circuit started its analysis by discussing the MHB. The Third Circuit generally agreed with the *AseraCare* court about what providers must show to Medicare for reimbursement for patients diagnosed as terminally ill.<sup>168</sup> The court also highlighted that the regulations declared that determining the timespan of a patient’s illness was an inexact science.<sup>169</sup> However, the court stated that inexactness “does not negate the fact that there must be clinical basis for the certification.”<sup>170</sup>

However, the Third Circuit entirely departed from *AseraCare* regarding what exactly was needed under the FCA to show falsity.<sup>171</sup> The “central question” before the court on appeal was whether a claim for reimbursement may be considered false under the FCA if a medical expert testifies that accompanying medical documentation does not support a patient’s prognosis of terminally ill.<sup>172</sup> The court answered that question with a “straightforward yes.”<sup>173</sup> The court explicitly declined to adopt the objective falsity standard and claimed the standard was inconsistent with statute.<sup>174</sup> Further, the court opined that the objective falsity standard conflated the FCA elements of “falsity” and “scienter” into one analysis.<sup>175</sup> Instead, the court found that conflicting medical testimony created a genuine dispute of material fact as to the element of falsity.<sup>176</sup>

Fundamental to the circuit court’s opinion was the meaning of “false”

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164. *Id.*

165. *Id.*

166. *Id.* (internal citations omitted).

167. *Id.* (quoting United States *ex rel.* Riley v. St. Luke’s Episcopal Hosp., 355 F.3d 370, 376 (5th Cir. 2004)).

168. *Id.* at 92.

169. *Id.* at 93.

170. *Id.*

171. *Id.* at 95.

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.* 96.

176. *Id.* at 95.

under the FCA statute.<sup>177</sup> “False” was an undefined term in the statute, so the court looked to common law to find its meaning.<sup>178</sup> Under common law, the court identified two ways a claim may be false: legal falsity and factual falsity.<sup>179</sup> Factual falsity occurred when “facts contained within the claim were untrue.”<sup>180</sup> Legal falsity occurred when a claimant “falsely certifies that it has complied with a statute or regulation” for which compliance “is a condition for government payment,” when, in fact, they have not complied with the statute.<sup>181</sup> Therefore, if Care Alternatives wrongfully certified that a patient was eligible for reimbursement, then Care Alternatives would have made a false statement under the legal falsity theory.<sup>182</sup> In the circuit court’s opinion, the district court had limited its analysis to factual falsity by implementing the objective falsehood standard.<sup>183</sup> Under the legal falsity standard, the relators could show that the Care Alternatives’ physician certification failed to meet the regulatory requirement that clinical information and other documentation supported a “terminally ill” prognosis.<sup>184</sup> Under this theory, the court stated that “disagreement between experts . . . may be evidence” of a legal falsity, which would satisfy the falsity element of the FCA.<sup>185</sup> Lastly, to support the idea of legal falsity, the court also relied on the *Polukoff* case to demonstrate the appropriateness of using both factual and legal falsity to evidence falsity under the FCA.<sup>186</sup>

The court also rejected the district court’s “bright-line rule that a doctor’s clinical judgment cannot be false.”<sup>187</sup> For this point, the court relied on the Sixth Circuit’s *Paulus* opinion, which emphasized that medical professional’s “opinions are not, and haven never been, completely insulated from scrutiny.”<sup>188</sup> Specifically, the court used *Paulus* to highlight that a medical opinion that is not honestly held “may trigger liability for fraud.”<sup>189</sup> However, the court also suggested that “a good faith medical opinion is not punishable.”<sup>190</sup> Overall, it was the

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177. *Id.*

178. *Id.*

179. *Id.* at 96.

180. *Id.*

181. *Id.*

182. *Id.* at 97. “In other words, our cases instruct that FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government.”

183. *Id.*

184. *Id.*

185. *Id.*

186. *Id.* (citing 10th circuit’s *Polukoff* and the 3rd circuit’s *Paulus* cases).

187. *Id.* at 98. (internal quotation marks omitted).

188. *Id.* (citing *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018)).

189. *Id.*

190. *Id.*

court's belief that the question of whether a defendant had committed fraud by misrepresenting underlying medical documentation or had acted in good faith was a suitable question for a jury to decide.<sup>191</sup> In the court's opinion, it was clear that the credibility of expert testimony was "exclusively" a judgment for the jury.<sup>192</sup>

The Third Circuit also addressed the *AseraCare* ruling and why it chose to depart from its sister circuit.<sup>193</sup> Specifically, the court highlighted the difference in the framing of the falsity question by the Government and the hospice provider.<sup>194</sup> Under the Government's framing in *AseraCare*, clinical information and accompanying documents must actually support the physician's certification.<sup>195</sup> Whereas from the defendant's point of view, the supporting documentation requirement was "only designed to address the mandate that there be a medical basis for the certification."<sup>196</sup> By adopting the approach suggested by *AseraCare*, the Third Circuit believed that its sister court "limited the relevant inquiry to whether the Government had adduced sufficient evidence to the accuracy of the physician's . . . judgment."<sup>197</sup> In the Third Circuit's opinion, this essentially excluded legal falsity and made plaintiffs rely entirely on factual falsity.<sup>198</sup>

The Third Circuit also suggested that the Eleventh Circuit "determined that clinical judgments cannot be untrue" because it held that "a reasonable difference of opinion among physicians . . . is not sufficient on its own" to show falsity under the FCA.<sup>199</sup> Again, the Third Circuit believed this approach limited falsity to factual falsity.<sup>200</sup> In the end, on the basis of legal falsity, the court held that physician expert testimony that disagrees with the hospice provider's certification does in fact create a triable issue of fact that should be left for a jury to decide.<sup>201</sup> In the case at hand, the relators' physician-expert testimony provided sufficient evidence to create a triable issue of fact regarding falsity.<sup>202</sup>

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191. *Id.*

192. *Id.*

193. *Id.* at 98-100.

194. *Id.* at 99.

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.* at 99-100.

199. *Id.* at 100.

200. *Id.* 100-01.

201. *Id.*

202. *Id.* at 101.

## IV. DISCUSSION

*AseraCare*, *Care Alternatives*, and the other previously discussed cases highlight a growing tension regarding how exactly plaintiffs are supposed to demonstrate the falsity element of the FCA in the hospice context. More specifically, does the plain language of the FCA and MHB statutes and regulations require more than simply dueling expert testimony to create a triable issue of fact that should be presented to a jury? *Care Alternatives* certainly suggests the answer to that question is a straightforward no.<sup>203</sup> However, although *Care Alternatives* characterizes the *AseraCare* holding as providing an inappropriate “bright-line rule” based on objective falsity, the *AseraCare* holding does nothing of the sort. First, *AseraCare* does not create a bright-line rule. In fact, *AseraCare* implicitly considered legal falsity as well as factual falsity in the premise of its analysis.<sup>204</sup> Secondly, based on the plain language of the statute and regulations governing end-of-life treatment, the law purposely grants a large amount of deference to a physician’s clinical judgment of terminal illness because of the highly subjective nature of the judgment compared to other areas of medical expertise. Moving forward, courts should move away from the *Care Alternatives* holding and realign themselves with the logic and holding of the *AseraCare* court.

The objective falsehood standard adopted in *AseraCare* (1) covers both factual and legal falsity, (2) does not create a bright-line rule, and (3) is the more appropriate reading of the statute based on Congress’ desire to grant flexibility to the physician making a judgment. This is not to say that a physician’s clinical judgment should never be questioned or subjected to a jury’s scrutiny. Rather, to create a triable issue of fact as to whether a physician’s clinical judgment was “false,” a plaintiff must first demonstrate underlying facts that support an inference that the physician did not honestly hold the clinical judgment he or she made. Of course, a plaintiff may always present facts that demonstrate a clinical judgment was inappropriate because the physician did not meet or perform one of the other explicit requirements necessary under statute to make an appropriate clinical judgment.

*A. Factual and Legal Falsity Are Both Considered Under AseraCare’s “Objective Falsehood” Standard*

One of the prominent reasons that *Care Alternatives* decided to depart from its sister court’s *AseraCare* ruling was because the *Care Alternatives* court believed the objective falsehood standard limited falsity to factual

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203. *Id.* at 95.

204. *Supra* Part IV.A.

falsity and disregarded legal falsity.<sup>205</sup> In reality, the *AseraCare* objective falsehood standard accounts for legal falsity as well as factual falsity. First, the objective falsehood standard can be applied to the requirement that medical documentation accompanying the certification of terminal illness “supports” the certification. Plaintiffs may still evidence falsity under the legal falsity theory by inquiring whether clinical information and other documentation accompanying a certification of terminal illness supports the physician’s certification. In fact, this is the exact approach the Government took in both *AseraCare* and *Care Alternatives*.

The court in *AseraCare* did not have an issue with the Government evidencing falsity under legal falsity theory. Rather, the issue was that the Government only provided an expert who said he personally disagreed with the doctor.<sup>206</sup> Moreover, the Government’s expert witness could not say that another doctor “who disagreed with him . . . was necessarily wrong.”<sup>207</sup> As the court stated in *AseraCare*, the dueling expert witnesses simply “fundamentally differed as to how a doctor should analyze a patient’s life expectancy.”<sup>208</sup> The Government did not succeed on their claim for that exact reason. It is important to distinguish the court’s issue with the lack of evidence from their overall framing of falsity. Plainly, the *AseraCare* court did not take issue with evidencing falsity through legal falsity; in fact, the court’s analysis implicitly supported its reasoning. Instead, the real issue was that the Government lacked any evidence to legal falsity other than its expert’s opinion, which the court concluded was insufficient.

It is simply wrong to state that *AseraCare* did not consider a legal falsity theory. The objective falsehood standard was not implemented to cabin falsity to just factual falsity. Instead, it simply required that something more than a difference in opinion was necessary to explain why the defendant’s clinical judgment was false. The objective falsehood

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205. *Care Alternatives*, 952 F.3d at 96. “Objective falsity standard is also at odds with this Court’s cases that have interpreted falsity to encompass a theory of liability based on non-compliance with regulatory instructions and not just objectively verifiable facts.” (internal quotation marks omitted).

206. *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1287 (11th Cir. 2019). The Government presented expert testimony that, in the expert’s own clinical judgment “the medical records of the patients at issue did not support . . . terminal illness.” (internal quotation marks omitted). The court’s issue was not with how the Government framed falsity under legal falsity theory. Rather the issue was that there was no other evidence on record besides the medical expert’s personal opinion that the Defendant’s clinical judgments were false. The court made this abundantly clear when later it stated, “a plaintiff alleging that a patient was falsely certified . . . must identify facts and circumstances surrounding the patient’s certification that are inconsistent with . . . proper . . . judgment.” *Id.* at 1297.

207. *Id.* at 1287, 1288. (The Government’s expert witness even “himself changed his opinion concerning the eligibility of certain patients over the course of the proceeding.”) Later, he explained his change of opinion on the fact that he “was not the same physician” three year previous than he was now. *Id.* at 1288. This in of itself serves as evidence to the overall incredibly subjective nature of the “terminal illness” clinical judgment.

208. *Id.*

standard still allows plaintiffs to raise a question of falsity under legal falsity, it simply requires underlying objective facts that support the apparent disagreement between doctors.<sup>209</sup> Due to the highly subjective nature of a terminally ill clinical judgment, this requirement is justified. Without such a requirement, all a plaintiff would need to find to create a triable issue of fact is a single doctor who was willing to disagree with the defendant-doctor's judgment, after an *ex post* review of the supporting documents.

Second, *AseraCare* held that a disagreement between experts, *without more*, does not create a triable issue of fact.<sup>210</sup> This framing does not foreclose a legal falsity theory of liability. It just means that another expert's opinion alone cannot raise a triable issue of fact regarding legal falsity. Instead, to raise a question of legal falsity, there needs to be an underlying fact that plaintiffs may point to and say, "this is why my expert is right and the defense's expert was wrong." Under this approach, plaintiffs may raise a triable issue of fact based on legal falsity, but the legal falsity must be based on something objective. Doing so does not dismantle legal falsity. Instead, it helps to make sure that juries are not making purely medical judgments or simply deciding which doctor's opinion they like best.

*Paulus* is a fitting example where the plaintiffs applied legal falsity theory to question whether clinical information actually supported the physician's judgment that the amount of blockage made a stent procedure necessary.<sup>211</sup> In *Paulus*, experts were not debating medical theory. Instead, the court noted that the amount of artery blockage that appeared on an angiogram was an objective fact that may be proven true or false and that the jury could decide.<sup>212</sup> This is a textbook example of legal falsity; however, the amount of blockage the doctor reported was an underlying objective fact that could have passed the objective falsehood standard of *AseraCare*. The plaintiff in *Paulus* had experts who disagreed, but it also had more. What moved the disagreement from a medical debate to a triable issue of fact was the objective percentage of blockage shown on the reports. A jury could decide whether the defendant-doctor lied about the blockage he witnessed on the angiogram. On the other hand, in *AseraCare*, the plaintiffs did not supply any other evidence of falsity besides their disagreeing expert.<sup>213</sup>

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209. *AseraCare*, 938 F.3d at 1301. "[T]he mere difference of reasonable opinion between physicians, *without more* . . . does not constitute an objective falsehood." (emphasis added).

210. *Id.*

211. *United States v. Paulus*, 894 F.3d 267, 270 (6th Cir. 2018).

212. *Id.* at 275. "We make it explicit now: The degree of stenosis *is* a fact capable of proof or disproof."

213. *AseraCare*, 938 F.3d at 1290. "The Government [had] failed to point the court to any admissible evidence to prove falsity other than [the doctor's] opinion."

*B. The Objective Falsehood Standard Does Not Create A Bright-Line Rule Protecting Medical Professionals*

The *Care Alternatives* court's characterization<sup>214</sup> of *AseraCare*'s objective falsehood standard as a bright-line rule that a doctor's clinical judgment cannot be "false," is simply a misunderstanding of the objective falsehood standard. The objective falsehood standard modestly requires that some underlying fact(s) be present to suggest falsity besides an expert's contrary medical opinion.<sup>215</sup> In fact, the *AseraCare* case laid out multiple avenues a plaintiff may take to prove a doctor's clinical judgment was false.<sup>216</sup> The only bright-line rule created by the objective falsehood standard is that there needs to be more than a medical disagreement among experts to evidence falsity.<sup>217</sup> In fact, the standard even leaves open the possibility for a purely medical disagreement to pass the objective falsehood test by having an expert testify that "no reasonable physician could have concluded a patient was terminally ill given the relevant medical records."<sup>218</sup> In this case, the objective falsehood standard would likely require an underlying reason as to why no doctor could have held the clinical judgment, but that could be supported by standard medical practices in the same way standard medical practices were used to support evidence falsity in the *Paulus* case.<sup>219</sup> Altogether, the objective falsehood standard is far from a bright-line rule that protects physicians' judgments under all circumstances. To the contrary, *AseraCare* carved out multiple specific ways that a plaintiff can evidence falsity of a physician's clinical judgment under the objective falsehood rule.

*C. The Overall Policy Objectives of the MHB Purposely Grant Deference to Doctors' Clinical Judgments of Terminal Illness*

It can still be argued that requiring underlying objective facts to create a triable issue on falsity under the legally false theory is too large of a

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214. *Care Alternatives*, 952 F.3d 89, 98 (3d Cir. 2020).

215. *AseraCare*, 938 F.3d at 1290.

216. *Id.* at 1297. "Certifying physician fails to review patient's medical records or otherwise familiarize himself with the patient's condition . . . [or] physician did not, in fact, subjectively believe that his patient was terminally ill . . . [or] no reasonable physician could have concluded that [the] patient was terminally ill given the relevant medical records." The court continued, "In each of these examples, the clinical judgment on which the claim is based contains a flaw that can be demonstrated through verifiable facts."

217. *Id.* "[A] reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest . . . claims . . . are false under the FCA."

218. *Id.*

219. *United States v. Paulus*, 894 F.3d 267, 271-72 (6th Cir. 2018). The court used both "the accepted standard of medical care" and what "the medical consensus appears to be" to help determine whether a stent was justified at certain varying levels of blockage. *Id.*



burden to place on plaintiffs bringing FCA actions. Although the requirement makes bringing an action against hospice providers more difficult,<sup>220</sup> more importantly, it aligns with the general deference given to medical professionals by statutes and regulations.

From a holistic view, the regulations and rulemaking commentary repeatedly suggest that a physician's clinical judgment should be granted deference because of the subjectivity involved in physicians' clinical judgments. First, the regulations explicitly declare that predicting life expectancy is not an exact science. Second, for this reason, the regulations allow for unlimited recertification of patients' terminal illness. At the end of the day, even in an *ex post* review, doctors are not always capable of predicting the exact time or timeframe when individuals die. Third, again due to the natural subjectivity of an individual's health, the regulations require that physicians consider "several factors" and both "subjective and objective medical findings." Finally, the regulations specifically disallow using "check the box" language in a physician's narrative explanation for terminal illness.

All these factors illustrate that the judgments physicians are asked to make are naturally complex and inexact. It is unfair to then have these judgments second-guessed *ex post facto* by a jury or their professional peers. Based on the number of factors that a physician is required to consider under the regulations, two different physicians can both consult the same factors, but can come to opposite clinical judgments based on how each physician weighs each individual factor. For this reason, it makes sense require some underlying objective fact that points to wrongness in an opposing physician's point-of-view. Without an underlying objective fact, dueling expert opinions offer nothing more than simply a difference in medical theory and opinion. Furthermore, based on the regulations' clear understanding of the subjectivity in the medical decision, one cannot say that a mere difference in medical opinion alone makes another physician's opinion false. The Government's expert witness in *AseraCare* admitted as much when he reached the opposite conclusion of *AseraCare*'s doctor but could not say this meant that the other doctor's opinion was wrong.

Respecting the deference shown to medical professionals in the statute is especially important in the hospice setting. *Care Alternatives* relied on both *Polukoff* and *Paulus* as examples of when a medical judgment can be considered false.<sup>221</sup> Although both cases do exemplify when a medical judgment may be deemed false, it is equally important to appreciate the

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220. See Christopher J. Donovan, Lisa M. Noller & Lori A. Rubin, *AseraCare FCA Ruling Is A Boon For Health Providers*, FOLEY & LARDNER LLP (Jan. 31, 2020), <https://www.foley.com/en/insights/publications/2020/01/aseracare-fca-ruling-boon-for-health-providers>.

221. *Care Alternatives*, 952 F.3d 89, 97-98 (3d Cir. 2020).

difference in type of medical opinions questioned in *Polukoff* and *Paulus* versus *AseraCare* and *Care Alternatives*.

*AseraCare* and *Care Alternatives* questioned physicians' clinical judgments of terminal illness. As previously discussed, these judgments are, medically speaking, incredibly subjective judgments that medical professionals are required to make to determine hospice eligibility. When no other evidence is presented as to the falsity of a physician's clinical judgment, juries are essentially asked to perform an after-the-fact review to determine which expert-opinion testimony and medical theory is more persuasive. Ideally, a jury would weigh all of the same factors medical professionals are asked to weigh and somehow determine from those factors, without a medical degree, which expert was correct; or at a minimum, whether the plaintiff's expert-testimony was persuasive enough that the jury believed the defendant's clinical judgment was false.

Alternatively, *Polukoff* and *Paulus* required juries to make a much less medically intensive judgment. In both cases, the jury had to decide on an underlying objective fact that did not require jurors to have a medical degree to understand. In *Paulus*, the jury needed to decide whether the blockage that the cardiologist reported on his reports was actually present on the angiogram. Essentially, the question was whether the doctor lied and misrepresented what he saw. In *Polukoff*, the question was whether the doctor's patients had the pre-existing conditions to justify reimbursement for their surgeries, or whether the doctor lied about the underlying reason for the procedure and created punctures in patients' hearts to justify reimbursement. In the end, both the *Polukoff* and *Paulus* juries considered whether the doctor lied or misrepresented facts, not which doctors' medical theories made more sense to them from a layman's perspective.

Both *Polukoff* and *Paulus* are examples of when a doctor's clinical judgment is false for the purposes of the FCA. However, both also represent cases that involved underlying facts and circumstances that a jury of laymen can decide without needing medical educations. Conversely, the jurors in *AseraCare* and *Care Alternatives* were asked to perform more complex and medically intensive analyses than the previous *Polukoff* and *Paulus* jurors. Due to the number of factors a physician is required to consider under the MHB guidelines, and the overall subjectivity of projecting an individual's projected lifespan generally, juries are simply incapable of concluding, as a matter of law, that a clinical judgment of terminal illness is false, without any other evidence to rely on besides contradicting expert testimony.

*D. Stricter Scrutiny of Medical Professionals Should be Accomplished  
Through Congress, Not Courts*

If the system needs a tougher “check” on doctors in the hospice setting, the place to look is Congress, who wrote the statutes in a way that granted the doctors a large degree of deference. It is simply not the courts’ job to re-write the law to require stricter scrutiny of doctors’ clinical judgments of terminal illness as the courts see fit. The plain language of the MHB regulations clearly conveys that Congress has an appreciation for the variety of subjective factors that should go into a physician’s clinical judgment, as well as an appreciation for the general difficulty in predicting how long a sick or elderly person is likely to live.

The law is written in a way that generally insulates physicians’ clinical judgments of terminal illness from scrutiny, but does not entirely insulate the judgments from examination. The regulations still set forth a variety of requirements that a hospice provider must meet in order to be reimbursed under Medicare. If a hospice provider or its medical professionals fail to meet the necessary requirements and wrongfully certify compliance, then those professionals can still be liable for their actions. Also, hospice providers may be held liable if they did not genuinely hold a belief that a patient was terminally ill or held a belief based on medical factors that were untrue. Under all of these circumstances, all that is required of plaintiffs is to show that their beliefs are evidenced by some underlying objective facts that demonstrate their belief.

In doing so, two things are accomplished: (1) medical professionals are protected against lawsuits in scenarios where reasonable differences in medical opinions exist; and (2) juries are not asked to make medical judgments they are incapable of making due to their lack of medical education. By requiring some underlying objective facts to demonstrate how a medical judgment was wrong, juries make rulings on facts that have medical implications, instead of making purely medical judgments.

#### V. CONCLUSION

Overall, *AseraCare*, *Care Alternatives*, and previous cases highlight a growing tension regarding how exactly plaintiffs are supposed to demonstrate the falsity element of the FCA in the context of the hospice setting. More specifically, does the plain language of the FCA and MHB statutes and regulations require more than simply dueling expert testimony to create a triable issue of fact for a jury? *Care Alternatives* certainly suggests the answer to that question is a straightforward no. However, although *Care Alternatives* characterizes the *AseraCare* holding as providing an inappropriate “bright-line rule” based on

objective falsity, in reality the *AseraCare* holding does nothing of that sort and is actually the more appropriate standard for courts to follow. Moving forward, courts should follow *AseraCare* and require more than mere dueling expert opinions to demonstrate falsity.

First, *AseraCare* does not create a bright-line rule that the *Care Alternatives* court claims it does. In fact, *AseraCare* implicitly considered legal falsity as well as factual falsity in the premise of its analysis and provides multiple examples of how a physician's clinical judgment can be proved false. Secondly, based on the plain language of the statutes and regulations governing end-of-life treatment, the law purposely grants a large amount of deference to physicians' clinical judgments of terminal illness because of the comparatively highly subjective nature of the judgment.

The objective falsity standard adopted in *AseraCare* (1) covers both factual and legal falsity, (2) does not create a bright-line rule, and (3) is the more appropriate reading of the statute based on Congress' desire to grant flexibility to physicians making judgments. This is not to say that a physician's clinical judgment should never be under scrutiny or submitted to a jury. Rather, to create a triable issue of fact regarding falsity of a clinical judgment, a plaintiff must evidence underlying facts that support the inference that the physician did not honestly hold the clinical judgment he or she made. Alternatively, the plaintiff can evidence facts that show the clinical judgment was inappropriately made because the physician did not meet or perform one of the other explicit requirements necessary under statute to make an appropriate clinical judgment. If individuals are not satisfied with the current standard, then Congress should act to tighten the standards and requirements of physicians in the hospice setting. Under no circumstance, however, is it appropriate for the courts to go beyond the requirements of the regulations and more strictly scrutinize medical professionals' clinical judgments simply because the court believes it to be better policy. Moving forward, courts should follow the *AseraCare* ruling when determining whether a physician's clinical judgment was false within the hospice setting.