

3-10-2021

## Hospice Care's Adventures in Fraudland: "Battle of the Experts" & Proving Falsity Under the False Claims Act

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### Recommended Citation

Elizabeth A. Caruso, Comment, *Hospice Care's Adventures in Fraudland: "Battle of the Experts" & Proving Falsity Under the False Claims Act*, 62 B.C. L. REV. E. SUPP. II.-21 (2021), <http://lawdigitalcommons.bc.edu/bclr/vol62/iss9/4/>.

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# HOSPICE CARE’S ADVENTURES IN FRAUDLAND: “BATTLE OF THE EXPERTS” & PROVING FALSITY UNDER THE FALSE CLAIMS ACT

**Abstract:** In 2020, in *United States ex rel. Druding v. Care Alternatives*, the Third Circuit held that medical expert testimony alone is enough to demonstrate that a clinical judgment certifying a patient for hospice care is false. In doing so, the court rejected the objective falsehood standard, a fact-based inquiry that requires more than a showing of a “reasonable disagreement” between medical experts to prove a claim is false. The holding has lasting implications for physician liability and allows questionable hospice care claims to flood the judiciary whenever a minor dispute over a patient’s life expectancy occurs. This Comment argues that the Third Circuit’s rejection of the objective falsehood standard does not align with either Supreme Court precedent or with the Centers for Medicare & Medicaid’s intent for the Medicare Hospice Benefit. Furthermore, this Comment asserts that the Supreme Court missed an opportunity to resolve the circuit split when it denied Care Alternatives’ petition for writ of certiorari in February 2021.

## INTRODUCTION

Congress meant for the False Claims Act (FCA) to encompass any attempt to defraud the government.<sup>1</sup> Since the mid-1980s, however, the FCA has become a dominant force against healthcare fraud.<sup>2</sup> Following Congress’s en-

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<sup>1</sup> See False Claims Act, 31 U.S.C. §§ 3729–3733 (describing ways the FCA may subject an individual to liability, how to bring an FCA suit, and how to determine plaintiff awards based on whether the government intervenes in a case or not); see also *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (noting that Congress intends the FCA to “reach all types of fraud” and is “broadly phrased”); Jonathan Lester, *The Winner Takes It All, but Who Gets to Play? The False Claims Act’s First to File Rule and Jurisdiction*, 61 B.C. L. REV. E. SUPP. II-410, II-414 to -15 (2020), <http://lawdigitalcommons.bc.edu/bclr/vol61/iss9/36/> [<https://perma.cc/HH62-ZU8F>] (describing how the FCA, through its amendments, progressed into a “powerful fraud-fighting tool[]” following its passage during the Civil War). See generally Press Release, U.S. Dep’t of Just., Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), <https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020> [<https://perma.cc/Y332-WJUA>] (giving examples of FCA enforcement, showing that, in 2020, the Department of Justice (DOJ) recovered false claim money in several areas, such as healthcare, goods and services, and education).

<sup>2</sup> See S. REP. NO. 99-345, at 2 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5267 (noting that the Department for Health and Human Services (HHS) significantly increased the number of fraud cases brought for prosecution between 1983 and 1986); see also Press Release, U.S. Dep’t of Just., *supra* note 1 (noting that the DOJ recovered more than \$1.8 billion in settlements and judgments from

actment of the Medicare Hospice Benefit (MHB) in 1983, both the number of Americans electing hospice care services and the number of Medicare-certified hospice providers significantly increased.<sup>3</sup> This rise in hospice elections and certified hospice providers has made the hospice care industry a prime target for the FCA.<sup>4</sup>

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the healthcare industry in fiscal year 2020). *See generally* Lester, *supra* note 1, at II.-414 to -15 (discussing how the FCA's amendments during the 1980s led to the FCA's use as a major enforcement mechanism against healthcare fraud and that the recoveries often come from many types of healthcare entities within the industry). Fraud within the healthcare system can take many forms and occurs when an entity intentionally fabricates the extent of a patient's healthcare service to the government, with the intent of receiving a greater payout. *See Health Care Fraud and Abuse*, JOHNS HOPKINS HEALTHCARE LLC, [https://www.hopkinsmedicine.org/johns\\_hopkins\\_healthcare/providers\\_physicians/health\\_care\\_fraud\\_and\\_abuse/](https://www.hopkinsmedicine.org/johns_hopkins_healthcare/providers_physicians/health_care_fraud_and_abuse/) [<https://perma.cc/T6H9-57RD>] (defining healthcare fraud and abuse). Examples of healthcare fraud can include, among others, billing for services that never occurred, billing for services that an entity knows are not medically needed, and incorrectly coding a medical service on a reimbursement claim in an attempt to receive a greater financial recovery for it—commonly known as “up-coding.” *See id.* (providing examples of how healthcare fraud occurs).

<sup>3</sup> *See* Mark T. Hughes & Thomas J. Smith, *The Growth of Palliative Care in the United States*, 35 ANN. REV. PUB. HEALTH 459, 460 (2014) (noting that the rise in palliative care over the years has coincided with an increased population of Americans 65 years and older). Hospice care incorporates a range of both conventional and holistic treatments into a patient's care plan that are intended to ease suffering caused from a terminal illness. *See* Medicare Program, 85 Fed. Reg. 47,070, 47,070 (Aug. 4, 2020) (to be codified at 42 C.F.R. pt. 418) (explaining the aims of hospice care). In 2018, for example, 1.55 million Medicare beneficiaries elected hospice care. NAT'L HOSPICE & PALLIATIVE CARE ORG., NHPCO FACTS AND FIGURES: HOSPICE CARE IN AMERICA 6 (2020), <https://www.nhpc.org/wp-content/uploads/NHPCO-Facts-Figures-2020-edition.pdf> [<https://perma.cc/SAP9-37P4>]. There were also 4,639 Medicare-certified hospice providers in 2018, a 13.4% increase since 2014. *Id.* at 20. For-profit Medicare hospice providers made up 69.7% of all hospice providers in the United States, an increase of 24.7% since 2014. *Id.* at 21. Only 3.4% of Medicare hospice providers were government-owned. *Id.* Between 2013 and 2018, newly certified hospice providers—those certified for only two to five years—increased the most in the industry. *Id.* at 23. In 2018, hospice providers that were certified for more than ten years comprised 55% of the industry. *Id.*

<sup>4</sup> *See* United States *ex rel.* Druding v. Care Alternatives (*Druding II*), 952 F.3d 89, 92 (3d Cir. 2020) (litigating FCA charges for alleged Medicare reimbursement fraud originating from false hospice care claims); *see also* United States *ex rel.* Lemon v. Nurses to Go, Inc., 924 F.3d 155, 157–58 (5th Cir. 2019) (litigating fraudulent hospice care claims); United States v. AseraCare, Inc., 938 F.3d 1278, 1281 (11th Cir. 2019) (same); United States v. Heartland Hospice, Inc., 386 F. Supp. 3d 884, 889 (N.D. Ohio 2019) (same); United States *ex rel.* Geschrey v. Generations Healthcare, LLC, 922 F. Supp. 2d 695, 701 (N.D. Ill. 2012) (same); United States *ex rel.* Wall v. Vista Hospice Care, Inc., 778 F. Supp. 2d 709, 713 (N.D. Tex. 2011) (same); *see, e.g.*, Press Release, U.S. Dep't of Just., New York Hospice Provider Settles Civil Healthcare Fraud Allegations (Aug. 19, 2020), <https://www.justice.gov/usao-edny/pr/new-york-hospice-provider-settles-civil-healthcare-fraud-allegations> [<https://perma.cc/6GLU-GWXM>] (noting that a NY hospice provider intentionally made false claims for hospice care treatment and agreed to pay a total of \$5.2 million in settlement). *See generally* Ashleigh Garrison, *Medicare's Most Indefensible Fraud Hotspot: Hospice Care*, CNBC (Aug. 2, 2018), <https://www.cnbc.com/2018/08/02/medicares-most-despicable-indefensible-fraud-hotspot-hospice-care.html> [<https://perma.cc/U6Y4-NWZH>] (explaining that hospice care centers engaging in fraudulent practices is an increasing problem); Douglas Frantz, *Hospice Boom Is Giving Rise to New Fraud*, N.Y. TIMES (May 10, 1998), <https://www.nytimes.com/1998/05/10/us/hospice-boom-is-giving-rise-to-newfraud.html?searchResultPosition=1> [<https://perma.cc/T97P-S7PC>] (describing how hospice care providers commit healthcare fraud by misrepresenting an individual's illness to qualify for hospice care).

Patients eligible for Medicare Part A qualify for the MHB and may elect to enter hospice care with a Medicare-certified hospice provider.<sup>5</sup> To receive hospice care services, a physician first certifies that a patient is terminally ill, meaning that—without curative treatment—he or she has a life expectancy of six months or less.<sup>6</sup> The Centers for Medicare & Medicaid Services (CMS) values physicians’ clinical judgments and has purposefully chosen not to provide rigidly defined hospice eligibility criteria.<sup>7</sup> Therefore, a hospice certification hinges on the certifying physician’s clinical judgment.<sup>8</sup>

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<sup>5</sup> See Medicare Program; Hospice Care, 48 Fed. Reg. 56,008, 56,008 (Dec. 16, 1983) (to be codified at 42 C.F.R. pts. 400, 405, 408, 409, 418, 420, 421, 489) (describing the Medicare Hospice Benefit (MHB), which includes hospice care as a covered service under federal health insurance, Medicare Part A). See generally *What’s Medicare?*, MEDICARE.GOV, <https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare> [<https://perma.cc/LXK3-TPQT>] (noting that the federal health insurance program, called Medicare, is available for individuals age 65 or older). Medicare Part A is for hospital insurance, which covers hospice care. *Id.* Hospice centers must meet federal requirements, including Centers for Medicare & Medicaid Services (CMS) certification and approval to participate in Medicare. *Hospices*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospices> [<https://perma.cc/2XWS-HF68>]. For approval to participate in Medicare, a hospice center must meet, among other things, requirements pertaining to maintaining “quality of care” and “infection control,” offering certain primary services, and hiring appropriate licensed professionals. See 42 C.F.R. § 418.50–.116 (2020) (listing hospice provider requirements to participate in the MHB). A hospice provider can be its own separate facility, part of a hospital or nursing home, or can take place in a patient’s home. *Hospice Care*, MEDICARE.GOV, <https://www.medicare.gov/coverage/hospice-care> [<https://perma.cc/W59R-VX2J>].

<sup>6</sup> See 42 U.S.C. § 1395x(dd)(3)(A) (defining “terminally ill” and describing certification requirements); 42 C.F.R. § 418.3 (defining “terminally ill”).

<sup>7</sup> See *AseraCare*, 938 F.3d at 1301 (noting that, although CMS has contemplated changing hospice eligibility criteria, it has chosen not to amend the current requirements (citing Medicare and Medicaid Programs; Hospice Conditions of Participation, 73 Fed. Reg. 32,008, 32,138 (June 5, 2008) (to be codified at 42 C.F.R. pt. 418))). Comments from CMS’s rulemaking also indicated that “well-founded clinical judgments should be granted deference.” *Id.* at 1295. A hospice certification relies on a physician’s or medical director’s clinical judgment and must include, at a minimum, (1) a diagnosis of a terminal illness, (2) clinical information that buttresses a terminally ill prognosis, and (3) a certifying physician’s explanation describing why the clinical information provided bolsters the prognosis. 42 C.F.R. § 418.22(b); see also *AseraCare*, 938 F.3d at 1295 (explaining that CMS did not use the term “criteria” when defining hospice certification requirements because it did not want to suggest that a patient’s illness must satisfy specific “clinical benchmarks” in order for a physician to certify a patient as terminally ill (citing Medicare and Medicaid Programs; Hospice Conditions of Participation, 73 Fed. Reg. at 32,138)). CMS also acknowledged that a certifying physician is best situated to make a terminally ill prognosis based on their knowledge and experience. *Id.* (citing Medicare Program, 78 Fed. Reg. 48,234, 48,247 (Aug. 7, 2013) (to be codified at 42 C.F.R. pt. 418)). See generally *AseraCare*, 938 F.3d at 1283 (explaining that CMS is run “locally” using Medicare Administrative Contractors that are responsible for managing claims and approving or denying payments); *About CMS*, CMS.GOV, <https://www.cms.gov/About-CMS/About-CMS> [<https://perma.cc/XGT8-AMXD>] (noting that CMS is part of HHS).

<sup>8</sup> See Medicare Program, 78 Fed. Reg. at 48,247 (discussing that a certifying physician must perform a thorough review of a patient’s clinical history before certifying him or her for hospice); see also *supra* note 7 and accompanying text (describing the certifying physician’s role in the hospice certification process).

In 2019, the Eleventh Circuit, in *United States v. AseraCare, Inc.*, considered whether dueling medical expert testimony regarding a patient's terminally ill prognosis is enough to demonstrate falsity under the FCA.<sup>9</sup> The court held that reasonably conflicting opinions, without additional factual evidence, is insufficient to create a triable issue of fact.<sup>10</sup> It explained that, as a subjective medical opinion, a clinical judgment is only false if it is "objectively false."<sup>11</sup> The objective falsehood standard requires a plaintiff to show that a physician certified a patient for hospice relying on an inadequately made clinical judgment.<sup>12</sup> In 2020, however, the Third Circuit, in *United States ex rel. Druding v. Care Alternatives (Druding II)*, faced a similar question and concluded that contesting medical expert testimony is enough to survive summary judgment.<sup>13</sup> In doing so, the court split from the Eleventh Circuit and rejected the objective falsehood standard.<sup>14</sup>

Part I of this Comment provides an overview of hospice certification requirements, the FCA, the objective falsehood standard, and the Third Circuit's holding in *Druding II*.<sup>15</sup> Part II examines the Supreme Court's ruling in *Universal Health Services, Inc. v. United States ex rel. Escobar* and its influence over circuit courts' application of the objective falsehood standard.<sup>16</sup> Lastly, Part III argues that the objective falsehood standard is appropriate to use for

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<sup>9</sup> See *AseraCare*, 938 F.3d at 1293 (noting that the statute's wording expresses that a clinical judgment used to certify a patient for hospice care "lies at the center of the eligibility inquiry").

<sup>10</sup> *Id.* at 1297. In *AseraCare*, the court concluded that the government needed to show more than a medical expert's dissent of a patient's terminally ill prognosis to demonstrate that a clinical judgment regarding hospice eligibility is false. *Id.*

<sup>11</sup> See *id.* at 1297, 1302 (discussing how to determine whether a clinical judgment is "objectively false," which requires additional factual evidence outside of a medical expert's opinion). Throughout the *AseraCare* case, the Eleventh Circuit uses terminology, such as "objective falsehood" and "objectively false." See *id.* at 1290, 1300, 1302. But see *United States ex rel. Druding v. Care Alternatives (Druding II)*, 952 F.3d 89, 90 (3d Cir. 2020) (noting that, for a successful FCA claim, plaintiffs do not need to prove a clinical judgment is "objectively false").

<sup>12</sup> *AseraCare*, 938 F.3d at 1297. Specifically, a claim would be false under the objective falsehood standard if a plaintiff could show "facts and circumstances" that demonstrate that a physician certified a patient for hospice relying on a clinical judgment that was not "properly formed and sincerely held." *Id.* at 1281, 1297. If a physician did not perform a comprehensive review of a patient's medical records before certifying, or did not believe a patient was eligible for hospice but certified him or her regardless, this could demonstrate that a physician's clinical judgment was not "properly formed." *Id.* at 1297.

<sup>13</sup> *Druding II*, 952 F.3d at 95. The Third Circuit concluded that medical expert testimony questioning a patient's hospice eligibility creates a triable issue of fact as to the falsity of a hospice certification claim. *Id.*

<sup>14</sup> *Id.* The *Druding II* court stated that the objective falsehood standard is incompatible with the FCA's interpretation of "false" and does not follow the Third Circuit's own falsity analysis as applied to the FCA. *Id.*

<sup>15</sup> See *infra* notes 18–54 and accompanying text.

<sup>16</sup> See *infra* notes 55–86 and accompanying text.

hospice certification claims and discusses why it properly aligns with Supreme Court precedent and CMS's intent for the MHB.<sup>17</sup>

### I. DOWN THE RABBIT HOLE: THE FCA AND HOSPICE CERTIFICATION, THE OBJECTIVE FALSEHOOD STANDARD, AND THE THIRD CIRCUIT'S HOLDING<sup>18</sup>

The False Claims Act (FCA) empowers the government to take action and recoup financial losses from those endeavoring to defraud the federal government.<sup>19</sup> Through its amendments, the FCA has advanced into a major legal instrument that the government uses to curtail Medicare reimbursement fraud.<sup>20</sup> Section A of this Part provides an overview of the MHB and how the FCA combats healthcare fraud.<sup>21</sup> Section B introduces the elements of an FCA claim, discusses what makes a claim “false,” and explains the objective falsehood standard.<sup>22</sup> Lastly, Section C discusses the Third Circuit's rejection of the objective falsehood standard.<sup>23</sup>

#### A. Hospice Care, the Medicare Hospice Benefit, and the FCA

Hospice care is an “interdisciplinary” palliative care program for terminally ill patients.<sup>24</sup> In 1983, Congress passed the MHB, giving Medicare bene-

<sup>17</sup> See *infra* notes 87–119 and accompanying text.

<sup>18</sup> Cf. LEWIS CARROLL, ALICE'S ADVENTURES IN WONDERLAND 1–14 (VolumeOne Publishing ed., 1998) (1865). The first chapter of the book is entitled “Down the Rabbit Hole” where Alice finds herself chasing after the White Rabbit straight down into his rabbit hole, not contemplating how she might find her way back out. *Id.* at 3.

<sup>19</sup> 31 U.S.C. §§ 3729–3733; see S. REP. NO. 99-345, at 1 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5267 (expressing that the aim of the False Claims Act was to provide the government with a way to recover losses caused by fraud against the government); see also *United States v. Bornstein*, 423 U.S. 303, 309 (1976) (noting that the original purpose of the FCA, enacted in 1863, was to thwart Civil War contractors' efforts to defraud the government).

<sup>20</sup> See Press Release, U.S. Dep't of Just., *supra* note 1 (noting that the DOJ recovered more than \$1.8 billion in healthcare fraud); see also S. REP. NO. 99-345, at 2 (stating that HHS raised triple the number of healthcare fraud cases for prosecution between 1983 and 1986).

<sup>21</sup> See *infra* notes 24–34 and accompanying text.

<sup>22</sup> See *infra* notes 35–43 and accompanying text.

<sup>23</sup> See *infra* notes 44–54 and accompanying text.

<sup>24</sup> See 42 C.F.R. § 418.3 (2020) (defining hospice care). A patient is terminally ill if the medical prognosis determines a life expectancy of six months or less without any curative medical intervention. *Id.* Hospice care includes a set of “interdisciplinary” services that a patient's individualized care program sets forth. *Id.* A hospice “interdisciplinary” team can be made up of a variety of health professionals from different specialties such as physicians, social workers, spiritual counselors, and therapists. *Id.* § 418.56. Hospice care shifts the types of medical services provided from curative care to palliative care, whereby the goal is to help a terminally ill patient feel physically and emotionally at ease in the final months of their life. Medicare Program; Hospice Care, 48 Fed. Reg. 56,008, 56,008 (Dec. 16, 1983) (to be codified at 42 C.F.R. pts. 400, 405, 408, 409, 418, 420, 421, 489). Palliative care focuses on the patient and family and aims to minimize the suffering a terminal illness may cause. 42 C.F.R. § 418.3. Curative care, in contrast, is care that is meant to cure a medical condition,

ficiaries the right to elect hospice care.<sup>25</sup> Patients qualify for the MHB if they are eligible for Medicare Part A and have a terminally ill prognosis.<sup>26</sup> A physician and medical director initially certify a patient for a ninety-day hospice care period and may recertify the patient for additional ninety-day or sixty-day periods.<sup>27</sup> The physician's clinical judgment serves as the basis for each certification.<sup>28</sup> The certification must "accompany" a patient's medical documentation, along with a physician's personal written report that "supports" the terminally ill prognosis.<sup>29</sup>

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meaning a patient can recover from their illness. Brooker Wheeler, *The ABC's of Curative, Palliative and Hospice Care*, WHEELER HEALTH (Dec. 18, 2018), <https://www.hopehealthco.org/blog/the-abcs-of-curative-palliative-and-hospice-care/> [<https://perma.cc/86HR-EEK7>]. An individual waives curative care once they elect hospice care under Medicare. See 42 C.F.R. § 418.24(b)(2) (noting that selecting hospice care constitutes a patient's agreement to receive palliative, as opposed to curative, care).

<sup>25</sup> 42 U.S.C. § 1395y(a)(1)(C) (noting that Medicare will not pay for palliative care services received in hospice that are not "reasonable and necessary"); see also Medicare Program, 78 Fed. Reg. 48,234, 48,236 (Aug. 7, 2013) (to be codified at 42 C.F.R. pt. 418) (stating that the MHB requires that services provided in hospice be "reasonable and necessary"); see *infra* note 43 and accompanying text (defining what "reasonable and necessary" means for purposes of Medicare reimbursement).

<sup>26</sup> 42 C.F.R. § 418.20; see *supra* note 5 and accompanying text (discussing Medicare eligibility and what Medicare Part A is).

<sup>27</sup> 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.21. An individual may elect to receive hospice care during multiple periods, the first being an initial 90-day period. 42 C.F.R. § 418.21. The hospice medical director and the patient's attending physician initially "certify in writing" prior to the start of the period that the patient is eligible for hospice. 42 U.S.C. § 1395f(a)(7). Following the initial ninety-day period, only one physician is required to recertify the patient for a subsequent ninety-day or sixty-day period. 42 C.F.R. § 418.21, 22(a)(5). There is no limit to the number of permitted sixty-day certification periods. *Id.* § 418.21. When a patient nears their third recertification, a hospice physician or nurse practitioner must meet with the patient in person and obtain additional clinical information that "supports" hospice care recertification. *Id.* § 418.22(a)(4). Every recertification thereafter mandates face-to-face meetings. *Id.* An "attending physician" is a doctor of medicine or osteopathy, nurse practitioner, or physician assistant employed with a hospice provider whom the patient identifies as being most familiar with their illness and can make an effective treatment plan for the patient's care while in hospice. See *id.* § 418.3 (defining "attending physician"). The MHB acknowledges that a patient's health may get better during his or her stay in hospice, so it permits patients to leave hospice and resume other medical treatment. *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1282–83 (11th Cir. 2019) (citing Medicare Program, 75 Fed. Reg. 70,372, 70,448 (Nov. 17, 2010) (to be codified at 42 C.F.R. pts. 409, 418, 424, 484, 489)). Even if a patient does exhibit signs of temporary improvement, a physician may still recertify the patient for hospice care if the patient's health is expected to worsen. 42 C.F.R. § 418.22(b); Medicare Program, 75 Fed. Reg. at 70,448.

<sup>28</sup> See *AseraCare*, 938 F.3d at 1295 (11th Cir. 2019) (noting that CMS acknowledges that determining a terminally ill patient's life expectancy is not an "exact science," however, a hospice certification still relies on a certifying physician's clinical judgment to determine if a patient is eligible).

<sup>29</sup> 42 U.S.C. § 1395f(a)(7)(A); see also 42 C.F.R. § 418.22(b)(1)–(2) (noting that medical documents that "support the medical prognosis must accompany the certification"); Medicare Program, 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014) (to be codified at 42 C.F.R. pts. 405, 418). In determining hospice eligibility, the medical director, at a minimum, must review the records that buttress the terminally ill diagnosis, along with any other medical issues or disorders that may be associated with the terminal illness. See 42 C.F.R. § 418.25(b)(1)–(3) (discussing requirements for admitting a patient to hospice care); see also *supra* notes 7, 27 and accompanying text (discussing certification and eligibility requirements).

Since the MHB’s passage, FCA cases alleging hospice fraud have risen.<sup>30</sup> Most often, these cases are initially *qui tam* actions.<sup>31</sup> Individuals—known as relators—file *qui tam* complaints *in camera* and the court then seals it for no less than sixty days.<sup>32</sup> During that time, the DOJ will decide whether to intervene.<sup>33</sup> If the DOJ declines to prosecute, the relator(s) may continue with the suit and potentially receive a portion of the recovery.<sup>34</sup>

### B. What Makes a Claim “False” Under the FCA?

A hospice provider can be liable for false claims under an implied false certification theory of liability.<sup>35</sup> Liability attaches if the hospice center intentionally submits or causes submission of a fabricated Medicare reimbursement claim for the purpose of receiving payment.<sup>36</sup> A hospice provider’s reimbursement claims may be false if the claims exclude or distort material information.<sup>37</sup> Therefore, the four *prima facie* elements of an FCA suit include: (1) falsity, (2) causation, (3) scienter (knowledge), and (4) materiality.<sup>38</sup>

<sup>30</sup> See *supra* note 4 and accompanying text (noting recent hospice care fraud cases).

<sup>31</sup> See Lester, *supra* note 1, at II.-411 (describing how an individual may bring an FCA claim on behalf of the U.S. government through a *qui tam* action); see, e.g., Press Release, U.S. Dep’t of Just., *supra* note 1 (noting that relators filed 672 *qui tam* suits in 2020 and the DOJ recovered over \$1.6 billion in *qui tam* settlements this past year). Compare United States *ex rel.* Druding v. Care Alternatives (*Druding II*), 952 F.3d 89, 92 (3d Cir. 2020) (plaintiffs were former employees of hospice care center and the government chose not to join the case seven years after relators initially filed the complaint), with *AseraCare*, 938 F.3d at 1282 (plaintiffs were former employees of hospice care center and the government intervened).

<sup>32</sup> 31 U.S.C. § 3730(b)(1)–(2). While the complaint is under seal, the court may not order service on the defendant. *Id.* § 3730(b)(2).

<sup>33</sup> *Id.* § 3730(b)(1)–(4). During the sixty-day period, or any extension periods, the government must decide whether or not to take on the case. *Id.* § 3730(b)(4)(A)–(B).

<sup>34</sup> *Id.* § 3730(d)(2). The court will determine the amount to collect for civil penalties and damages, but it cannot be less than 25% or more than 30% of the amount recovered. *Id.* If the relator’s claim is successful, they are also entitled to recover any expenses the court deems “reasonable,” including attorney expenses. *Id.*

<sup>35</sup> See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016) (defining the implied false certification theory). The implied false certification theory states that a claim may be false when the claim wrongly implies adherence to any material statutes and regulations that would prompt government payment. *Id.*

<sup>36</sup> 31 U.S.C. § 3729(a)(1)(A). Specifically, a person is liable under the FCA if that person “knowingly” submits or allows submission of a “false or fraudulent” claim for the purposes of obtaining “payment or approval” from the government. *Id.* The term “knowingly” (or “knowingly”) means an individual who has “actual knowledge,” or “acts in deliberate ignorance,” or demonstrates “reckless disregard” concerning the veracity of the particulars. *Id.* § 3729(b)(1)(A)(i)–(iii). The FCA does not require evidence showing “specific intent to defraud” the government. *Id.* § 3729(b)(1)(B).

<sup>37</sup> *Id.* § 3729(a)(1)(B). Under the FCA, the term “material” means anything included in the submitted claim that may be a critical factor in persuading the government to approve or deny the claim for payment. *Id.* § 3729(b)(4).

<sup>38</sup> See *id.* § 3729(a) (defining what makes a claim “false or fraudulent”); see also United States *ex rel.* Druding v. Care Alternatives (*Druding II*), 952 F.3d 89, 94 (3d Cir. 2020) (noting that plaintiff must prove the four *prima facie* elements of an FCA claim to survive summary judgment (citing Unit-



Courts generally recognize two types of false reimbursement claims: *factually false* and *legally false* claims.<sup>39</sup> A factually false claim conveys inaccurate facts.<sup>40</sup> A legally false claim occurs when a claimant (1) wrongly certifies—either explicitly or impliedly—adherence with statutes or regulations that are essential for payment, or (2) deliberately excludes noncompliant information that is material and known to the person or entity submitting the claim.<sup>41</sup> Some courts have adopted the objective falsehood standard, requiring plaintiffs to provide additional objective evidence to demonstrate a claim is false.<sup>42</sup> As an example, circuit courts have inconsistently applied this falsity standard in medical necessity and hospice certification claims.<sup>43</sup>

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ed States *ex rel.* Petratos v. Genentech, Inc., 855 F.3d 481, 487 (3d Cir. 2017)). Unlike the terms “knowingly” or “material,” Congress never defined the terms “false” or “fraudulent,” and the Supreme Court did not speak to the issue until 2016 in *Universal Health Services, Inc. v. United States ex rel. Escobar*. See 136 S. Ct. 1989, 1999 (2016) (holding that the common-law meanings of “false” and “fraudulent” apply to the FCA). “False” means something that a person purposefully crafted to be untrue with the intent to deceive others. See *False*, BLACK’S LAW DICTIONARY (11th ed. 2019). “Fraudulent” is a term that also embodies the common-law meaning of “fraud.” See *Escobar*, 136 S. Ct. at 1999 (noting that when Congress wrote the FCA, it did not define “false” or “fraudulent,” therefore, the terms retain their common-law meaning). Throughout this Comment, the term “false” is also used to encompass the term “false or fraudulent” in relation to the FCA’s phrasing.

<sup>39</sup> See *Druding II*, 952 F.3d at 96–97 (discussing the types of false claims); United States *ex rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011) (same).

<sup>40</sup> *Wilkins*, 659 F.3d at 305; see also United States *ex rel.* Polukoff v. St. Mark’s Hosp., 895 F.3d 730, 741 (10th Cir. 2018) (noting that to prove factual falsity, a plaintiff must demonstrate that a submitted claim contains inaccurate information).

<sup>41</sup> See *Polukoff*, 895 F.3d at 741 (explaining legal falsity and two types of theories that fall under legal falsity—express and implied legal falsity). An example of express legal falsity is a claim that affirmatively and falsely certifies that a hospice provider complied with a relevant legal requirement that is essential for payment. *Id.* An example of implied legal falsity is the actual submission of a false claim in which, by submitting the claim, the submitter wrongly implies that it should receive payment. *Id.* The question of whether the falsity analysis includes both factual and legal falsity has been a point of contention among courts. Compare *Druding II*, 952 F.3d at 97 (noting that an inquiry of falsity should include both factual and legal falsity), with *Druding v. Care Alternatives, Inc.* (*Druding I*), 346 F. Supp. 3d 669, 688 (D.N.J. 2018) (adopting the view that a plaintiff needs factual evidence to show a physician made a “knowingly false determination,” which *Druding II* criticized as only analyzing factual falsity). Legal falsity can include scenarios involving factual falsity. *Druding II*, 952 F.3d at 96–97.

<sup>42</sup> See United States v. AseraCare, Inc., 938 F.3d 1278, 1297 n.10 (11th Cir. 2019) (noting that district courts have held that for a claim to be false under the FCA, a plaintiff must show “objectively verifiable fact[s]” that are in conflict with the accounts made in a claim (quoting United States *ex rel.* Wall v. Vista Hospice Care, Inc., 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011))); see also United States *ex rel.* Yannacopolous v. Gen. Dynamics, 652 F.3d 818, 836 (7th Cir. 2011) (holding that a statement can only be false under the FCA if the statement “represents an objective falsehood”); United States *ex rel.* Morton v. A Plus Benefits, Inc., 139 F. App’x 980, 982 (10th Cir. 2005) (holding that the FCA “requires proof of an objective falsehood” (citing United States *ex rel.* Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999))).

<sup>43</sup> Compare *Druding II*, 952 F.3d at 95 (rejecting the objective falsehood standard), and *Winter ex rel.* United States v. Garden Reg’l Hosp. & Med. Ctr., 953 F.3d 1108, 1113 (9th Cir. 2020) (same), and United States *ex rel.* Scott v. Ariz. Ctr. for Hematology & Oncology, PLC, No. CV-16-03703, WL 2059926, at \*12 (D. Ariz. 2020) (same), with *AseraCare*, 938 F.3d at 1297 (embracing the objec-

### C. The Third Circuit Rejects the Objective Falsehood Standard in the Context of Hospice Care Certifications

In 2020, in *United States ex rel. Druding v. Care Alternatives (Druding II)*, the Third Circuit addressed the issue of whether and when clinical judgments regarding hospice care certifications are false.<sup>44</sup> In 2018, in *Druding v. Care Alternatives, Inc. (Druding I)*, former employees of Care Alternatives hospice center brought a *qui tam* action in the District Court of New Jersey.<sup>45</sup> The relators alleged that Care Alternatives submitted false claims to the government for ineligible hospice care patients.<sup>46</sup> At trial, the parties presented competing medical expert testimony.<sup>47</sup> The relators' medical expert concluded that of the 603 hospice certification periods he reviewed, thirty-five percent did not justify a need for hospice.<sup>48</sup> Care Alternatives' medical expert, howev-

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ative falsehood standard). Although a certifying physician's or hospice medical director's clinical judgment controls hospice care certifications, CMS must deem a medical service "reasonable and necessary" to approve payment of medical necessity claims. See 42 U.S.C. § 1395y(a)(1)(A) (explaining that Medicare will not cover services used to diagnose or treat an illness or injury if that service is not "reasonable and necessary"). CMS, when determining whether a procedure is "reasonable and necessary," considers the following, *inter alia*: (1) whether the procedure is "safe and effective"; (2) whether the procedure is "experimental or investigational"; (3) whether the procedure is "appropriate" and performed based on accepted medical standards; and (4) whether the environment for the procedure meets a patient's "medical needs" and is equipped with qualified employees. See CTRS. FOR MEDICARE & MEDICAID SERVS., REVISED MEDICARE PROGRAM INTEGRITY MANUAL 13.5.4 (2019) (describing factors that are taken into account when considering whether to approve a medical necessity claim for reimbursement). Any palliative care given once a patient is in hospice must meet the reasonable and necessary standard for approval of payment. 42 U.S.C. § 1395y(a)(1)(C).

<sup>44</sup> 952 F.3d at 92. The main questions the Third Circuit addressed were (1) how to properly analyze falsity under the FCA in the context of a hospice certification claim, and (2) whether a medical expert's opinion challenging a certifying physician's terminally ill prognosis could demonstrate that a clinical judgement, and therefore, a hospice certification claim, is false. *Id.* at 92, 95.

<sup>45</sup> *Druding I*, 346 F. Supp. 3d at 671. Care Alternatives hired many types of employees, such as chaplains, social workers, physicians, and therapists. *Id.* at 673. These employees worked with independent physicians who acted in the capacity of hospice medical directors. *Id.* The employees and the independent physicians formed an "interdisciplinary" committee that met bimonthly to discuss current hospice patient care plans and any patients due for recertification. *Id.*

<sup>46</sup> *Id.* at 673. For example, one plaintiff alleged that a patient was not eligible for hospice because the patient walked on her own, engaged in conversation, and gained weight while in hospice care. *Id.* at 677. Another plaintiff alleged that Care Alternatives told her to indicate on the certification form that a patient could not converse with others, even though the patient was able to engage in conversation. *Id.* at 678. The patient also had schizophrenia, an illness that would have precluded hospice care eligibility, yet Care Alternatives admitted him anyway. *Id.* A third plaintiff, who was not a physician, testified that, although she believed 10% of patients at Care Alternatives were not hospice eligible, she had never reported any questionable certifications to Care Alternative's compliance department. *Id.* at 679. Other plaintiffs testified that Care Alternatives altered medical records to make patients appear eligible. *Id.* at 680.

<sup>47</sup> See *id.* at 681 (outlining medical expert testimony given for plaintiff and defendant).

<sup>48</sup> *Id.* The relators' medical expert, Dr. Jayes, explained that making a terminally ill prognosis depends on a physician's judgment and experience, as well as available medical sources. *Id.* When determining whether Care Alternatives' patients were hospice eligible, Dr. Jayes used guidelines from the National Hospice and Palliative Care Organization and other industry guidance documents that

er, concluded that a physician could have plausibly reached the opposite conclusion for each certification period the relator's expert deemed ineligible.<sup>49</sup> The district court followed Third Circuit precedent and concluded that "reasonable" variations in opinion between medical experts could not support a finding that a clinical judgment is false.<sup>50</sup> In granting summary judgment, the court used the objective falsehood standard and held that the relators' medical expert did not sufficiently show that the hospice claims were false.<sup>51</sup>

The relators appealed to the Third Circuit, which held that the objective falsehood standard was not appropriate to use.<sup>52</sup> The court split from the Eleventh Circuit, stating that the objective falsehood standard: (1) is incompatible with the common-law meaning of "false" under the FCA; (2) diverges from the circuit's own interpretations of the requirements for legal falsity; and (3) merges the elements of *falsity* and *knowledge* by requiring objective evidence to prove falsity.<sup>53</sup> The court concluded that an expert medical opinion can show a claim violates regulations that require support for a terminally ill prognosis and, therefore, is false.<sup>54</sup>

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hospice centers generally use to determine patient eligibility. *Id.* In reviewing forty-seven medical records, he concluded that twenty-six were eligible for hospice during all certification periods, whereas sixteen were eligible for only a part of their care. *Id.* In his testimony, Dr. Jayes also stated that a "reasonable physician" could have disagreed with his findings and that making a terminally ill prognosis is a challenging undertaking. *Id.* at 688.

<sup>49</sup> *Id.* at 681.

<sup>50</sup> *Id.* at 687–88. The court cited to a previous Third Circuit case, where the court stated that opinions and conclusive statements—including those that are "scientific"—in which "reasonable minds" may vary cannot be false. *Id.* at 687 (citing *United States ex rel. Hill v. Univ. of Med. & Dentistry of N.J.*, 448 F. App'x 314, 316 (3d Cir. 2011)). The court stated that the "ultimate issue" to determine was whether the physician certified a patient for hospice knowing that they were ineligible, not about whether the clinical judgment itself was right or wrong. *Id.* at 688.

<sup>51</sup> *See id.* at 688. (stating that "diverging opinions cannot create a genuine issue of material fact about the falsity of a physician's determinations that the patient meets hospice eligibility where, as here, there is no factual evidence that Defendant's certifying doctor was making a knowingly false determination"). This statement signals that varying medical expert opinions concerning a patient's hospice eligibility do not lend to the relevant issue, which is whether a physician certified a patient for hospice believing that the patient was not in fact eligible. *See id.* (discussing that the hospice eligibility inquiry is not about whether a clinical judgment is right or wrong).

<sup>52</sup> *United States ex rel. Druding v. Care Alternatives (Druding II)*, 952 F.3d 89, 94 (3d Cir. 2020) (stating that the Third Circuit had not yet accepted the objective falsehood standard or ever used it in any of its false claims cases). When discussing the conflation issue, the court noted that scienter is a more difficult element to satisfy under the FCA and would therefore prevent FCA liability over an ordinary disagreement between medical experts. *Id.* at 110.

<sup>53</sup> *See id.* at 95–98 (explaining the court's reasoning for rejecting the objective falsehood standard). The Third Circuit also stated that "objectivity" was appropriate to incorporate into the FCA, but aligned more with the *scienter* element, rather than the *falsity* element. *Id.* at 100.

<sup>54</sup> *Id.* at 97–98. The Third Circuit held that, under the FCA, falsity must include a legal falsity analysis, and therefore, the district court should not have narrowed its falsity analysis to factual falsity. *See id.* at 96–97 (relying on a Tenth Circuit case to make its assertion that the proper falsity analysis under the FCA includes legal falsity, which also can include factual falsity (citing *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018))); *see also supra* note 41 and ac-

## II. A MAD TEA-PARTY: FIVE CIRCUITS ATTEMPT TO SOLVE THE “FALSITY OF CLINICAL JUDGMENTS” RIDDLE AFTER THE SUPREME COURT ADDS A TWIST<sup>55</sup>

Congress never defined the words “false” or “fraudulent” when it passed the False Claims Act (FCA) in 1863.<sup>56</sup> Judicial interpretation defined these terms, resulting in a variety of falsity standards.<sup>57</sup> Over 153 years later, in *Universal Healthcare Services, Inc. v. United States ex rel. Escobar*, the Supreme Court clarified their meanings.<sup>58</sup> Section A of this Part discusses how the Supreme Court defined “false” and “fraudulent.”<sup>59</sup> Section B analyzes the Sixth and Tenth Circuits’ holdings that clinical judgments can be false and trigger FCA liability.<sup>60</sup> Section C explains the Eleventh Circuit’s adoption of the objective falsehood standard as applied to clinical judgments for hospice certification.<sup>61</sup> Lastly, Section D describes the Tenth Circuit’s most recent decision rejecting the objective falsehood standard in the context of medical necessity.<sup>62</sup>

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companying text (discussing factual and legal falsity). The MHB requires that a patient have a terminally illness and that that documentation supporting the prognosis accompany the certification. *See supra* notes 7, 27–29 and accompanying text (discussing hospice certification and eligibility requirements). The Third Circuit stated that under the legal falsity analysis, the relators needed to show that Care Alternatives did not satisfy the requirements under 42 C.F.R. § 418.22(b). *Druding II*, 952 F.3d at 97. Therefore, a challenging medical expert opinion could show evidence that the medical reports provided did not justify a terminally ill prognosis. *Id.* A lack of support for the prognosis demonstrates that the clinical judgment used to certify a patient for hospice care is false. *Id.* The court also cited to a Sixth Circuit case that relied on medical expert testimony to show that a cardiologist lied about the severity of arterial blockage in his patients’ clinical records. *See id.* at 98 (citing *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018)). In *United States v. Paulus*, the Sixth Circuit stated that opinions may trigger FCA liability when the person making the opinion does not earnestly believe the opinion, or when they are aware of information that is irreconcilable with the opinion. 894 F.3d at 275 (citing RESTATEMENT (SECOND) OF TORTS § 539(1)(a) (AM. L. INST. 1976)). In reaching this holding, the Sixth Circuit ultimately rejected the bright-line rule that a doctor’s clinical judgment can never be false. *Id.* at 275; *see also infra* notes 68–71 and accompanying text (discussing the *Paulus* case in more detail).

<sup>55</sup> *Cf.* LEWIS CARROLL, *ALICE’S ADVENTURES IN WONDERLAND* 95–111 (VolumeOne Publishing ed., 1998) (1865). The seventh chapter of the book is entitled “A Mad Tea-Party” where Alice attends a party that turns into a discussion of riddles. *Id.* Alice claims that to say what you mean and to mean what you say are the same thing, but everyone at the party disagrees. *Id.* at 98. Alice becomes annoyed and leaves the tea party. *Id.* at 110–11.

<sup>56</sup> *See* 31 U.S.C. § 3729(b) (lacking definitions for “false” or “fraudulent”); *Universal Healthcare Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016) (noting that Congress never explicitly defined what “false or fraudulent” means under the FCA).

<sup>57</sup> *See supra* note 41 and accompanying text (discussing whether the falsity analysis under the FCA includes both factual and legal falsity).

<sup>58</sup> *See infra* notes 63–64 and accompanying text.

<sup>59</sup> *See infra* notes 63–67 and accompanying text.

<sup>60</sup> *See infra* notes 68–74 and accompanying text.

<sup>61</sup> *See infra* notes 75–79 and accompanying text.

<sup>62</sup> *See infra* notes 80–86 and accompanying text.

*A. The Supreme Court Broadly Defines What Makes a Claim False Under the FCA and Holds That Opinions Can Be False Statements*

In *Escobar*, the Supreme Court held that the FCA comprises the common-law meanings of the terms “false” and “fraudulent.”<sup>63</sup> Common-law fraud can include, *inter alia*, claims that contain “half-truths.”<sup>64</sup> In reaching this conclusion, the Court cited to a 2015 Supreme Court decision: *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*.<sup>65</sup> In *Omnicare*, the Court held that, for purposes of attaching FCA liability to securities regulations, disingenuous or intentionally deceptive opinions can be false statements.<sup>66</sup> In *Escobar*, the Court discussed that the more “rigorous” materiality and scienter requirements would assuage concerns that its holding increased physician liability.<sup>67</sup>

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<sup>63</sup> *Universal Healthcare Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999, 2002 (2016) (citing *Sekhar v. United States*, 570 U.S. 729, 732–33 (2013)). In 2013, in *Sekhar v. United States*, the Court noted that when a statute does not define a term, a court should apply its common-law meaning. 570 U.S. at 732–33. The issues in *Escobar* centered on the requirements for proving an FCA claim based on the implied false certification theory. 136 S. Ct. at 1999. The Court did not want to provide a rigid rule for determining whether a claim is false, so it instead adopted a “demanding” materiality test, the *Escobar* materiality test. *See id.* at 2002–03 (discussing reasoning for not implementing a restricted view of what makes a claim false). The *Escobar* materiality test requires that (1) compliance with a regulation, statute, or contract be material to the government’s decision to provide payment, and (2) that the alleged violator had knowledge that such compliance was material to the government’s decision to approve payment. *See id.* (describing what satisfies the materiality test).

<sup>64</sup> *See Escobar*, 136 S. Ct. at 2000, 2001 n.3 (discussing that a person must divulge a sufficient amount of information such that their statement does not misinform others in both tort and contract law). “Half-truths” are “representations that state the truth only so far as it goes, while omitting critical qualifying information.” *Id.* at 2000.

<sup>65</sup> *See id.* at 2004 (reversing and remanding the First Circuit’s judgment because the complaint did not line up with the Supreme Court’s common-law interpretation of “false” or “fraudulent” in 31 U.S.C. § 3729(a)(1)(A) (citing *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 195–96 (2015))).

<sup>66</sup> *See Omnicare*, 575 U.S. at 184 (noting that § 11 of the Securities Act of 1933 regarding false statements may apply to opinions). In *Omnicare*, investors claimed that *Omnicare*’s registration statement filed with the Securities and Exchange Commission contained opinions that were “materially false.” *Id.* at 180–81. Under § 11’s false statement provision, a company may be liable if the registration statement contains (1) a false material fact or (2) leaves out a material fact that, if included, would make the statement “misleading.” *Id.* at 179; *see also* 15 U.S.C. § 77(k)(a) (explaining a security buyer’s right of action for statements an issuer makes in a registration statement). To determine if a statement is misleading, the court engages in an “objective inquiry” using a “reasonable investor” standard. *Omnicare*, 575 U.S. at 176. The Supreme Court asserted that an opinion could be false if the opinion-holder does not truthfully believe the opinion or provides fictional facts to bolster the opinion’s truth. *Id.* at 185–86. The Court also concluded that “sincere statements of pure opinion” are not untrue material claims even if someone shows later in time that the opinion is inaccurate. *Id.* at 186.

<sup>67</sup> *See Escobar*, 136 S. Ct. at 2002 (discussing its materiality standard). The Supreme Court reiterated that the materiality standard is “rigorous” and that the FCA is not a tool for prosecuting trivial noncompliance with statutes or regulations. *Id.* at 2003. Only a material misrepresentation that impacts the government’s decision to provide payment can trigger FCA liability. *Id.* at 2002. Even if the government expressly identifies a provision that is essential for payment, it does not automatically mean it is material. *Id.* at 2003. Materiality can include evidence that a defendant had knowledge that

### B. The Sixth and Tenth Circuits Hold That Clinical Judgments Can Be False in the Context of Medical Necessity

In 2018, in *United States v. Paulus*, the Sixth Circuit Court of Appeals addressed whether claims submitted for interpreting angiograms were false.<sup>68</sup> The cardiologist allegedly exaggerated the amount of arterial blockage in patients' records to facilitate claim approvals.<sup>69</sup> The court held that interpreting the severity of arterial blockage is a verifiable fact.<sup>70</sup> Importantly, the Sixth Circuit stated that clinical judgments can trigger FCA liability when a person asserts an opinion they do not truly believe or when they have knowledge of facts that contradict their opinion.<sup>71</sup>

Also in 2018, in *United States ex rel. Polukoff v. St. Mark's Hospital*, the Tenth Circuit Court of Appeals similarly addressed the falsity of a physician's

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the government refused payment for certain claims in the past due to violations of certain "statutory, regulatory, or contractual requirement[s]." *Id.* The *Escobar* ruling has affected how lower courts use the objective falsehood standard in the context of clinical judgments. Compare *United States ex rel. Druding v. Care Alternatives (Druding II)*, 952 F.3d 89, 95 (3d Cir. 2020) (rejecting the objective falsehood standard), and *Winter ex rel. United States v. Garden Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1113 (9th Cir. 2020) (same), with *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019) (embracing the objective falsehood standard). Interestingly, because of *Escobar*'s reference to *Omnicare*, circuit courts have cited to *Omnicare* to both support and discredit the objective falsehood standard. *Escobar*, 136 S. Ct. at 2004 (citing *Omnicare*, 575 U.S. at 194–95). Compare *Druding II*, 952 F.3d at 95 (noting that, because opinions can be false statements under securities regulations, medical opinions can be false (citing *Omnicare*, 575 U.S. at 183–86)), with *AseraCare*, 938 F.3d at 1297 (stating that even if a medical expert can show a clinical judgment is inaccurate, it is not false if the certifying physician truthfully believed that the patient was eligible for hospice care at the time of certification (citing *Omnicare*, 575 U.S. at 185–86)).

<sup>68</sup> *United States v. Paulus*, 894 F.3d 267, 271–72 (6th Cir. 2018) (addressing how cardiologists measure arterial blockage and determine whether a cardiac procedure is medically necessary).

<sup>69</sup> *Id.* at 272–73. Dr. Paulus, a cardiologist at King's Daughters Medical Center (KDMC) in Ashland, Kentucky, was ranked first in the nation for the amount billed to Medicare for angiograms. *Id.* at 272. Angiograms are images that a cardiac catheterization procedure produces that can allow a physician to see the amount of arterial blockage. *Id.* at 271. If an angiogram reveals at least 70% blockage, a stent is inserted to open the artery and improve blood flow with the intent of preventing heart attacks. *Id.* Cardiologists may interpret angiograms differently, leading to an "inter-observer variability" between 10% and 20%. *Id.* at 272. This variability generally occurs more often when the angiogram shows blockage in the 50%–70% range. *Id.* In 2008, HHS began investigating Dr. Paulus and auditing his angiogram cases. *Id.* at 272–73. The auditing cardiologist at HHS determined that of nineteen angiogram cases, seven cases were medically unnecessary. *Id.* at 273. A private insurance company also performed an audit of Dr. Paulus and concluded that out of eleven angiograms, at least half were not medically necessary. *Id.*

<sup>70</sup> *Id.* at 275. The Sixth Circuit concluded that if a physician knowingly exaggerated the amount of blockage viewed on an angiogram, then they have submitted a false claim. *Id.*

<sup>71</sup> *Id.* at 275–76. The Sixth Circuit further concluded that Dr. Paulus was not contributing his own medical opinion, but was distorting facts by consistently lying about the severity of blockage on angiograms to receive reimbursement for medically unnecessary procedures. *Id.* at 276. Although the court did not explicitly reject or adopt the objective falsehood standard, it disagreed with the district court's conclusion that clinical judgments are subjective, and therefore, can never be verified or disputed. *Id.* at 275. The Sixth Circuit reiterated that it wanted to set a well-defined standard that proving a statement is false requires proving that a statement can be verified or challenged. *Id.*

clinical judgment.<sup>72</sup> There, a physician performed cardiac surgical procedures allegedly knowing the procedures violated CMS's medical necessity guidelines.<sup>73</sup> In its holding, the Tenth Circuit declared that a clinical judgment can be false under the FCA because the FCA covers a wide range of fraud, an opinion is not absolved of liability, and a claim for medically unnecessary services or procedures triggers liability.<sup>74</sup>

### *C. The Eleventh Circuit Embraces the Objective Falsehood Standard in the Context of Hospice Care Certification*

In 2019, in *United States v. AseraCare, Inc.*, the Eleventh Circuit reviewed the question of when a clinical judgment is false with respect to hospice eligibility.<sup>75</sup> AseraCare, a hospice care network, allegedly submitted false claims for palliative services performed for patients who were not terminally ill.<sup>76</sup> The

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<sup>72</sup> *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 737 (10th Cir. 2018). Dr. Polukoff filed a *qui tam* action against Dr. Sorensen, Sorenson Cardiovascular Group, and Intermountain Healthcare, Inc., alleging that the parties submitted false Medicare reimbursement claims for medically unnecessary cardiac procedures. *Id.* at 738. The government declined to intervene. *Id.* at 739.

<sup>73</sup> *Id.* at 737. Dr. Polukoff claimed that Dr. Sorensen's procedures were not medically necessary and, therefore, the reimbursement claims submitted were legally false. *Id.* at 739. Dr. Sorensen performed patent foramen ovale (PFO) procedures on certain patients suffering from migraines because he believed that the procedure could treat their migraines. *Id.* He allegedly was aware that Medicare and Medicaid would not approve reimbursement if the PFO procedure was performed to alleviate migraines. *Id.* To receive reimbursements, Dr. Sorensen allegedly altered patient records to make it appear that he performed the PFO procedures in compliance with certain stroke guidelines that he knew Medicare would approve. *Id.*

<sup>74</sup> *Id.* at 742. Therefore, if Medicare deems a procedure not reasonable and necessary, then a physician's certification that it is medically necessary may be false under the FCA. *Id.* at 743. The Tenth Circuit concluded that Dr. Sorensen's claims were not factually false because he did in fact perform PFO procedures. *Id.* at 741. The court, however, determined that the claims were legally false because the procedures performed were not reasonable and necessary as per Medicare's requirements. *Id.*; see CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 43, at 13.5.4 (discussing the factors to consider when determining whether a service or procedure is medically reasonable and necessary for purposes of Medicare reimbursement).

<sup>75</sup> *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1281 (11th Cir. 2019). *AseraCare* was a *qui tam* action, and the government chose to intervene. *Id.* The government alleged that AseraCare falsely certified patients as terminally ill to qualify them for hospice care and receive palliative services that AseraCare could submit for Medicare reimbursement. *Id.* From 2007 to 2012, nearly 90% of AseraCare's revenues came from Medicare payments. *Id.* at 1282.

<sup>76</sup> *Id.* The government alleged that flawed clinical judgments formed the basis of the terminally ill prognoses. *Id.* at 1281. The court pointed out that the government did not allege that the certifying physicians made terminally ill prognoses based on incomplete medical records or inaccurate medical information. *Id.* at 1285, 1288. AseraCare used a local Medicare Administrative Contractor, Palmetto, to process AseraCare's hospice claims for payment. *Id.* at 1283. Mary Jane Schultz, a registered nurse and former medical director at Palmetto, testified that Palmetto initially reviewed hospice care claims via an automated system that would check the claim to ensure no information was missing. *Id.* The system would then scan the claim for "red flags," or information that might indicate questionable hospice eligibility. *Id.* Ms. Schultz claimed that as a result of the automated review system, she pro-

court concluded that the objective falsehood standard properly assessed when a clinical judgment is false and held that the standard requires more than a showing of varying medical expert opinions.<sup>77</sup> Notably, the court stated that if a physician performed a thoughtful review of a patient's medical records and truthfully believed the patient was hospice-eligible, then the clinical judgment is not false regardless of whether a medical expert says otherwise after reviewing the same records.<sup>78</sup> Furthermore, the court stated that if its holding troubled Congress or CMS, then they should redefine hospice eligibility criteria.<sup>79</sup>

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cessed many claims for payment without reviewing the medical information that supported the claim. *Id.* It was only if the system flagged any information that a medical team at Palmetto would then review the claim's medical documentation to determine if the government should approve or deny payment of the claim. *Id.* The government began its investigation into AseraCare by selecting 2,180 records of patients who were in hospice care for one, continuous year. *Id.* at 1284. The government then sampled 223 patients from the 2,180 records. *Id.* at 1284–85. The government's medical expert, Dr. Solomon Liao, concluded that 123 patients from the sample were not eligible for hospice care. *Id.* at 1285. The relators in the case also alleged that AseraCare physicians did not perform an adequate review of patient medical records and "merely rubber-stamped" patients as terminally ill. *Id.* The court noted that a hospice certification contains two representations. *Id.* at 1296. First, a physician represents that a patient is terminally ill, which relates to the validity of the physician's clinical judgment. *Id.* Second, a hospice provider represents that a physician confirmed a patient is eligible, which relates to the hospice provider's affirmation that the clinical judgment made is appropriate. *Id.* The court determined that the government made no claims against AseraCare regarding AseraCare's confirmation that its physicians made appropriately formed clinical judgments, therefore, the central question the court addressed was *when* a clinical judgment regarding a terminally ill prognosis is false. *Id.* The government did not contend that AseraCare submitted claims for "phantom patients," forged certifications, or had any employees lie or keep pertinent medical information from certifying physicians. *Id.* at 1285.

<sup>77</sup> *Id.* at 1297. Only showing that two medical experts reasonably disagree over a terminally ill prognosis is not enough to prove that clinical judgments or claims that relied on those clinical judgments are false under the FCA. *Id.* The court explained that in order to trigger FCA liability regarding a hospice claim, a plaintiff must show "facts and circumstances" that are in conflict with a "properly formed and sincerely held clinical judgment." *Id.*

<sup>78</sup> *See id.* at 1296 (noting that "after the fact" review of medical records cannot prove a clinical judgment is false, even if such review demonstrates a clinical judgment is incorrect). The court provided several ways to satisfy the objective falsehood requirement. *Id.* at 1297. First, the court noted that if a certifying physician did not perform a comprehensive review of a patient's medical records before providing a prognosis, then the clinical judgement is false. *Id.* Second, if the physician did not truthfully believe a patient was terminally ill, then the clinical judgment is also false. *Id.* Third, if a medical expert, after reviewing the same set of medical information, shows that no "reasonable physician" would have determined a terminally ill prognosis, then the certifying physician's clinical judgment is false. *Id.* All three examples the court provided reflected a situation in which confirmable facts could demonstrate that a false clinical judgment was the premise for a hospice certification claim, and therefore, the claim was false. *Id.* In addition, the court noted that although clinical judgments are indeed tied to a patient's clinical documentation, CMS did not intend for physicians to be worried that a well-thought-out prognosis could later be challenged in court. *Id.* at 1295.

<sup>79</sup> *Id.* at 1301. The court addressed the fact that CMS and Congress could have promulgated stricter guidelines for determining hospice eligibility if they wanted. *Id.* (citing Medicare and Medicaid Programs, 73 Fed. Reg. 32,008, 32,138 (June 5, 2008) (to be codified at 42 C.F.R. pt. 418)).



*D. The Ninth Circuit Embraces the Third Circuit's Reasoning and Rejects the Objective Falsehood Standard in the Context of Medical Necessity*

In 2020, in *Winter ex rel. United States v. Garden Regional Hospital & Medical Center, Inc.*, the Ninth Circuit rejected the objective falsehood standard.<sup>80</sup> The relator alleged that Garden Regional Hospital certified medically unnecessary hospital admissions.<sup>81</sup> The court stated that the objective falsehood standard was not the appropriate analysis to use because the FCA did not differentiate between objective and subjective falsity, and did not include an exception for medical opinions.<sup>82</sup> Similar to the Sixth Circuit's analysis in *Paulus*, the court determined that subjective opinions can be false if a person making an opinion does not candidly believe the opinion or implicates fictitious facts to support the opinion's truth.<sup>83</sup> The court also addressed the Eleventh Circuit's holding in *AseraCare*.<sup>84</sup> First, the court concluded that the Eleventh Circuit did not address whether it is ever possible for a clinical judgment to be false, only whether a medical expert's opinion by itself is enough to demonstrate falsity.<sup>85</sup> Second, the court narrowly interpreted the Eleventh Circuit's holding to apply only to hospice claims.<sup>86</sup>

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<sup>80</sup> *Winter ex rel. United States v. Garden Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1117 (9th Cir. 2020) (noting that the FCA does not require a showing of an objective falsehood).

<sup>81</sup> *Id.* at 1115. Jane Winter, the relator, filed the *qui tam* action alleging that patient hospital admissions did not meet the hospital's admissions criteria and the medical records did not support a need for hospitalization. *Id.* Winter noted that a nursing facility sixty miles away sent a large number of its Medicare beneficiary patients to Garden Regional's emergency room. *Id.* The hospital subsequently admitted many of these patients. *Id.* The company that owned the nursing home, RollinsNelson, acquired another company, S&W, which managed Garden Regional. *Id.* Winter observed that the increase in hospital admissions coincided with the RollinsNelson's acquisition of S&W. *Id.* Winter alleged that both RollinsNelson and S&W pressured physicians to admit the nursing home patients to Garden Regional when it was not medically necessary. *Id.* Winter alleged that sixty-five hospital admissions were not medically necessary and that Garden Regional submitted false claims to Medicare totaling nearly \$1.3 million over a two-month period. *Id.*

<sup>82</sup> *Id.* at 1117.

<sup>83</sup> *Id.*; see *United States v. Paulus*, 894 F.3d 267, 270 (6th Cir. 2018) (rejecting the objective falsehood standard); see also *supra* notes 68–71 and accompanying text (discussing the factual background and holding of *Paulus*).

<sup>84</sup> See *Winter*, 953 F.3d at 1118 (mentioning that the court's rejection of the objective falsehood standard did not conflict with the Eleventh Circuit's holding); see also *AseraCare*, 938 F.3d at 1301 (holding that a "reasonable disagreement" among medical experts, without additional evidence, does not demonstrate a clinical judgment is false).

<sup>85</sup> *Winter*, 953 F.3d at 1118–19 (citing *AseraCare*, 938 F.3d at 1297–98). The court understood the Eleventh Circuit's holding to mean that a "reasonable disagreement" among medical experts, with no additional evidence, was never enough to prove falsity. *Id.* (citing *AseraCare*, 938 F.3d at 1297–98). The court stated that the Eleventh Circuit did not hold that all subjective opinions were never false, particularly since it identified scenarios where a medical opinion could be false. *Id.* at 1119 n.7 (citing *AseraCare*, 938 F.3d at 1302).

<sup>86</sup> *Id.* at 1119. In *Winter*, the court noted that the Eleventh Circuit distinguished *AseraCare* from *Paulus*—a case which dealt with medical necessity certifications—by explaining that the statute proscribes Medicare reimbursement for services that are not reasonable and necessary. *Id.* at 1120 (citing

### III. THROUGH THE LOOKING GLASS: THE OBJECTIVE FALSEHOOD STANDARD APPROPRIATELY ANALYZES THE FALSITY OF CLINICAL JUDGMENTS AND ALIGNS WITH CMS'S INTENT FOR THE MEDICARE HOSPICE BENEFIT<sup>87</sup>

The Third Circuit's decision in 2020, in *United States ex rel. Druding v. Care Alternatives (Druding II)*, missed an opportunity to apply the objective falsehood standard to clinical judgments for hospice care eligibility.<sup>88</sup> Section A of this Part explains the relevant distinction between *when* and *whether* a medical opinion can be false.<sup>89</sup> Section B discusses why the objective falsehood standard is the appropriate standard for analyzing the falsity of a clinical judgment.<sup>90</sup> Finally, Section C analyzes how the Third Circuit's holding conflicts with CMS's intent for the MHB and overly expands FCA liability for hospice providers.<sup>91</sup>

#### A. "When" and "Whether" a Clinical Judgment Can be False

There is an important distinction between *when* and *whether* a clinical judgment can be false under the FCA.<sup>92</sup> In *Druding II*, the Third Circuit rejected the district court's assertion that clinical judgments cannot be false for purposes of FCA liability.<sup>93</sup> The Sixth, Ninth, Tenth, and Eleventh Circuits have answered the question of *whether* a clinical judgment can be false, agreeing that courts may scrutinize clinical judgments.<sup>94</sup> In doing so, these circuits fol-

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*AseraCare*, 938 F.3d at 1300). Given that the Ninth Circuit distinguished *Winter* from *AseraCare* and narrowly confined *AseraCare*'s holding to hospice certifications, it follows that *Winter*'s holding should likewise be narrowly understood to only apply to medical necessity claims. Compare *AseraCare*, 938 F.3d at 1281 (case concerning the falsity of hospice certification claims), with *Winter*, 953 F.3d at 1108 (case concerning the falsity of medical necessity claims).

<sup>87</sup> Cf. LEWIS CARROLL, *THROUGH THE LOOKING GLASS AND WHAT ALICE FOUND THERE* (London, MacMillan & Co. 1871). *Through the Looking Glass* is the sequel to *Alice's Adventures in Wonderland*, where Alice goes through a mirror into an alternate world where everything appears reversed. *Id.*

<sup>88</sup> See *United States ex rel. Druding v. Care Alternatives (Druding II)*, 952 F.3d 89, 95–98 (3d Cir. 2020) (rejecting the objective falsehood standard); see also *supra* notes 44–54 and accompanying text (discussing the case and holding in *Druding II*); *infra* notes 104–107 and accompanying text (same).

<sup>89</sup> See *infra* notes 92–98 and accompanying text.

<sup>90</sup> See *infra* notes 99–107 and accompanying text.

<sup>91</sup> See *infra* notes 108–119 and accompanying text.

<sup>92</sup> See *Winter ex rel. United States v. Garden Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1118–19 (9th Cir. 2020) (noting that the Eleventh Circuit only asked whether differing opinions between medical experts, without additional evidence, is enough to prove falsity (citing *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297–98 (11th Cir. 2019))); see also *supra* notes 84–86 and accompanying text (discussing how *Winter* distinguished itself from *AseraCare*).

<sup>93</sup> *Druding II*, 952 F.3d at 98.

<sup>94</sup> See *supra* notes 68–86 and accompanying text (discussing the holdings of the circuit court cases dealing with the falsity of medical necessity claims and hospice certification claims). Regardless

low the Supreme Court's position that opinions, in certain circumstances, can be false—lending to the question of *when* opinions can be false.<sup>95</sup> The Eleventh Circuit in 2019, in *United States v. AseraCare, Inc.*, however, went further and considered *when* medical expert testimony is sufficient to show a clinical judgment is false and how one could determine whether a physician appropriately made a clinical judgment.<sup>96</sup> The Third Circuit interpreted the Eleventh Circuit's holding as meaning that medical expert testimony is not sufficient to prove falsity and that clinical judgments are never false.<sup>97</sup> The Eleventh Circuit, however, only stated that opposing medical expert opinions, with no additional evidence, is not enough to prove falsity.<sup>98</sup>

*B. The Objective Falsehood Standard Aligns with Supreme Court Precedent & Appropriately Determines When Medical Expert Testimony May Prove a Clinical Judgment is False*

In *AseraCare*, the Eleventh Circuit acknowledged that some evidence is relevant to proving both *knowledge* and *falsity*, making it difficult to analyze these elements separately from one another.<sup>99</sup> The objective falsehood standard

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of whether these Circuit courts chose to embrace or reject the objective falsehood standard, they were all in agreement that clinical judgments can be false. *See Winter*, 953 F.3d at 1113 (holding that clinical judgments can be false); *see also AseraCare*, 938 F.3d at 1297 2 (same); *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) (same); *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018) (same).

<sup>95</sup> *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999, 2001 (2016) (holding that “misrepresentations by omission” and half-truths can make a claim false under the FCA); *see also Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 176 (2015) (holding that opinions can be false if the opinion-holder does not truthfully believe the opinion or fabricates facts to make the opinion appear true); *supra* notes 63–67 and accompanying text (discussing the *Escobar* and *Omnicare* cases).

<sup>96</sup> *See AseraCare*, 938 F.3d at 1296–97, 1302 (addressing *when* a medical opinion is false and providing ways in which one could determine whether a certifying physician truly believed and “properly formed” their own clinical judgment); *see also supra* notes 75–79 and accompanying text (discussing the Eleventh Circuit's holding in *AseraCare*).

<sup>97</sup> *Druding II*, 952 F.3d at 100. The Third Circuit noted that the Eleventh Circuit held that clinical judgments are not false. *Id.* Adding to this, the court explained that because subjective opinions can be false under common-law, so can medical opinions, and therefore, challenging medical expert testimony can provide evidence that a clinical judgment is false. *Id.*

<sup>98</sup> *See AseraCare*, 938 F.3d at 1297 (holding that a plaintiff must show how an appropriately made clinical judgment conflicts with the “facts and circumstances” associated with the hospice care certification when alleging that a patient was falsely certified for hospice care). The court also stated that if a certifying physician truly believes their own clinical judgment, and thoroughly reviews the medical records prior to certifying, then the physician's terminally ill prognosis is not false, regardless of whether a medical expert concludes otherwise. *Id.* If medical expert evidence, however, can demonstrate that a “reasonable physician” examining the patient's case could not assign a terminal prognosis then the certifying physician's clinical judgment could be false. *Id.*; *see supra* notes 75–79 and accompanying text (discussing the Eleventh's Circuit's holding in *AseraCare*).

<sup>99</sup> *See AseraCare*, 938 F.3d at 1302–05 (explaining how the district court bifurcated the trial to hear the element of falsity separately and erred in this decision). The district court granted Care Alter-

acknowledges this overlap of evidence by requiring additional factual evidence to determine falsity.<sup>100</sup>

The objective falsehood standard also aligns with Supreme Court precedent on how opinions can be false, which can include: (1) if a person does not candidly believe their own opinion; (2) if a person states half-truths; or (3) if a person fabricates facts to support an opinion.<sup>101</sup> The Court emphasized that if an individual truly believes their opinion, it cannot be false, even if proven incorrect later in time.<sup>102</sup> Thus, the Court's stance on false opinions requires proof of factual evidence regardless of whether those facts may also apply to the FCA's *knowledge* requirement.<sup>103</sup>

The Third Circuit held that medical expert opinions could prove a hospice certification was false if they proved the claim was noncompliant with statuto-

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native's motion to bifurcate the trial into two phases: one phase exclusively on the falsity element of the FCA, and a second phase on the remaining elements of the FCA. *Id.* at 1286. The court precluded the government from presenting any evidence that also supported knowledge of falsity in phase one. *Id.* at 1303. The government contested bifurcating the trial and stated that the "elements of falsity and knowledge are not so distinct and separable that they may be tried separately without injustice." *Id.* at 1304.

<sup>100</sup> See *id.* at 1296–97 (noting that a hospice claim is not false if the certifying physician's terminally ill prognosis does not exhibit an objective falsehood); see also *supra* notes 75–79 (discussing *AseraCare* and examples the Eleventh Circuit provided on how to prove objective falsity). If a medical expert is unable to show anything other than a reasonably varying opinion over a terminally ill prognosis, then the certifying physician's clinical judgment is not false. *AseraCare*, 938 F.3d at 1296–97.

<sup>101</sup> See *supra* notes 63–67, 95 and accompanying text (describing relevant Supreme Court cases discussing when opinions can be false).

<sup>102</sup> *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 186 (2015). Justice Kagan, writing for the majority, noted that to categorize a candidly held opinion—that may turn out to be inaccurate—as a false material assertion would improperly converge "facts and opinions." *Id.* at 183. She went on to state that a fact possesses certainty, whereas an opinion is a belief or viewpoint. *Id.* An opinion naturally conveys that some probability of inaccuracy exists. *Id.* Therefore, when a person gives an opinion, they are inferring that the opinion provided is frankly held, that they "believe[] that [the] basis for the opinion is sufficient," and that they are "not certain of [the] result." See *id.* at 203 (Scalia, J., concurring) (discussing what it means when a person gives an opinion). Justice Kagan emphasized that § 11 of the Securities Act of 1933 expressly stated that liability for opinions could only attach to "untrue statements of . . . fact," not "untrue statements." *Id.* at 183 (Kagan, J.); see also 15 U.S.C. § 77(k)(a) (explaining a security buyer's right of action for statements a security issuer makes in a registration statement).

<sup>103</sup> See *AseraCare*, 938 F.3d at 1304 (noting that it is not possible to analyze the falsity and knowledge elements of an FCA claim separately without some degree of inequity). In *Omnicare*, the Supreme Court stated that a plaintiff must show facts that demonstrate a "reasonable person" would find the statement misleading. *Omnicare*, 575 U.S. at 194. In applying *Omnicare*'s statement to medical opinions, a plaintiff would need to identify facts that prove a "reasonable physician" would not believe a patient was terminally ill. See *AseraCare*, 938 F.3d at 1297 (stating that if a medical expert determined that no "reasonable physician" would determine a patient was eligible for hospice after reviewing the medical records, then a clinical judgment could be false); *Omnicare*, 575 U.S. at 194 (applying the "reasonable person" standard).

ry certification requirements.<sup>104</sup> If a certifying physician truly believed a patient was terminally ill, however, the Third Circuit's holding would conflict with Supreme Court precedent.<sup>105</sup> Alternatively, a medical expert could show, for example, that a certifying physician: (1) did not review the patient's medical records before certifying, and therefore, did not make a well-thought-out prognosis; (2) intentionally omitted relevant facts in the certification report that would preclude hospice eligibility; or (3) created untrue facts in order to make a patient appear eligible.<sup>106</sup> These types of objective findings would lead a medical expert to deduce that no "reasonable physician" would have thought a patient was hospice eligible.<sup>107</sup>

### *C. The Objective Falsehood Standard Aligns With CMS's Intent For Hospice Eligibility Criteria*

A patient first makes the difficult decision to elect hospice care and waive any curative treatment.<sup>108</sup> When a patient receives approval for hospice, CMS

<sup>104</sup> See *United States ex rel. Druding v. Care Alternatives (Druding II)*, 952 F.3d 89, 97 (3d Cir. 2020) (noting that a plaintiff could prove legal falsity by showing that Care Alternatives did not meet certain regulatory requirements for properly certifying hospice claims); see also 42 C.F.R. § 418.22 (certification requirements of terminal illness); *supra* notes 7, 27–29 and accompanying text (discussing hospice certification and eligibility requirements). Section 418.22(b) requires that a clinical judgment serve as the basis for a hospice certification. 42 C.F.R. § 418.22(b). It also requires that the physician provide an explanation that supports a terminally ill prognosis. *Id.* § 418.22(b)(3). The physician must confirm via signature that the physician's explanation is based on a review of the patient's medical records or a patient examination. *Id.* § 418.22(b)(3)(iii). In *AseraCare*, the court noted that to assert that a clinical judgment is wrong by evaluating the medical documentation on its own would improperly read into the regulation's language. 938 F.3d at 1294. The requirements only state that relevant medical documentation "accompany" the hospice certification. *Id.* The court went on to say that as long as a physician performs an adequate review of the medical records before certifying a patient as terminally ill, then the clinical judgment appropriately determines eligibility for a patient. *Id.*

<sup>105</sup> See *Omnicare*, 575 U.S. at 186 (noting that truthfully made opinions are not false, even if they are proven wrong after the fact); see also *supra* notes 63–67, 102 and accompanying text (discussing relevant Supreme Court cases).

<sup>106</sup> See *AseraCare*, 938 F.3d at 1297, 1302 (providing examples of what amounts to an objective falsehood and explaining how to determine whether a certifying physician's clinical judgement was "truly communicated"); see also 42 C.F.R. § 418.22 (listing the requirements for certification); *supra* notes 27–29 and accompanying text (discussing hospice eligibility and certification requirements).

<sup>107</sup> See *AseraCare*, 938 F.3d at 1297 (noting that the government needed to show more than a reasonably varying opinion over a terminally ill prognosis); see also *supra* notes 63–67 and accompanying text (discussing the Supreme Court's interpretation of "false" or "fraudulent" under the FCA). The Eleventh Circuit, in *AseraCare*, stated that in order to demonstrate a false hospice certification, a plaintiff must bring forth "facts and circumstances" that prove a clinical judgment was not "properly formed." 938 F.3d at 1297.

<sup>108</sup> See Medicare Program, 79 Fed. Reg. 50,452, 50,471 (Aug. 22, 2014) (to be codified at 42 C.F.R. pts. 405, 418) (noting that the patient and physician share in any decisions made concerning hospice care, and that patients are entitled to access all benefits available to them under Medicare at the appropriate time). CMS went on to explain that beneficiaries of hospice care have "certain guaran-

relies on a physician to make an appropriate clinical judgment as to whether that patient is eligible.<sup>109</sup> Unlike medical necessity issues where CMS only reimburses for reasonable and necessary services, hospice eligibility criteria are not so categorical.<sup>110</sup> CMS has acknowledged that patients do not always show appreciable deterioration in their health at the time of recertification.<sup>111</sup> It is not possible to predict the life expectancy of a patient with complete certainty.<sup>112</sup> If it were possible, statutory requirements would not continue to permit unlimited sixty-day recertification periods.<sup>113</sup>

Furthermore, providing such strict guidelines could deny a Medicare patient's entitlement to hospice care.<sup>114</sup> Congress was cognizant of this when it enacted the MHB.<sup>115</sup> Moreover, CMS has not amended the hospice eligibility

ted rights," including the right to ask for a second review should a physician determine they are no longer eligible for hospice care. *Id.*

<sup>109</sup> See 42 C.F.R. § 418.22(b) (stating that a hospice certification relies on the physician's or medical director's clinical judgment and clinical documentation supporting the prognosis must accompany the certification); see also *AseraCare*, 938 F.3d at 1295 (stating "[w]e believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill" (quoting Medicare Program, 78 Fed. Reg. 38,234, 48,247 (Aug. 7, 2013) (to be codified at 42 C.F.R. pt. 418))). In *AseraCare*, the court observed that CMS chose the word "support," rather than "demonstrate or prove," inferring that CMS did not expect medical records to "objectively" prove a terminally ill prognosis. 938 F.3d at 1294.

<sup>110</sup> Compare 42 U.S.C. § 1395y(a)(1)(A) (providing clear guidance that Medicare may not reimburse for services that are not reasonable and necessary), with 42 C.F.R. § 418.22 (providing that hospice certification relies on the clinical judgment of the certifying physician with no clear criteria given other than that supporting documentation must accompany the certification and medical information must support the prognosis). See *supra* notes 27–29, 43 and accompanying text (discussing hospice eligibility and certification requirements, and the factors to consider when determining whether a service or procedure is medically reasonable and necessary for purposes of Medicare reimbursement); see also *AseraCare*, 938 F.3d at 1295 (discussing that CMS has the right to deny approval for any hospice services that it does not deem reasonable and necessary (citing 79 Fed. Reg., at 50,470)).

<sup>111</sup> See *AseraCare*, 938 F.3d at 1293 (discussing how CMS understands the complexity of determining a terminally ill prognosis and how a physician must weigh many considerations when a patient's illness has not appreciably worsened (citing Medicare Program, 79 Fed. Reg. at 50,471)); see also Medicare Program, 78 Fed. Reg. at 48,243 (recognizing that hospice care needs are unique and involve a holistic treatment approach); Medicare Program, 74 Fed. Reg. 39,384, 39,399 (Aug. 6, 2009) (to be codified at 42 C.F.R. pt. 418) (noting that patients may not "show measurable decline" when they are due for recertification). If a physician feels that a patient's lack of "measurable decline" warrants justification, the physician can include that in the certification's progress note. Medicare Program, 74 Fed. Reg. at 39,399.

<sup>112</sup> See *AseraCare*, 938 F.3d at 1304 (stating that CMS has recognized that making a terminally ill prognosis is not an "exact science" (citing Medicare Program, 79 Fed. Reg. at 50,470)); see also *supra* notes 7, 27–29 and accompanying text (explaining hospice eligibility and the certification process and requirements).

<sup>113</sup> See 42 C.F.R. § 418.22 (noting that although there are additional recertification procedures to follow, there is no specified limit to the amount of 60-day recertification periods).

<sup>114</sup> See *supra* note 108 and accompanying text (discussing a Medicare beneficiary's role in electing hospice care).

<sup>115</sup> See Medicare Program, 79 Fed. Reg. at 50,471 (noting that CMS has always believed that there are individual considerations to take into account when determining if a patient is terminally ill

criteria.<sup>116</sup> Such inaction implies that CMS continues to hold clinical judgments regarding hospice eligibility in high regard.<sup>117</sup> The objective falsehood standard minimizes liability for clinical judgments made in earnest that, although conceivably imprecise, are not false.<sup>118</sup> By applying the objective falsehood standard, questionable hospice certification claims do not survive summary judgment and do not unnecessarily inundate the judiciary.<sup>119</sup>

## CONCLUSION

The United States Court of Appeals for the Third Circuit's 2020 decision in *United States ex rel. Druding v. Care Alternatives (Druding II)* conflicts with CMS's intent for the Medicare Hospice Benefit and leaves physicians more vulnerable to FCA liability. The Third Circuit neglected to acknowledge that the objective falsehood standard appropriately aligns with the Supreme Court's precedent regarding false opinions. The objective falsehood standard recognizes that certain factual evidence can speak to both the FCA's *falsity* and *knowledge* elements. Thus, something more than conflicting medical expert testimony is needed to prove a clinical judgment is false, even if the evidence also pertains to the *knowledge* element. Applying this falsity standard ensures that physicians can have confidence that their clinical judgments will stand up

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and should receive hospice care services); see also *AseraCare*, 938 F.3d at 1301 (noting that CMS could have chosen more demanding clinical criteria to determine whether a patient was eligible for hospice—which would have “minimized the role of clinical judgment[s]”—however, it purposefully chose to elevate the importance of a clinical judgment in determining hospice eligibility).

<sup>116</sup> See Medicare Program, 85 Fed. Reg. 47,070, 47,070 (Aug. 4, 2020) (to be codified at 42 C.F.R. pt. 418) (showing that in the latest Medicare Program update released, there have been no proposed changes to the hospice eligibility criteria as defined in 42 C.F.R. § 418.22); see also *supra* note 7 and accompanying text (explaining that the court in *AseraCare* acknowledged that, at the time the case was heard, CMS had not amended the hospice eligibility criteria and that comments made from CMS's rulemaking indicated that “well-founded clinical judgments should be granted deference”); *AseraCare*, 938 F.3d at 1295.

<sup>117</sup> See *supra* note 116 and accompanying text (discussing that CMS has not proposed any changes to hospice eligibility criteria). When CMS considered changing the format of the patient election statement and addendum that the patient fills out at the time of certification, CMS stated that it did not want to provide any examples of completed forms because every patient's terminally ill prognosis is different and should be evaluated individually. Medicare Program, 85 Fed. Reg. at 47,088.

<sup>118</sup> See *AseraCare*, 938 F.3d at 1301 (acknowledging that it will be more difficult now for a plaintiff to prove falsity using the objective falsehood standard because it will not be enough to simply secure a medical expert that can disagree with a clinical judgment after reviewing “cold medical records”); see also *Omicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 182–86 (2015) (discussing the difference between a fictional fact and a frankly held opinion that may turn out to be inaccurate, but is not false).

<sup>119</sup> See *AseraCare*, 938 F.3d at 1301 (stating that the objective falsehood standard will be a more demanding standard to satisfy); see also FED. R. CIV. P. 9(b), 56(a) (setting forth the procedure for pleading in the case of fraud and summary judgment); *supra* notes 63–67, 102 and accompanying text (discussing relevant Supreme Court cases concerning falsity of opinions and explaining that an earnestly held opinion is not a false material fact).

in court. Likewise, the objective falsehood standard minimizes the risk of denying Medicare patients their hospice benefits simply because their terminal illness did not run its course in six months or the patient did not show considerable debility at the time of recertification.

Docketed September 16, 2020, Care Alternatives filed a petition for a writ of certiorari. On February 22, 2021, the Supreme Court denied Care Alternatives' petition. The Court missed an opportunity to provide needed guidance on the falsity of clinical judgments and the use of the objective falsehood standard in determining when a clinical judgment is false.

ELIZABETH A. CARUSO

**Preferred citation:** Elizabeth A. Caruso, Comment, *Hospice Care's Adventures in Fraudland: "Battle of the Experts" & Proving Falsity Under the False Claims Act*, 62 B.C. L. REV. E. SUPP. II.-21 (2021), <http://lawdigitalcommons.bc.edu/bclr/vol62/iss9/4/>.