

## **A Farewell to Falsity** ***Shifting Standards in Medicare Fraud Enforcement***

*Isaac D. Buck*<sup>†</sup>

*For the better part of a decade, Americans have had a front-row seat to a fervent and turbulent debate over the future of their health care system. The passage of the Patient Protection and Affordable Care Act of 2010 (ACA), the most comprehensive health reform effort since the mid-1960s, ushered in a new era in health law and policy, granting millions of Americans access to health care. After multiple legal challenges and congressional efforts that ultimately failed to slay the law, the ACA had become entrenched by the end of the Obama administration, even though pieces of the law had failed to work exactly as planned. Now, with the surprising election of President Donald Trump, reenergized Republicans are targeting the law once more, and it suddenly appears more vulnerable than ever. Dynamic uncertainty again permeates the national debate.*

*Although most powerful protections of the ACA may evaporate—no small event, to be sure—the value-based era which it unleashed seems here to stay. Indeed, this era—focused on efficiency, standardization, and quality within American medicine—has just begun to bear fruit. Illustrated prominently by recent changes to Medicare that alter how the program pays its doctors for services they provide to its beneficiaries, America is moving away from the old strictures of fee-for-service medicine. At the same time, traditional legal tools, and particularly the federal government’s most prominent anti-fraud tool, the civil federal False Claims Act (FCA), seem to be facing new limits. This has been recently evident in medical necessity-based fraud cases, and particularly highly publicized fights that have targeted the burgeoning industry of hospice care.*

*This Article tracks this development, ultimately arguing that the move to “reimbursement-based regulation” may be a positive step in finally reining in the worst excesses of American health care. But it also cautions against the deceptive simplicity of allowing medical heterogeneity and clinical complexity to prevent application of America’s most powerful anti-*

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<sup>†</sup>Associate Professor, University of Tennessee College of Law; Juris Doctor, University of Pennsylvania Law School; *Master of Bioethics*, University of Pennsylvania; Bachelor of Arts, Miami University (Ohio). Any errors or omissions are my own.

*fraud tools to its medical industry. Just because reimbursement policy has shifted to shoulder some of the regulatory burden of overtreatment does not mean that health care fraud—like fee-for-service medicine—should be confined to the past.*

*In the end—and regardless of whatever legislation the national debate surrounding American health care produces—American medicine must adequately address its susceptibility to overtreatment, its incentives toward financial excess and waste, and its inability to push providers and entities into adopting more efficient practices. Medicare is finally moving quickly to bring about effective changes, and the program is seeking clarity in the midst of a period of tremendous uncertainty for American health care.*

I.INTRODUCTION .....	3
II.SUCCESSES AND CHALLENGES FOR THE FALSE CLAIMS ACT.....	5
III.A NEW FRONT: HOSPICE FRAUD .....	9
A. An Explosion of Hospice Care .....	10
B. Why Hospice Attracts the FCA .....	13
IV.UNITED STATES V. ASERACARE.....	17
A. About AseraCare .....	17
B. Procedural History .....	18
C. A Summary of the Allegations .....	21
1. Wrongful Certification.....	21
2. Pressure on Employees .....	23
3. Enrollment Shortcuts .....	25
4. Muddying the Numbers .....	26
D. The Trial .....	27
1. The November 2015 Opinion .....	28
2. The March 2016 Opinion.....	30
V.HETEROGENEITY AS AN ANTAGONIST TO FRAUD .....	32
A. The Siblings and Progeny of AseraCare.....	33
1. U.S. ex rel. Morton v. A Plus Benefits, Inc. ....	33
2. United States ex rel. Wall v. Vista Hospice Care, Inc.	34
3. United States ex rel. Polukoff v. St. Mark's Hospital.	36
B. The Problem of Reasonable Clinical Judgment.....	40
C. Medical Necessity as Relevant to Intent.....	42
VI.MOVING TO REIMBURSEMENT-BASED INCENTIVES.....	45
VII.CONCLUSION .....	51

## I. INTRODUCTION

Nothing seems certain about the future of American health care administration and delivery in 2018. With the stunning election of President Donald Trump, and with Republican majorities governing both houses of Congress, Washington remains poised to cut, refocus, and replace portions of former President Barack Obama's signature domestic achievement, the Patient Protection and Affordable Care Act of 2010 (ACA). Subject to swirling and shifting political winds, the bruised but resilient ACA—responsible for the health insurance of millions of Americans who lacked it prior to passage—teeters on the brink.<sup>1</sup>

But while the public stirs, embroiled in a reopened debate focused on the future of health reform, other pieces of the health care enterprise continue their quiet value-based shift that was launched during the Obama administration. Like a projectile without gravity to slow it, new value-based mechanisms, pressures, and incentives are increasingly pushing doctors into more creative and efficient forms of practice. Medicare, after seemingly succumbing to a dominant fee-for-service paradigm for decades, has awakened, and the program is pushing providers into thinking more saliently about—and *doing* more regarding—quality and cost. In addition to shoring up Medicare's finances as it faces increasing financial pressure and swelling enrollment, a new reimbursement policy imposes a new soft pressure against providers. Concerns from the evidence-based world of quality and efficiency are seeping into Medicare's reimbursement formulas. And as a result, Medicare may finally be on the path to gaining control over its leaky finances.

Unmasked by this new value-based era, the old dominant cost-control regime is showing its wear. The hard law decision-making that has characterized the extent of federal control over the cost of Medicare is fraying. The hallmark of this regime—reliant on the federal civil False

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<sup>1</sup> To be clear, the ACA stretches its tentacles into nearly every corner of health law, clearly complicating efforts to make it completely disappear. And it has proven to be vital for millions of Americans. Now voluntary, the Medicaid Expansion under the ACA is responsible for coverage for individuals living below 138 percent of the poverty line in thirty-four states. See *Status of State Action on the Medicaid Expansion Decision*, KAISER FAMILY FOUND., <http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?currentTimeframe=0> (last updated Sept. 11, 2018). Even though down from 2016, the battered health insurance exchanges still saw more than 9.2 million Americans sign up on the federal exchanges. See Robert Pear, *Affordable Care Act Sign-Ups Dip Amid Uncertainty and Trump Attacks*, N.Y. TIMES (Feb. 3, 2017), <https://www.nytimes.com/2017/02/03/us/politics/affordable-care-act-obama-care-sign-up.html>. The ACA has reformed the fraud and abuse laws, giving the federal government increased power to target health care fraud and abuse. It has also reformed and elevated the quality of insurance plans that Americans receive. All of these reforms are theoretically at risk.

Claims Act (FCA),<sup>2</sup> a 150-year-old statute high on brute force and low on nuance—is finally looking its age. And a growing number of federal court cases, featuring allegations of fraudulent medical necessity, seem willing to reject the application of the stilted FCA to the heterogeneous and complicated world of medical practice. Whether the cases are legally defensible is up for debate, but what is clear is that the enforcement world seems poised to change. And where the old law answer gives way, the new soft law of incentives and pressures is taking its place.

This Article summarizes that development. Using a case study of the burgeoning popularity of Medicare’s hospice benefit—a new target of the Department of Justice (DOJ)’s FCA enforcement regime—this Article chronicles this shift, focusing on changes brought by reimbursement policy and their relation to the future development of the FCA in medical necessity-based fraud cases. And while recent trends do not sound the death knell for the FCA’s applicability to these cases (for the most prominent, an appeal remains), recent noteworthy cases have damaged it.

This Article proceeds in six parts. In Part II, the modern FCA enforcement mechanism, focused on new areas of rapid development and inconsistency, are introduced. In Part III, the federal government’s new focus on hospice fraud is documented. In Part IV, *U.S. v. AseraCare*,<sup>3</sup> perhaps the strongest case in support of a new era in health care fraud and abuse enforcement—and one whose appeal remains pending at the time of this writing—is summarized. Next, in Part V, the challenges that characterize fraud-based enforcement in this area—particularly focused on medical necessity-based fraud—are chronicled. Finally, in Part VI, Medicare’s new value-based reimbursement regime—ushered in by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015—is presented. It is MACRA that has revamped and evolved Medicare reimbursement policy—and has pushed American health care into embracing new value-based mechanisms.

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<sup>2</sup> 31 U.S.C. §§ 3729–3733 (2018).

<sup>3</sup> *United States v. AseraCare Inc. (AseraCare I)*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015), *appeal docketed*, No. 16-13004 (11th Cir. May 27, 2016).

## II. SUCCESSES AND CHALLENGES FOR THE FALSE CLAIMS ACT

The FCA has been used as a primary tool to prosecute cases of health care fraud,<sup>4</sup> but it also has been used as a potent fraud-fighting tool for any alleged government-related fraud in the modern era—from housing,<sup>5</sup> to education,<sup>6</sup> to environmental matters.<sup>7</sup> The FCA has been particularly active during the last decade; counting from the beginning of the modern era of FCA enforcement (beginning in 1986),<sup>8</sup> sixty percent of the federal government’s recoveries under the FCA—three of every five dollars recovered—have been made since January 2009.<sup>9</sup> And although the specific

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<sup>4</sup> Fiscal year 2016 continued a period featuring aggressive action by the DOJ in fighting health care fraud. See Press Release, U.S. Dep’t of Justice Office of Pub. Affairs, Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud (Feb. 11, 2013), <https://www.justice.gov/opa/pr/departments-justice-and-health-and-human-services-announce-record-breaking-recoveries> (“In the past fiscal year, our relentless pursuit of health care fraud resulted in the disruption of an array of sophisticated fraud schemes and the recovery of more taxpayer dollars than ever before. This report demonstrates our serious commitment to prosecuting health care fraud and safeguarding our world-class health care programs from abuse.”).

<sup>5</sup> *The False Claims Act & Federal Housing Administration Lending*, U.S. DEP’T. OF JUSTICE OFFICE OF PUB. AFFAIRS (Mar. 15, 2016), <https://www.justice.gov/opa/blog/false-claims-act-federal-housing-administration-lending>:

The Justice Department has powerful tools to address this type of misconduct. One tool, a statute called the False Claims Act, allows the department to investigate and sue entities that submit false statements and claims to the government, recover losses caused by those entities and deter similar misconduct by others. In order to protect America’s taxpayers and homeowners, the department has used the False Claims Act in a series of settlements and actions against lenders that knowingly submitted or caused the submission of false claims for FHA mortgage insurance by approving FHA insured loans that the lenders knew were not eligible.

*Id.*

<sup>6</sup> See, e.g., Press Release, U.S. Dep’t of Justice Office of Pub. Affairs, For-Profit College Company to Pay \$95.5 Million to Settle Claims of Illegal Recruiting, Consumer Fraud and Other Violations (Nov. 16, 2015), <https://www.justice.gov/opa/pr/profit-college-company-pay-955-million-settle-claims-illegal-recruiting-consumer-fraud-and>.

<sup>7</sup> See, e.g., Press Release, U.S. Dep’t of Justice Office of Pub. Affairs, Lockheed Martin Agrees to Pay \$5 Million to Settle Alleged Violations of the False Claims Act and the Resource Conservation and Recovery Act (Feb. 29, 2016), <https://www.justice.gov/opa/pr/lockheed-martin-agrees-pay-5-million-settle-alleged-violations-false-claims-act-and-resource>.

<sup>8</sup> See Joe W. Harper & Jaci L. Overmann, *Analysis of DOJ’s False Claims Act Recoveries in FY 2016, Recent Trends and Predictions for Future: \$4.7 Billion Year*, NAT’L. L. REV. (Jan. 6, 2017), <https://www.natlawreview.com/article/analysis-doj-s-false-claims-act-recoveries-fy-2016-recent-trends-and-predictions> (noting the start of “the modern era of FCA enforcement” as beginning in 1986 “when Congress significantly revised the statute to incentivize more qui tam cases”).

<sup>9</sup> Press Release, U.S. Dep’t of Justice Office of Pub. Affairs, Justice Department Recovers Over \$4.7 Billion From False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016),

direction of the Trump administration's DOJ is not known at the time of this writing,<sup>10</sup> the federal government continues to lean on the FCA to provide the balance of fraud recoveries—a posture that decisively began in conjunction with the inauguration of President Obama.<sup>11</sup> Isolating for health care fraud recoveries reveals a similar pattern: in total, the DOJ has recovered nearly \$20 billion in health care fraud claims since January of 2009, which is “57 percent of the health care fraud dollars recovered in the thirty years since the 1986 amendments to the False Claims Act.”<sup>12</sup>

Unsurprisingly, 2016 was another banner year for FCA enforcement at the DOJ. The federal government recovered more than \$4.7 billion in cases featuring FCA allegations in fiscal year 2016, which was the “third highest annual recovery in False Claims Act history.”<sup>13</sup> And \$2.5 billion of the \$4.7 billion recovered due to the FCA were recoveries from the health care industry.<sup>14</sup> Notably, the \$2.5 billion in recoveries signified an uptick from

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<https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016> [hereinafter Justice Department Recovers Over \$4.7 Billion] (noting that 60 percent of recoveries against federal programs have occurred since 2008). Further, during the Obama administration, 5,106 qui tam cases were filed (compared to 2,930 during the previous eight years under President George W. Bush), and the total recovery exceeded \$31 billion (compared to nearly \$14 billion recovered during the previous eight years under President Bush). See Harper & Overmann, *supra* note 8.

<sup>10</sup> Commentators do not seem to agree on what type of DOJ enforcement to expect under the Trump administration. See Peter J. Henning, *How Trump's Presidency Will Change the Justice Dept. and S.E.C.*, N.Y. TIMES: DEALBOOK (Nov. 9, 2016), <https://www.nytimes.com/2016/11/10/business/dealbook/how-trumps-presidency-will-change-the-justice-dept-and-sec.html> (written before the confirmation of Jeff Sessions) (“One area that is easy to cut is the money devoted to white-collar crime” and “[t]here is rarely any great hue and cry about fewer prosecutors being available to pursue health care fraud or price-fixing, the types of cases that do not generate big headlines, so moving people out of those areas is unlikely to draw much notice. Starving white-collar investigations to devote more attention to other priorities has been seen before.”); Stephen Kuperberg, *Do Not Expect Lax Financial Enforcement Under Trump*, LAW360 (Dec. 23, 2016), <https://www.law360.com/articles/876528/do-not-expect-lax-financial-enforcement-under-trump> (“Private whistleblowers under qui tam provisions . . . figure to profit handsomely by uncovering and reporting financial fraud. So too do private plaintiffs in matters that could trigger federal investigations in realms such as banking fraud, antitrust and health care fraud. Actions by these private litigants have grown significantly over the past few decades and show no sign of abating.”).

<sup>11</sup> Justice Department Recovers Over \$4.7 Billion, *supra* note 9; Harper & Overmann, *supra* note 8; Bibeka Shrestha, *FCA Recoveries Top \$3B for 2nd Year in a Row*, LAW360 (Dec. 19, 2011), <https://www.law360.com/articles/294719/fca-recoveries-top-3b-for-2nd-year-in-a-row> (“The U.S. Department of Justice said . . . it had raked in more than \$3 billion in civil False Claims Act settlements and judgments – mostly in health care fraud cases – during fiscal year 2011, marking the second consecutive year the department surpassed the \$3 billion mark.”). Further, FCA recoveries “since January 2009 [through the end of fiscal year 2011] total[ed] \$8.7 billion – the largest three-year total in the department’s history.” *Id.*

<sup>12</sup> Justice Department Recovers Over \$4.7 Billion, *supra* note 9.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* (“In many of these cases, the Department was instrumental in recovering additional millions of dollars for state Medicaid programs. This is the seventh consecutive year the

2018]

## A FAREWELL TO FALSITY

7

fiscal year 2015, which saw \$1.9 billion in FCA-related health care fraud recoveries.<sup>15</sup> This was aided by two large settlements with pharmaceutical companies.<sup>16</sup> Indeed, nearly fifty percent of the \$2.5 billion recovered was extracted from the drug and medical device industry.<sup>17</sup> In all, according to the DOJ, the FCA is responsible for more than \$31 billion in federal government recoveries since 2009.<sup>18</sup>

But this era of aggressive FCA enforcement is juxtaposed against an enforcement environment that features a substantial amount of uncertainty regarding the application of the law. Much of the confusion within FCA enforcement centers around its core component of falsity, and has been especially present in two types of FCA claims. Both of these types of claims credit the sanctity of scientific and clinical judgment while seemingly minimizing the force of law, blunting the reach of the powerful regulatory state within American health care.

The first type of claim features allegations against pharmaceutical companies—where the conception of falsity under the FCA and another law, the Food, Drug, and Cosmetic Act (FDCA),<sup>19</sup> are in direct conflict. The second type of claim arises in so-called medical necessity-based fraud cases, in which the DOJ alleges that fraud has occurred because the care administered (and subsequently billed for) was not medically necessary. This second claim has become an area of focus and interest for relators, government officials, and health care providers, and is the primary focus of this Article.<sup>20</sup>

But first, as Professor Joan Krause has written about recently regarding pharmaceutical companies, the legal standard of falsity as applied in different contexts has become inextricably complicated.<sup>21</sup> Her observations suggest an inconsistent treatment of the falsity requirement under disparate,

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Department's civil health care fraud recoveries have exceeded \$2 billion.”).

<sup>15</sup> Press Release, U.S. Dep't of Justice Office of Pub. Affairs, Justice Department Recovers Over \$3.5 Billion from False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015), <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.

<sup>16</sup> Harper & Overmann, *supra* note 8 (noting a \$785 million settlement by Wyeth and a \$390 million settlement by Novartis Pharmaceuticals). The numbers reflect both federal and state settlement amounts.

<sup>17</sup> Justice Department Recovers Over \$4.7 Billion, *supra* note 9.

<sup>18</sup> *Id.*

<sup>19</sup> 21 U.S.C.A. §§ 301–399 (2018).

<sup>20</sup> See Michael W. Youtt et al., *False Claims Act Actions—The Developing Case Law Regarding If and When Opinions of Medical Necessity Can Be Fraudulent*, 27 HEALTH LAW. 36, 36 (2015) (“The filing of False Claims Act actions alleging the false or fraudulent submission of claims for medically unnecessary Medicare or Medicaid items or services is a growing trend.”).

<sup>21</sup> See Joan H. Krause, *Truth, Falsity, and Fraud: Off-Label Drug Settlements and the Future of the Civil False Claims Act*, 71 FOOD & DRUG L. J. 401 (2016).

but related, legal regimes. Developing case law under the FDCA, including the seminal 2012 Second Circuit decision in *U.S. v. Caronia*,<sup>22</sup> has resulted in an anomalous—and undoubtedly inconsistent—regulatory scenario.<sup>23</sup>

Specifically, these trends complicate situations for pharmaceutical companies whose sales representatives tout truthful, yet unapproved (by the Food and Drug Administration (FDA)), scientific information regarding a pharmaceutical drug's effectiveness.<sup>24</sup> Under *Caronia*, sales representatives who relay truthful but unapproved drug information cannot be said to have violated the FDCA because the statements made—while violative of the FDA's marketing laws, as they disseminate information that has not been vetted or approved by the FDA—are *scientifically true*.<sup>25</sup> That is, *some* courts<sup>26</sup> are finding that truthful, but off-label, unapproved scientific marketing is not violative of the FDCA. In effect, courts are carving out an area of truthful marketing from the reach of the FDCA, which may have a number of detrimental effects.<sup>27</sup>

The challenge of choosing to enforce off-label marketing in this way, however, means that the legal standard—that is, whether or not the pharmaceutical sales marketing staff can advertise and market a drug in a certain way—hinges on whether the statement is scientifically true, and not on whether the statement has been approved by the FDA.<sup>28</sup> This new application could have a number of deleterious effects, not the least of which is the challenge surrounding *how exactly* one knows whether the statement is scientifically true. But, beyond this challenge, this trend has confused application of the fraud laws to these scenarios. Indeed, as Professor Krause notes, this new theory of liability regarding falsity has not yet migrated out of FDCA enforcement and into FCA enforcement, and, consequently, a glaring inconsistency currently exists.<sup>29</sup> Notwithstanding the FDCA's

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<sup>22</sup> *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) (vacating Caronia's conviction under the federal Food, Drug, and Cosmetic Act).

<sup>23</sup> Krause, *supra* note 21, at 403 (“Yet logic suggests that if manufacturers have a First Amendment right to *discuss* truthful off-label uses of their products, bills submitted to Medicare or Medicaid when the drugs are *used* for those indications should not be considered false.”) (emphasis in original).

<sup>24</sup> *Id.* at 403.

<sup>25</sup> *Id.* at 418.

<sup>26</sup> See *Jones v. Medtronic*, 89 F. Supp. 3d 1035, 1047 (D. Ariz. 2015), *aff'd & vacated in part*, No. 15-15653, 2018 WL 3912167 (9th Cir. 2018) (“Courts differ as to whether ‘off-label’ promotion and use violates FDA requirements. Some courts hold that federal law does not bar off-label promotion, while other courts hold that the FDCA’s misbranding provisions ban off-label promotion.”).

<sup>27</sup> *Id.*; see also Christopher T. Robertson, *The Tip of the Iceberg: A First Amendment Right to Promote Drugs Off-Label*, 78 OHIO ST. L. J. 1019 (2017); Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO ST. L. J. 1053 (2017).

<sup>28</sup> Krause, *supra* note 21, at 418.

<sup>29</sup> *Id.* at 403.



2018]

## A FAREWELL TO FALSITY

9

application to truthful, but off-label marketing, under FCA enforcement, whether or not the marketing is scientifically true is immaterial; when off-label marketing leads to a prescription and a reimbursement, the FCA is violated.<sup>30</sup> Based on current FCA precedent, off-label marketing of a drug transforms its claim for *reimbursement* into a false claim for purposes of FCA liability.

As a result, a pharmaceutical company's sales and marketing personnel—if engaged in truthful, but off-label, marketing—may not be prosecuted under the FDCA because the statements made were not scientifically false, but they continue to face liability under the FCA.<sup>31</sup> Strangely, there has been an inadequate effort made to address this inconsistency, and a quiet equipoise has been reached.

The second type of shift—on which the balance of this paper, as well as previous scholarship,<sup>32</sup> focuses—features the enduring problem of medical necessity-based fraud. New court-made doctrine has limited the DOJ's ability to reach these types of cases with the FCA. Besides uprooting settled notions of falsity, this new doctrine is likely to change the settlement calculus for defendants targeted in a medical necessity-based FCA case.<sup>33</sup> Specifically, in these cases—and in one particularly prominent case—courts have begun to push back on the notion that the DOJ can maintain FCA liability for care that is allegedly lacking in medical necessity. In addition to signaling a change for all providers, this shift has particular implications for doctors who rely on Medicare's hospice benefit, which is explored deeply below.

## III. A NEW FRONT: HOSPICE FRAUD

Recent cases featuring FCA enforcement have illustrated an increased focus on hospice care as posing a potentially potent threat of fraud within the American health care marketplace.<sup>34</sup> Hospice care, defined as care that

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<sup>30</sup> *Id.* at 419 (noting that “off label promotion leads to a violation of the FCA on the somewhat circular theory that claims for non-covered drugs are false because the drugs are not being used for medically accepted (i.e., covered) purposes”).

<sup>31</sup> *Id.*

<sup>32</sup> See Isaac D. Buck, *Breaking the Fever: A New Construct for Regulating Overtreatment*, 48 U.C. DAVIS L. REV. 1261 (2015) (proposing a reconceptualization of the harm of medical necessity-based overtreatment, from care that is lacking in medical necessity to care that is excessively administered).

<sup>33</sup> Indeed, because of the potency of the FCA, many medical necessity-based fraud cases have heretofore ended in settlement, and the interest in these cases has remained academic.

<sup>34</sup> See, e.g., Robert W. Markette & Anne M. Ruff, *Hospice Providers Under Increased Governmental Scrutiny*, 16 J. HEALTH CARE COMPLIANCE 45, 45–46 (2014) (“This growth is leading to increased scrutiny of the hospice industry.”); Kris B. Mamula, *Hospice Fraud Becoming a Costly Problem for Medicare*, PITTSBURGH POST-GAZETTE (Mar. 6, 2016), <http://www.post-gazette.com/business/healthcare-business/2016/03/06/Hospice-fraud->

focuses on palliation, or pain relief, as opposed to curative treatment, often is administered outside of the hospital and applies a “team-oriented approach to expert medical care, pain management, and emotional and spiritual support expressly tailored to the patient’s needs and wishes.”<sup>35</sup> A quickly growing piece of the Medicare budget,<sup>36</sup> the hospice benefit has enjoyed increasing usage and societal acceptance in recent years. An analysis of (1) the hospice benefit’s growing prominence within American health care and Medicare, and (2) hospice’s increasing attractiveness to FCA enforcement, follows immediately below.

#### A. *An Explosion of Hospice Care*

To understand why federal regulators and prosecutors have increasingly focused on hospice, one need look no further than the number of Americans utilizing the services and the amount of money Medicare spends on it. In short, the number of Americans utilizing hospice services has risen sharply over the last couple of decades.<sup>37</sup> Specifically, according to National Hospice and Palliative Care Organization (NHPCO) estimates, the number of Americans who have sought and received hospice services has risen from 1.38 million in 2010, to 1.46 million in 2011, to 1.5 million in 2012 and 2013, to 1.67 million in 2014.<sup>38</sup>

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estimates-at-65-billion/stories/201603060044 (“No one knows how big the problem of hospice fraud is . . . but federal investigators prosecuted more than 60 cases in the last year alone, involving hundreds of millions of dollars nationwide.”); Press Release, U.S. Dep’t of Justice U.S. Attorney’s Office, S. Dist. Miss., Cleveland Mississippi Hospice Owner Sentenced for Healthcare Fraud and Ordered to Pay Over 5 Million Dollars in Restitution (Sept. 14, 2016), <https://www.justice.gov/usao-sdms/pr/cleveland-mississippi-hospice-owner-sentenced-healthcare-fraud-and-ordered-pay-over-5> [hereinafter Cleveland Mississippi Hospice Owner Sentenced] (documenting criminal charges and restitution as a result of an elaborate health care fraud scheme).

<sup>35</sup> See Kathleen Tschantz Unroe & Diane E. Meier, *Palliative Care and Hospice: Opportunities to Improve Care for the Sickest Patients*, 25 NOTRE DAME J. L. ETHICS & PUB. POL’Y 413, 415 (2011) (“The hospice [Medicare] benefit was designed for clearly dying patients to provide team-based palliative care, usually at home. Hospice is appropriate when curative treatments are no longer beneficial, when the burdens of treatments outweigh benefits, or when patients enter the last weeks to months of life.”); see also *Hospice Care*, NAT’L HOSPICE & PALLIATIVE CARE ORG., <http://www.nhpc.org/about/hospice-care> (last updated Apr. 3, 2017).

<sup>36</sup> See Sam Halabi, *Selling Hospice*, 42 J. L. MED. & ETHICS 442, 442 (2014) (“Now, hospice is one of the fastest growing costs of Medicare, which began covering hospice in 1983.”).

<sup>37</sup> See NHPCO’s Facts and Figures: Hospice Care in America, 2015 Edition, NAT’L HOSPICE & PALLIATIVE CARE ORG., [https://www.nhpc.org/sites/default/files/public/2015\\_Facts\\_Figures.pdf](https://www.nhpc.org/sites/default/files/public/2015_Facts_Figures.pdf) [hereinafter NHPCO’s Facts and Figures] (last visited Feb. 8, 2017).

<sup>38</sup> *Id.* at 4. Reportedly, 1.2 million Americans die each year in hospice care, which is nearly half of the 2.6 million deaths that occur annually in America. See Eric Adler, *A Good Death: As End of Life Nears, An Unexpected Friendship Forms in KC Hospice*, KAN. CITY STAR (Apr. 23, 2016), <http://www.kansascity.com/news/local/article73547107.html>.

In addition to the raw number of hospice utilizers, this growth also represents an increase in the proportion of Medicare decedents relying on hospice services at the end of life.<sup>39</sup> In 2001, less than nineteen percent of Medicare decedents had spent time receiving hospice care.<sup>40</sup> By 2007, that number had jumped to thirty percent,<sup>41</sup> and by 2014, the number approached fifty percent.<sup>42</sup> For those Medicare decedents battling cancer, the number grew from thirty-seven percent in 2001 to forty-three percent in 2007.<sup>43</sup>

Accompanying the growth in the number of patients seeking hospice care, the amount of hospice agencies has concurrently boomed.<sup>44</sup> The overall number of hospices in the United States has steadily increased, with 5,150 in 2010 to 6,100 in 2014.<sup>45</sup> Of these, more than 4,000 are Medicare-certified hospice providers, up from just 1,000 in 1992, to 2,000 in 1996, and 3,000 in 2007.<sup>46</sup> A majority of these 4,000 hospices are for-profit hospice agencies.<sup>47</sup> Indeed, as of 2014, about sixty percent of hospice-providing agencies had for-profit ownership.<sup>48</sup>

Spending on hospice care has soared: Medicare spending on the service quadrupled between 2000 and 2008.<sup>49</sup> In both 2013 and 2014, Medicare

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<sup>39</sup> NHPCO's Facts and Figures, *supra* note 37, at 4.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* Interestingly, the typical length of hospice service varies quite drastically. More than thirty-five percent of those who access hospice services either die or are discharged within seven days of admission. *Id.* at 5. About eighteen percent of those who access hospice services spend between thirty and eighty-nine days receiving services. *Id.* And just more than ten percent of those accessing hospice receive services for more than 180 days. *Id.* Indeed, the fact that the average hospice stay is so short gives rise to the argument that hospice services are underutilized. See Leah Eskenazi, *Why Hospice Care Could Benefit Your Loved One Sooner than You Think*, PBS NEWSHOUR (Jan. 29, 2015, 6:10 PM), <http://www.pbs.org/newshour/updates/hospice-care-might-benefit-loved-one-sooner-think/> ("People often wait too long before seeking hospice care. . . . It seems that misinformation about the benefit coupled with our general discomfort talking about end of life prevents Medicare beneficiaries and their families from taking advantage of the valuable benefit.")

<sup>42</sup> *Ten FAQs: Medicare's Role in End-of-Life Care*, KAISER FAMILY FOUND. (Sept. 26, 2016), <http://kff.org/medicare/fact-sheet/10-faqs-medicares-role-in-end-of-life-care/> [hereinafter *Ten FAQs*].

<sup>43</sup> NHPCO's Facts and Figures, *supra* note 37, at 4.

<sup>44</sup> *Id.* at 8.

<sup>45</sup> *Id.* at 8 (the first hospice program opened in 1974).

<sup>46</sup> *Id.* at 9.

<sup>47</sup> *Id.* at 9 ("The number of for-profit Medicare-certified hospice providers has been steadily increasing over the past several years . . . . In contrast, the number of Medicare-certified not-for-profit or government providers has declined over the same period.")

<sup>48</sup> *National Center for Health Statistics: Hospice Care*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchs/fastats/hospice-care.htm> (last updated July 6, 2016). See also Halabi, *supra* note 36, at 443 (noting that "the economic and commercial structure of hospice provision has also radically changed").

<sup>49</sup> See Markette & Ruff, *supra* note 34, at 45–46:

In its report on hospice, MedPAC noted that from 2000 to 2008, Medicare

spent more than \$15 billion on hospice care,<sup>50</sup> which overshadowed the \$2.9 million Medicare spent on hospice in 2000.<sup>51</sup> For those in the final year of life, “[h]ospice care accounts for about 10 percent of traditional Medicare spending.”<sup>52</sup>

As a sign of hospice services’ growth and their increasing prominence in the American health care system, *The Washington Post* published a groundbreaking series in late 2013 and 2014 on the increasing profitability of the hospice industry in the United States.<sup>53</sup> The series highlighted how, within recent years, profits have ballooned within the industry.<sup>54</sup> It also raised the profile of the hospice industry, highlighting the new era of hospice fraud enforcement. How, exactly, the hospice benefit became a major target for anti-fraud efforts and FCA enforcement is explored immediately below.

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hospice spending had quadrupled. MedPAC went on to raise concerns about the growth in hospice utilization, and the report specifically noted that one of the drivers of this growth was the increased election of hospice services by non-cancer patients, which accounted for 69 percent of all hospice patients in 2008.

*Id.*

<sup>50</sup> See *The Medicare Hospice Benefit*, NAT’L HOSPICE & PALLIATIVE CARE ORG., at 3 (Oct. 2015), [http://www.nhpco.org/sites/default/files/public/communications/Outreach/The\\_Medicare\\_Hospice\\_Benefit.pdf](http://www.nhpco.org/sites/default/files/public/communications/Outreach/The_Medicare_Hospice_Benefit.pdf) (noting that Medicare expenditures on hospice “remained flat” between 2012 and 2013); *Fact Sheet: Medicare Hospice Transparency Data (CY2014)*, CTRS. FOR MEDICARE & MEDICAID SERVS.: NEWSROOM (Oct. 6, 2016), <https://www.cms.gov/newsroom/fact-sheets/medicare-hospice-transparency-data-cy2014>.

<sup>51</sup> See Mamula, *supra* note 34.

<sup>52</sup> *Ten FAQs*, *supra* note 42.

<sup>53</sup> See Peter Whoriskey & Dan Keating, *Hospice Firms Draining Billions from Medicare*, WASH. POST (Dec. 26, 2013), [https://www.washingtonpost.com/business/economy/medicare-rules-create-a-booming-business-in-hospice-care-for-people-who-arent-dying/2013/12/26/4ff75bbe-68c9-11e3-ae56-22de072140a2\\_story.html?utm\\_term=.7dee235da9f9](https://www.washingtonpost.com/business/economy/medicare-rules-create-a-booming-business-in-hospice-care-for-people-who-arent-dying/2013/12/26/4ff75bbe-68c9-11e3-ae56-22de072140a2_story.html?utm_term=.7dee235da9f9).

<sup>54</sup> See Peter Whoriskey, Dan Keating, & Tobey, *Healthy Growth in Hospice Profits*, WASH. POST (Dec. 26, 2013), <http://apps.washingtonpost.com/g/page/business/healthy-growth-in-hospice-profits/689/> (using data gathered from hospice in California, a Washington Post review found that (1) net operating profit per patient in the hospice sector rose from \$353 in 2002 to \$1975 in 2012, (2) net operating profit overall rose from \$25 million in 2002 to \$265 million in 2012, (3) the average length of hospice care stretched from 44 days in 2002 to 66 days in 2012 (including non-cancer cases growing from 41 days in 2002 to 76 days in 2012), (4) the amount of facilities offering hospice has boomed from 173 facilities in 2002 to 431 facilities in 2012, and (5) the number of patients in hospice has nearly doubled—from 71,535 in 2002 to 134,126 in 2012).

### B. *Why Hospice Attracts the FCA*

The booming business of Medicare's hospice benefit has raised questions about the costly incentives that exist within it.<sup>55</sup> Indeed, put bluntly, "concerns are rising about treatments for patients who aren't near death."<sup>56</sup> This rapid growth of the industry, vague clinical standards around necessity, and dark incentives flowing from reimbursement policy, have placed the hospice benefit squarely within the sights of the DOJ.<sup>57</sup>

In order to be a reimbursable service within the Medicare program, hospice services—and the patients for which they are intended<sup>58</sup>—must comply with and meet particular regulatory requirements.<sup>59</sup> Specifically, a physician or medical director must "specify that the individual's prognosis is for a life expectancy of six months or less if the terminal illness runs its course," the provider must supply clinical information that demonstrates this judgment, the "physician must include a brief narrative explaining the clinical findings that supports a life expectancy of [six] months or less as part of the certification and recertification forms," and the physician must sign and date the certification.<sup>60</sup> This certification serves as the center of the conflict around cases of alleged hospice fraud—including the complexity, heterogeneity, and uncertainty that comes with it.<sup>61</sup>

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<sup>55</sup> See Markette & Ruff, *supra* note 34, at 45–46 ("MedPAC also noted that the hospice reimbursement system, which reimbursed the hospice a flat amount for each day of hospice service, created an incentive to try to admit patients who would remain on hospice for longer periods of time.").

<sup>56</sup> Peter Whoriskey, *As More Hospices Enroll Patients Who Aren't Dying, Questions About Lethal Doses Arise*, WASH. POST (Aug. 21, 2014), [https://www.washingtonpost.com/news/storyline/wp/2014/08/21/as-more-hospices-enroll-patients-who-arent-dying-questions-about-lethal-doses-arise/?utm\\_term=.cefcfac5ac4a](https://www.washingtonpost.com/news/storyline/wp/2014/08/21/as-more-hospices-enroll-patients-who-arent-dying-questions-about-lethal-doses-arise/?utm_term=.cefcfac5ac4a) ("As the hospice industry has grown, hospices are more frequently enrolling patients who aren't near death.").

<sup>57</sup> See Halabi, *supra* note 36, at 450–51 (detailing FCA allegations against Vitas Innovative Hospice Care); see also Markette & Ruff, *supra* note 34, at 71 ("The increased suspicion of the hospice industry has also led to an increase in the number of hospices being sued under the federal False Claims Act. . . . Following the lead of the OIG and MedPAC, these lawsuits have focused on issues related to patient eligibility and include allegations that hospices have admitted ineligible patients, kept patients on hospice services for which they were ineligible, and provided medically unnecessary services."); Mark H. Schlein, *Non-Pharmaceutical False Claim Cases*, ANNUAL AAJ-PAPERS 118 (2012) (noting that hospice fraud is "high on the HHS OIG list" and is "widespread.").

<sup>58</sup> See, e.g., 42 C.F.R. § 418.3 (2014) (mandating that "[t]erminally ill means that the individual has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course").

<sup>59</sup> See 42 U.S.C. § 1395(dd) (2018) (laying out the hospice program, requirements, certification, and definitions); see also 42 C.F.R. § 418.22 (2011) (laying out requirements to meet the certification of terminal illness).

<sup>60</sup> 42 C.F.R. §§ 418.22(b)(1)–(3), (5) (2011).

<sup>61</sup> See Bernice Yeung, *AseraCare Hospice, San Francisco-Owned Company, Accused of Medicare Fraud*, HUFFINGTON POST (Jan. 6, 2012), [https://www.huffingtonpost.com/2012/01/06/aseracare-hospice-medicare-fraud\\_n\\_1190658.html](https://www.huffingtonpost.com/2012/01/06/aseracare-hospice-medicare-fraud_n_1190658.html) (quoting a relator's attorney calling

With an increasing emphasis on the hospice benefit, and a growing number of citizens reaching retirement age, both the Office of Inspector General (OIG) within the Department of Health and Human Services, and the DOJ, have turned attention to the problem of hospice fraud.<sup>62</sup> The DOJ's focus is illustrated by a flurry of recent settlements.<sup>63</sup> In one such settlement, the DOJ alleged that the hospice agency's "business practices were designed to maximize the number of patients for whom it could bill Medicare without regard to whether the patients were eligible for and needed hospice."<sup>64</sup> Further, the allegations focused on actions undertaken by the defendants that "allegedly included discouraging doctors from recommending that ineligible patients be discharged from hospice[,] and failing to ensure that nurses accurately and completely documented patients' conditions in the medical records."<sup>65</sup> In another recent settlement, the OIG Special Agent in Charge lamented that "[p]atients are being falsely diagnosed as terminally ill in order

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the terminal illness certification "as much a metaphysical question as a medical question" and noting that "[t]here's a lot of wiggle room, and where there's wiggle room, you have people who will take advantage of it for their financial gain").

<sup>62</sup> See, e.g., Suzanne Murrin, *Hospices Should Improve Their Election Statements and Certifications of Terminal Illness*, U.S. DEP'T OF HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GEN. (Sept. 2016), <https://oig.hhs.gov/oei/reports/oei-02-10-00492.pdf>.

<sup>63</sup> See, e.g., Press Release, U.S. Dep't of Justice Office of Pub. Affairs, Minnesota-Based Hospice Provider to Pay \$18 Million for Alleged False Claims to Medicare for Patients Who Were Not Terminally Ill (Jul. 13, 2016), <https://www.justice.gov/opa/pr/minnesota-based-hospice-provider-pay-18-million-alleged-false-claims-medicare-patients-who> [hereinafter Minnesota-Based Hospice Provider to Pay \$18 Million] (noting that the settlement resolved allegations under the FCA that Evercare Hospice and Palliative Care "claimed Medicare reimbursement for hospice care for patients who were not eligible for such care because they were not terminally ill"); Press Release, U.S. Dep't of Justice U.S. Attorney's Office, N. Dist. Iowa, Hospice to Pay More Than \$1 Million to Resolve False Claims Act Allegations (Dec. 18, 2015), <https://www.justice.gov/usao-ndia/pr/iowa-hospice-pay-more-1-million-resolve-false-claims-act-allegations> (noting a settlement of nearly \$1.1 million to settle allegations that "Iowa [h]ospice knowingly submitted false claims to the government for payment of [hospice] services because, during some or all of the period that certain patients were receiving hospice care, the patients did not have a medical prognosis of six months or less if their illnesses ran their normal course"); Jennifer Williams & Rose Betts, *Guardian Hospice Pays \$3 Million to Resolve Medicare Fraud Allegations*, ATLANTA BUS. CHRON. (Oct. 2, 2015), <http://www.bizjournals.com/atlanta/news/2015/10/02/guardian-hospice-pays-3-million-to-resolve.html> (noting that the settlement ended claims that defendants sought reimbursement for hospice services for patients who were not terminally ill, and that they failed to "properly train . . . staff and medical directors on the hospice eligibility criteria, set[] aggressive targets to recruit and enroll patients, and fail[ed] to properly oversee the Atlanta hospice"); *Hospice to Pay Millions in Settlement for Medicare Fraud*, WASH. TIMES (Feb. 12, 2015), <https://www.washingtontimes.com/news/2015/feb/12/hospice-to-pay-millions-in-settlement-for-medicare/> (noting that Good Shepherd Hospice Inc. entered into a settlement following allegations from the federal government that Good Shepherd "pressured employees to meet census and hospice admissions targets" and that "employees were paid bonuses based on the number of patients enrolled").

<sup>64</sup> Minnesota-Based Hospice Provider to Pay \$18 Million, *supra* note 63.

<sup>65</sup> *Id.*

to line the pockets of hospice owners who are treating Medicare like their own personal ATM.”<sup>66</sup>

These allegations are not unique, and they led the OIG to file a report in the fall of 2016 entitled, “Hospices Should Improve Their Election Statements and Certifications of Terminal Illness.”<sup>67</sup> There remains little room for misunderstanding; in the report, the OIG found that “[p]revious OIG work has raised concerns that some election statements used by hospices are misleading[,] and that physicians are sometimes not involved in care planning and may rarely visit beneficiaries.”<sup>68</sup> The report contained examples of hospice services fraudulently submitting false claims regarding hospice eligibility.<sup>69</sup> Importantly for the instant purposes, the report noted that fourteen percent of GIP (“general inpatient”) stays were accompanied by a deficient certification in violation of federal rules.<sup>70</sup> And “in [ten] percent of stays, the certifying physician did not include a narrative at all or included only the beneficiary’s diagnosis.”<sup>71</sup> As a result, the OIG asserted “that the certifying physician did not explain the clinical findings that support a life expectancy for the beneficiary of [six] months or less.”<sup>72</sup>

These developments have also led the Centers for Medicare and Medicaid Services (CMS) to alert providers to the potential waste and abuse that could exist within the hospice program related to terminal illness certification. Policy papers encourage hospice providers to “train[] staff on hospice eligibility, medical necessity, and proper documentation to avoid any undue penalties or sanctions[,]”<sup>73</sup> and push them to “make sure staff members understand anti-fraud efforts,” and to “provide proper training regarding the False Claims Act.”<sup>74</sup>

The concern is based upon undeniable trends. According to a 2014 report published in the *Journal of Palliative Medicine* in which the authors reviewed more than one million Medicare records, they found that “[m]ore

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<sup>66</sup> Cleveland Mississippi Hospice Owner Sentenced, *supra* note 34, at 8.

<sup>67</sup> Murrin, *supra* note 62, at 12.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* (noting in one case that “the hospice owner also paid health care professionals for referring patients to his hospice even though they were not appropriate for hospice care”).

<sup>70</sup> *Id.* at 11.

<sup>71</sup> *Id.* at 11.

<sup>72</sup> *Id.* at 11.

<sup>73</sup> *Program Integrity—An Overview for Hospice Providers*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 2016), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/hospice-provideroverview-factsheet.pdf> [hereinafter *Program Integrity—An Overview for Hospice Providers*].

<sup>74</sup> *Hospice Toolkit: Program Integrity—An Overview for Medicaid Hospice Providers*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 2016), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/hospice-provideroverview-booklet.pdf>.

than one-third of patients who were released alive from hospices did not re-enroll in a hospice and were still alive six months after being released.<sup>75</sup> This tracks an undeniable increase in the *length* of time that individuals are using the hospice benefit—as “[t]he average length of a stay [in hospice] rose to 86 days in 2011 from 54 days in 2000.”<sup>76</sup> By 2014, that number was 88 days.<sup>77</sup> There has been a marked split between for-profit and nonprofit hospice entities regarding the average length of stay in hospice: in 2013, the average stay for for-profit hospice was 105 days, while the average stay for nonprofits was 68 days.<sup>78</sup>

Finally, even though they tend to vary wildly, states’ “live discharge” rates, that is, the percentage of individuals who are discharged from the hospice program alive, are rising overall.<sup>79</sup> According to a recent report, the live discharge percentage ranged from forty-one percent in Mississippi, to thirty-five percent in Alabama, to seventeen percent and sixteen percent in Arkansas and Tennessee, respectively.<sup>80</sup> Live discharge rates exceeded twenty-five percent in five states—in addition to Mississippi and Alabama, the rates were highest among Oklahoma, South Carolina, and Utah.<sup>81</sup> This means that in these five states, more than one in every four patients certified for Medicare’s hospice benefit ends up being discharged from the program alive, raising questions about the certification process.

All of this data pressures the enforcement agencies tasked with overseeing Medicare expenditures. Although these trends do not conclusively prove that some providers are taking advantage of Medicare’s hospice benefit, they also seem to suggest an undeniable shift in hospice care provision—from shorter to longer stays.<sup>82</sup> Whether or not these shifts are indicative of health care fraud hinge on whether or not the hospice care has

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<sup>75</sup> See Joan M. Teno et al., *A National Study of Live Discharges from Hospice*, 17 J. PALLIATIVE MED. 1081 (2014), [http://online.liebertpub.com/doi/abs/10.1089/jpm.2013.0595?](http://online.liebertpub.com/doi/abs/10.1089/jpm.2013.0595?journalCode=jpm) journalCode=jpm; Peter Whoriskey & Dan Keating, *Rising Rates of Hospice Discharge in U.S. Raise Questions About Quality of Care*, WASH. POST (Aug. 6, 2014), [https://www.washingtonpost.com/business/economy/leaving-hospice-care-alive-rising-rates-of-live-discharge-in-the-us-raise-questions-about-quality-of-care/2014/08/06/13a4e7a0-175e-11e4-9e3b-7f2f110c6265\\_story.html?tid=a\\_inl&utm\\_term=.3662fb5e6967](https://www.washingtonpost.com/business/economy/leaving-hospice-care-alive-rising-rates-of-live-discharge-in-the-us-raise-questions-about-quality-of-care/2014/08/06/13a4e7a0-175e-11e4-9e3b-7f2f110c6265_story.html?tid=a_inl&utm_term=.3662fb5e6967).

<sup>76</sup> Mamula, *supra* note 34.

<sup>77</sup> See *Hospice Services*, in REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 300 (Mar. 2016), <http://www.medpac.gov/docs/default-source/reports/chapter-11-hospice-services-march-2016-report-.pdf> (last visited Feb. 17, 2017).

<sup>78</sup> See Mamula, *supra* note 34.

<sup>79</sup> See Whoriskey & Keating, *supra* note 75 (noting that, between 2000 and 2012, “the overall rate of live discharges increased from 13.2 percent of hospice discharges to 18.1 percent in 2012”).

<sup>80</sup> Whoriskey & Keating, *supra* note 75.

<sup>81</sup> *Id.*

<sup>82</sup> See Mamula, *supra* note 34.



been certified as medically necessary by a physician<sup>83</sup>—which is where the center of the battle against hospice fraud currently resides.

#### IV. UNITED STATES V. ASERACARE

Attempting to use the FCA as a powerful tool against perceived greed and ballooning profits from health care companies is nothing new, but the progression and resolution of *United States v. AseraCare*<sup>84</sup>—featuring a prominent hospice provider, multiple attention-grabbing court decisions, and important new standards for medical-necessity based FCA cases—is unmatched. Because of the complex medical necessity-based conflict that can exist within the hospice reimbursement structure, the amount of allegations from multiple relators featuring medical necessity-based allegations, and the result of the *AseraCare* case in early 2016, hospice fraud enforcement is garnering increasing interest and attention.<sup>85</sup> No matter the ultimate resolution of the *AseraCare* case—an appeal is pending before the Eleventh Circuit at the time of this writing<sup>86</sup>—it provides a worthwhile lens through which to examine the legal issues at stake. The story of this seminal case—from the allegations through the trials—follows immediately below.

##### A. About AseraCare

AseraCare Hospice (“AseraCare”) is, undeniably, a large for-profit hospice chain.<sup>87</sup> It owns facilities in nineteen states,<sup>88</sup> and admits 10,000 patients annually.<sup>89</sup> AseraCare is described as a hospice and palliative care company,<sup>90</sup> but also offers multifaceted services for those facing the end of life—including nursing care, bereavement counseling, spiritual support, pet

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<sup>83</sup> See Buck, *supra* note 32; *Program Integrity—An Overview for Hospice Providers*, *supra* note 73.

<sup>84</sup> U.S. *ex rel.* Paradies v. AseraCare, Inc., No. 2:12-cv-00245 (N.D. Ala. May 2, 2008).

<sup>85</sup> See Ina Jaffe, *HHS Inspector General’s Report Finds Flaws and Fraud in U.S. Hospice Care*, NPR: POLICY-ISH (Jul. 31, 2018), <https://www.npr.org/sections/health-shots/2018/07/31/634075540/hhs-inspector-generals-report-finds-flaws-and-fraud-in-u-s-hospice-care>.

<sup>86</sup> See Lois Norder, *Pending Court Ruling Could Be Pivotal in Health Care Fraud Case*, ATLANTA J. CONST. (Mar. 6, 2018), <https://www.myajc.com/news/crime—law/pending-court-ruling-could-pivotal-health-care-fraud-cases/g2MehFpQxMYRliqv3lan1I/>.

<sup>87</sup> See Whoriskey & Keating, *supra* note 53.

<sup>88</sup> See Lisa Schencker, *Hospice Provider AseraCare Scores a Win in Unusual False Claims Case*, MOD. HEALTHCARE (Mar. 31, 2016), <http://www.modernhealthcare.com/article/20160331/NEWS/160339976>.

<sup>89</sup> See *id.* (“AseraCare facilities see about 10,000 patient admissions each year, according to court documents. Most patients are enrolled in Medicare.”).

<sup>90</sup> See Melinda Crosby, *The Ugly Face of Profiteering in Hospice Care—For-Profit Effects on the Field*, NONPROFIT Q. (Sept. 20, 2016), <https://nonprofitquarterly.org/2016/09/20/ugly-face-profiteering-hospice-care-profit-effects-field/> (noting the prevalence of hospice fraud in the health care system).

and music therapy, nutrition counseling, social worker counseling, personal care assistance, and rehabilitation therapy.<sup>91</sup> Its services are available in three different settings—at home, in nursing facilities, and at assisted living facilities.<sup>92</sup>

AseraCare is owned by Golden Living, LLC (“Golden Living”), one of the largest private companies in the United States.<sup>93</sup> Founded in 1963 and based in Plano, Texas, Golden Living, which also owns other health care companies including Aegis Therapies and 360 Healthcare Staffing, had grown to employ 42,000 workers by 2016.<sup>94</sup> Its total revenue in 2015 topped \$3 billion.<sup>95</sup> It is self-described as “one of the nation’s premier providers of health care services for the aging.”<sup>96</sup>

Nevertheless, AseraCare would become the target of fraud allegations made both by private relators and the federal government claiming that the company engaged in hospice fraud to illegitimately boost its profits.<sup>97</sup> The three private relators’ lawsuits, based on violations of the federal FCA, were originally filed in 2008, 2009, and 2010.<sup>98</sup> All three lawsuits, which were filed in Alabama, Wisconsin, and Georgia, alleged similar fraudulent conduct by AseraCare.<sup>99</sup>

#### B. *Procedural History*

The *AseraCare* action has a unique procedural history. The DOJ initially intervened in the lawsuit filed in the Northern District of Alabama—by relators and former employees Dawn Richardson and Marsha Brown.<sup>100</sup>

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<sup>91</sup> See ASERACARE HOSPICE, <http://www.aseracare.com/services/> (last visited Jan. 23, 2017).

<sup>92</sup> *Id.*

<sup>93</sup> See *America’s Largest Private Companies 2017: #150 Golden Living*, FORBES, <http://www.forbes.com/companies/golden-living/> (last visited Oct. 10, 2018).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> Press Release, AseraCare Hospice, AseraCare Hospice Responds to U.S. Attorney / Department of Justice Filing (Jan. 3, 2012), <http://www.modernhealthcare.com/assets/pdf/CH7701013.PDF> [hereinafter *AseraCare Hospice Responds to U.S. Attorney*].

<sup>97</sup> See Norder, *supra* note 86.

<sup>98</sup> One lawsuit was filed in May of 2008 by relators Debora Paradies, London Lewis, and Roberta Manley in the Eastern District of Wisconsin. Motion to Procedurally Consolidate at 2, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Jul. 13, 2012) [hereinafter *Motion to Procedurally Consolidate*]. A second lawsuit was filed on March 27, 2009, by relators Dawn Richardson and Marsha Brown in the Northern District of Alabama, and a third was filed by relator Joseph L. Micca, in the Northern District of Georgia. *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> See Press Release, U.S. Dep’t of Justice Office of Pub. Affairs, U.S. Files Complaint Against National Chain of Hospice Providers Alleging False Claims on the Medicare Program (Jan. 3, 2012), <https://www.justice.gov/opa/pr/us-files-complaint-against-national-chain->

Specifically, the U.S. government intervened, and that complaint was unsealed on December 22, 2011.<sup>101</sup> On January 3, 2012, through a public press release, the DOJ announced its reasons for intervening in the FCA whistleblower lawsuit against AseraCare.<sup>102</sup>

In addition to the lawsuit filed by Richardson and Brown in Alabama, the other two lawsuits—filed in Georgia and Wisconsin—raised similar allegations, so the parties sought to consolidate all three cases in the Northern District of Alabama.<sup>103</sup> On January 23, 2012, District Court Judge J.P. Stadtmueller granted transfer of the action pending before the Eastern District of Wisconsin to the Northern District of Alabama due to “convenience and the interests of justice.”<sup>104</sup> And after requesting a transfer on December 13, 2011,<sup>105</sup> the Northern District of Georgia granted a transfer of Counts III and VI of relator Joseph L. Micca’s complaint (these featured the hospice fraud allegations) to the Northern District of Alabama.<sup>106</sup> This latter transfer was made on June 22, 2012.<sup>107</sup>

Once the lawsuits were transferred and consolidated, the DOJ filed a

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hospice-providers-alleging-false-claims-medicare [hereinafter U.S. Files Complaint Against National Chain of Hospice Providers].

<sup>101</sup> See Joe Carlson, *Feds File Suit Against Hospice Provider AseraCare*, MODERN HEALTHCARE (Jan. 3, 2012), <http://www.modernhealthcare.com/article/20120103/NEWS/301039961>. The DOJ had initially intervened in the case brought by Brown and Richardson, and a consolidated complaint in intervention in 2012 was filed after other actions were combined with it. *Id.*

<sup>102</sup> U.S. Files Complaint Against National Chain of Hospice Providers, *supra* note 100.

<sup>103</sup> See Motion to Procedurally Consolidate, *supra* note 98.

<sup>104</sup> *United States v. AseraCare, Inc.*, No. 08-cv-384-JPS, 2012 WL 187519, at \*2 (E.D. Wis. Jan. 23, 2012) (“Underlying this dispute is the existence of two similar False Claims Act [] actions, one in the Northern District of Georgia, and one in the Northern District of Alabama, both of which have been unsealed at this juncture . . . . The Georgia and Alabama actions were also brought against AseraCare, by different relators, for at least similar Medicare fraud claims. The United States has intervened in the Alabama action and filed its complaint against AseraCare.”). In granting transfer, the Court noted the “duplicative discovery and overlapping issues” as well as a “relatively similar set of core facts.” *Id.* at \*12.

<sup>105</sup> See *Sweet Home is Alabama for FCA Case, Judge Says: United States v. AseraCare*, 17 WESTLAW J. HEALTH CARE FRAUD 9, at \*1 (2012).

<sup>106</sup> Motion to Procedurally Consolidate at 3, U.S. *ex rel. Paradies v. AseraCare, Inc.*, No. 2:12-cv-00245-KOB (N.D. Ala. Jul. 13, 2012). Interestingly, on the claims not severed and transferred, Golden Living Nursing Homes settled the claims with Dr. Micca on January 2, 2013. See Press Release, U.S. Dep’t of Justice U.S. Attorney’s Office, N. Dist. Ala., Golden Living Nursing Homes Settle Allegations of Substandard Wound Care (Jan. 2, 2013), <https://www.justice.gov/usao-ndga/pr/golden-living-nursing-homes-settle-allegations-substandard-wound-care> (claims focused on “inadequate and worthless wound care services to residents at two of its Atlanta area nursing homes”). The settlement amounted to \$613,300. *Id.*

<sup>107</sup> See U.S. *ex rel. Micca v. GGNSC Holdings, LLC*, No. 1:10-CV-1055-ODE, 2012 WL 13028161 (Jun. 22, 2012).

consolidated complaint in intervention on August 2, 2012,<sup>108</sup> and again on November 2, 2012.<sup>109</sup> All three actions were transferred to the District Court for the Northern District of Alabama on August 28, 2012,<sup>110</sup> before Chief Judge Karon Owen Bowdre,<sup>111</sup> and they were formally and finally consolidated on October 17, 2012.<sup>112</sup>

According to a DOJ press release in early 2012 announcing its decision to intervene, “the government allege[d] that AseraCare violated the False Claims Act when it misspent millions of taxpayer dollars intended for Medicare recipients who have a prognosis of six months or less to live and need hospice care.”<sup>113</sup> Further, “the government contend[ed] that AseraCare Hospice knowingly submitted false claims to Medicare for hospice care for patients who were not terminally ill.”<sup>114</sup> Quoted in the press release, Joyce White Vance, U.S. Attorney for the Northern District of Alabama, stated that “Medicare benefits, including the hospice benefits, are intended only for those individuals who are appropriately qualified . . . . We must protect the public welfare and tax-funded benefits programs.”<sup>115</sup>

In response to the DOJ’s intervention decision, AseraCare published a news release, which contained statements from its hospice president, chief medical officer, and general counsel.<sup>116</sup> In addition to denying the allegations and emphasizing how unpredictable disease patterns and progressions are, the statement from AseraCare’s General Counsel, David Beck, noted that the lawsuit was “especially troubling because we believe it could constrain certain patients—most notably those who suffer from

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<sup>108</sup> See United States’ Response to Defendants’ Motion to Dismiss The Action or, in the Alternative, to Dismiss Relators’ Complaint Originally Filed in 2:09-cv-00627-AKK at 3, Richardson and Brown ex rel. U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Oct. 24, 2012).

<sup>109</sup> See Yeung, *supra* note 61; Consolidated Complaint in Intervention, U.S. ex rel. Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012).

<sup>110</sup> See Consolidation Order at 2, U.S. ex rel. Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Aug. 28, 2012), (“The court finds that the cases should be consolidated for discovery purposes pursuant to the court’s discussion with counsel at the status conference.”).

<sup>111</sup> See United States’ Consolidated Complaint in Intervention at 2, U.S. ex rel. Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012).

<sup>112</sup> See Notice of Consolidation, Richardson and Brown ex rel. U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Oct. 17, 2012) (for the three cases, noting that “for all subsequent pleadings, please use case style contained in notice and electronically file all pleadings in the lead case 2:12-cv-0245-KOB,” including associated cases 2:12-cv-00245-KOB, 2:09-cv-00627-JOB, and 2:12-cv-02264-KOB).

<sup>113</sup> U.S. Files Complaint Against National Chain of Hospice Providers, *supra* note 100.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> See AseraCare Hospice Responds to U.S. Attorney, *supra* note 96.

unpredictable disease—from utilizing the hospice benefit.”<sup>117</sup> The statement highlighted that, under Medicare regulations, “two independent physicians” must certify the patient’s eligibility, and that CMS, “which administers hospice, ha[s] repeatedly stated that there is no limit to how long a patient may remain under hospice care as long as the patient’s doctor certifies that a patient is terminally ill and has a six-month prognosis.”<sup>118</sup> Finally, noting that CMS “has expressly recognized that a medical prognostication of life expectancy is not always exact,” AseraCare management highlighted the fact that “the federal government provided clear guidance that there is no limit on how long an individual may receive hospice care as long as he or she meets these eligibility criteria.”<sup>119</sup>

### C. A Summary of the Allegations

For the instant presentation, the allegations presented below—which include the multiple relators’ complaints and the federal government’s intervention complaints—are divided into four categories: (1) wrongful certification, in which AseraCare allegedly certified patients that should not have been certified for hospice care; (2) alleged pressure on employees—specifically that employees were unfairly pressured to push admission and census-building over quality of care concerns; (3) enrollment shortcuts that AseraCare allegedly employed in order to admit as many patients to the hospice benefit as possible; and (4) other enrollment techniques that sought to conceal AseraCare’s alleged hospice fraud. These four categories of allegations are addressed in turn.

#### 1. Wrongful Certification

The crux of the complaints focused on the allegation that AseraCare had “knowingly submitted false claims to Medicare for hospice care for patients who were not terminally ill.”<sup>120</sup> Specifically, the DOJ’s complaint alleged that AseraCare “milked Medicare’s hospice benefit by pressuring its employees to enroll people into hospice who weren’t dying and resisted discharging them despite evidence they weren’t deteriorating.”<sup>121</sup> Along these lines, one of the relators alleged that she was pressured “to admit non-qualifying patients” and “to dump problem patients without regard to

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<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 1–2.

<sup>119</sup> *Id.* at 2.

<sup>120</sup> See U.S. Files Complaint Against National Chain of Hospice Providers, *supra* note 100.

<sup>121</sup> See Jordan Rau, *Lawsuit Accuses Company of Fraudulently Cycling Patients Through Nursing Homes, Hospice Care*, KAISER HEALTH NEWS (Jan. 4, 2012), <http://khn.org/news/hospice-medicare-fraud-lawsuit-aseracare/>.

qualification.”<sup>122</sup>

These allegations centered around AseraCare’s purported efforts to fraudulently increase Medicare reimbursements by over-enrolling patients in hospice services.<sup>123</sup> The DOJ’s “complaint outlined several cases in which AseraCare allegedly kept elderly people despite evidence they weren’t dying.”<sup>124</sup> In addition to the hospice allegations, the relators alleged that AseraCare “referred and re-referred” patients until Medicare had paid the “maximum number of days of skilled nursing care, including rehabilitative therapy . . . home health care, and hospice care.”<sup>125</sup>

Based on the complaint filed by relators Brown and Richardson, a substantial amount of the individuals enrolled in the hospice benefit in AseraCare’s south Alabama locations were allegedly discharged from the program alive, with relators alleging that a “shockingly high percentage[] of AseraCare’s patients [did] not die in six months.”<sup>126</sup> Allegedly, “between 35.5% and 78.6% of AseraCare’s discharged patients were non-terminal in south Alabama between 2005 and early 2009.”<sup>127</sup> This was evidence of the admission of patients who were not sick enough for the hospice benefit, the relators alleged, and was clear proof of fraud perpetrated on the federal government via the Medicare program.<sup>128</sup>

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<sup>122</sup> Qui Tam Complaint at 3, U.S. *ex rel.* Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Mar. 31, 2009).

<sup>123</sup> *Id.*

<sup>124</sup> Rau, *supra* note 121 (according to government allegations, “[t]he patient admitted for end-stage heart disease, which usually renders people unable to walk, was able to go to the graduation and field trip even as he was kept on hospice for more than a year. When he was finally discharged, it was because he needed treatment for other medical conditions . . .”). In a subsequent complaint, the government alleged that this individual also “went out with a family friend and picked berries,” and, thirteen months after being admitted as a hospice patient, “had no chest pain, was not using oxygen, and was still able to walk to the dining room.” United States’ Consolidated Complaint in Intervention at 19–20, U.S. *ex rel.* Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012). This patient was allegedly discharged fourteen months after entering the hospice program. *Id.* Another patient “diagnosed with end-stage ‘debility,’ was not losing weight as is typically the case, according to the legal filing, and instead went out for a trip to Wendy’s and another to go birdwatching.” Whoriskey & Keating, *supra* note 53. A final patient was allegedly admitted to AseraCare’s hospice program in April 2007. United States’ Consolidated Complaint in Intervention at 18, U.S. *ex rel.* Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012). As of September of 2009, the patient was still alive, and still enrolled in hospice. *Id.*

<sup>125</sup> Qui Tam Complaint at 13, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009) (describing the alleged “cycling” that has taken place at AseraCare).

<sup>126</sup> *Id.* at 27–29.

<sup>127</sup> *Id.* at 28.

<sup>128</sup> *Id.* at 29.

## 2. Pressure on Employees

The government alleged that AseraCare accomplished this fraud by forcing its employees to constantly tend to and improve its enrollment numbers. Specifically, the DOJ alleged that the company engaged in a sustained pattern “of intensely pressuring employees to enroll as many hospice patients as possible [and] setting high targets.”<sup>129</sup> According to the government’s allegations, AseraCare tied its staff’s “[j]ob retention” to “maintaining census, or the number of patients for whom AseraCare could bill Medicare or other insurance.”<sup>130</sup> Drops in the census numbers (those enrolled in hospice) worried staff members because the company had allegedly threatened layoffs.<sup>131</sup>

As a result, staff members were allegedly hesitant to discharge patients who did not seem to meet the hospice criteria out of fear of a “census” decline.<sup>132</sup> According to the allegations, AseraCare did not only threaten layoffs, but also rewarded enrollment increases, as AseraCare’s compensation and promotion structure was based on admissions.<sup>133</sup> The company’s Provider Relations Managers (PRMs) were allegedly “compensated in direct proportion to the number of patients admitted and billed to Medicare for [h]ospice treatment and [were] routinely terminated if they fail[ed] to meet their monthly targeted number of referrals.”<sup>134</sup>

The company allegedly had a clear focus on attracting patients to its program—not unlike many other for-profit health care companies, but AseraCare’s efforts were aggressive. According to an individual who served as chaplain for the company, an AseraCare director was described as one who “would be like, ‘Get a patient, get a patient, get a patient,’” in an effort

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<sup>129</sup> Rau, *supra* note 121.

A regional sales director in 2007 was placed on a correction action plan in part because his region failed to admit at least 33 people each week for hospice care. In June 2006, the company offered a massage chair as a prize to the employee who “[won] the game” by meeting its admission goal and being the first to admit a patient in July . . . . An outside auditor . . . suggested in a report that the company’s personnel policies were affecting clinical decisions, . . . [and he noted that] since the company laid employees off when the number of hospice patients dwindled, workers were “resistant to patient discharge” even if the patients no longer were eligible for Medicare hospice benefits.

*Id.*

<sup>130</sup> United States’ Consolidated Complaint in Intervention at 13, U.S. *ex rel.* Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012).

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> Qui Tam Complaint at 20, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009).

<sup>134</sup> *Id.*

to improve the company's bottom line.<sup>135</sup> An email written by one of the company's regional vice presidents demonstrated how much employees were pushed to aggressively admit patients to AseraCare's hospice program.<sup>136</sup> Additionally, AseraCare's employees were allegedly pressed to enroll more patients in its hospice program.<sup>137</sup> According to the allegations, it was common for AseraCare employees to "troll public hospitals, tour public housing complexes[, and] ride along with Meals-on-Wheels food deliveries" in an effort to seek more patients.<sup>138</sup>

When discussing hospice as an option with families and patients, the relators' complaint notes that AseraCare directed its employees "to 'listen for the yes.'"<sup>139</sup> Further, allegedly, "AseraCare [h]ospice employees [were] specifically taught by management to tell reluctant potential patients: '[w]hile you're thinking about it' enroll in hospice 'just for a few days.'"<sup>140</sup> Additionally, "officials gave advice to their recruiters on how to close a deal with families who are 'not ready yet' for hospice."<sup>141</sup> Allegedly, Aseracare directed its recruiters to emphasize "the urgency of a decision, and [to say] things like, '[w]e only have [ten] minutes left.'"<sup>142</sup> Finally, a training presentation attached to the relators' lawsuit pushed trainees to deploy key phrases such as, "at least you'll be covered at night," and encouraged employees to forcefully advocate for admission with phrases including, "try us," and "your doctor wants the best."<sup>143</sup>

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<sup>135</sup> Whoriskey & Keating, *supra* note 53.

<sup>136</sup> *Id.*

"In order to make our admission goal for the month, we are down to the wire, and need today to be a huge admit day for every region," a regional vice president wrote in an e-mail, according to the lawsuit. "Mobilize your teams, get them into the game this morning . . . when we call on them, they always respond with referrals and a push to convert those referrals into admits ASAP."

*Id.*

Another email reflects the same aggressive business practice. According to the government's allegations, the director of operations for hospice Region 3 wrote the following: "The highest admit day ever was in Region 1 with 16. We can get there too—today is the day for really focused action. Go around the barriers and make this happen now, your families need you." United States' Consolidated Complaint in Intervention at 12, U.S. *ex rel.* Paradies v. AseraCare, Inc., No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012).

<sup>137</sup> See Whoriskey & Keating, *supra* note 53.

<sup>138</sup> Yeung, *supra* note 61.

<sup>139</sup> Qui Tam Complaint at 22, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat'l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009).

<sup>140</sup> *Id.*

<sup>141</sup> Whoriskey & Keating, *supra* note 53.

<sup>142</sup> *Id.*

<sup>143</sup> Qui Tam Complaint at 50, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat'l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009).



### 3. Enrollment Shortcuts

Because of the pressure placed on admitting new enrollees into its hospice program, AseraCare allegedly used shortcuts to ensure that individuals could continue to be admitted to the program.<sup>144</sup> For instance, the government alleged that a nurse “was told on numerous occasions to admit more patients” and that “[i]f this nurse determined that a patient did not qualify for hospice under Medicare, she said that another nurse was sent to re-evaluate the patient.”<sup>145</sup> The government also alleged that admissions nurses, and not physicians, regularly made hospice eligibility determinations, in violation of Medicare rules.<sup>146</sup>

In at least one instance, AseraCare allegedly had a physician—who was required to certify eligibility for hospice—“sign multiple Certifications of Terminal Illness forms in blank and then use[] the pre-signed forms in furtherance of billing Medicare for inadmissible patients.”<sup>147</sup> In incredible testimony, Roberta Manley, one of the relators and Aseracare’s Patient Care Coordinator in Milwaukee between April 2007 and January 2008,

testified about how the medical director of that agency, Dr. Mateo, “was doing his drawings” and “wasn’t participating” during the interdisciplinary team meetings. She further testified that she prepared for meetings by setting up Dr. Mateo’s sketch pad, crayons, and coloring pencils and would present papers to Dr. Mateo with “little stickies” where he should sign if he was present to sign them or would use a pre-signed form if he was not at the meeting.<sup>148</sup>

The plaintiffs also alleged that an AseraCare employee said that “a mere suspicion that the patient had cancer or a lung disorder was sufficient to admit the patient for a trial 90 day period.”<sup>149</sup> If “the initial suspicion had proven groundless,” then AseraCare employees were allegedly instructed to

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<sup>144</sup> See, e.g., United States’ Consolidated Complaint in Intervention at 13, U.S. *ex rel. Paradies v. AseraCare, Inc.*, No. 2:12-cv-00245-KOB (N.D. Ala. Nov. 2, 2012).

<sup>145</sup> *Id.*

<sup>146</sup> See *id.* at 14.

<sup>147</sup> Complaint for Damages and Injunctive Relief Under the False Claims Act at 7–8, U.S. *ex rel. Paradies v. AseraCare, Inc.*, No. 2:08-cv-00384-JPS (E.D. Wis. May 2, 2008) (also noting that “Interdisciplinary Plans of Care (IPOC), which are billings to the United States, are also pre-signed by physicians and submitted . . . in support of claims of payment”). This allegation was also made in a relator’s complaint that “discretion is invariably left to nurses, who then submit the paperwork for the signature of an M.D. *in absentia* without a direct examination of the admitted [h]ospice patient.” Qui Tam Complaint at 23, Richardson and Brown *ex rel. U.S. v. Golden Gate Nat’l Senior Care LLC*, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009).

<sup>148</sup> *AseraCare I*, 153 F. Supp. 3d 1372, 1380–81 (N.D. Ala. 2015).

<sup>149</sup> Complaint for Damages and Injunctive Relief Under the False Claims Act at 12, United States *v. AseraCare, Inc.*, No. 2:08-cv-00384-JPS (E.D. Wis. May 2, 2008).

change the diagnosis to ensure that the patient remained enrolled in the program.<sup>150</sup>

#### 4. Muddying the Numbers

Finally, one of the relators alleged that she was pressured “to aggressively target imminent-death patients in order to intentionally shrink AseraCare’s average length of stay and average per patient expenditure, and thus to evade detection of [the company’s] fraudulent billing of Medicare.”<sup>151</sup> According to the government, “AseraCare instruct[ed] its nurses, nurse supervisors, and marketers to develop practices for identifying and aggressively recruiting such ‘last breath’ patients.”<sup>152</sup> It was also alleged that employees were pushed to “solicit oncologists for ‘last breath’ referrals.”<sup>153</sup> This way, according to the DOJ, AseraCare could be sure to keep its average expenditures per patient and average days stayed in AseraCare’s hospice programs low, so that its otherwise long stays would not be noticed by federal regulators.

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Based on the allegations in the FCA action referenced above, the DOJ alleged that AseraCare fraudulently sought, and improperly received, \$67.5 million in reimbursements from Medicare.<sup>154</sup> Subject to the treble damages

<sup>150</sup> *Id.*

<sup>151</sup> Qui Tam Complaint at 3, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009).

<sup>152</sup> *Id.* at 31. *See also* Whoriskey & Keating, *supra* note 53 (“In some cases, hospice recruiters even specifically sought out ‘last-breath’ patients—those who would die quickly—to bring their average down, according to the lawsuit.”).

<sup>153</sup> Qui Tam Complaint at 32, Richardson and Brown *ex rel.* U.S. v. Golden Gate Nat’l Senior Care LLC, No. 2:09-cv-00627-KOB (N.D. Ala. Mar. 31, 2009).

Vice President of Sales . . . advised Plaintiff-Relator . . . that she needed to enroll more short length of stay patients . . . [It was suggested that the relator] should not attempt to persuade them that patients should abandon chemotherapy for palliative care—which might cut into the oncologists’ profits—but should rather solicit the doctors to refer their patients to AseraCare in the last few days of their lives. In that way the oncologists could maximize profits and AseraCare could maximize “last breath” referrals and—by increasing the denominator of the Aggregate Cap equation—allowable Medicare reimbursements. Under Defendants’ scheme, oncologists are encouraged by Defendants to impose on cancer patients the horrific effects of aggressive chemotherapy until the patients are on the verge of death—days or even hours from death and far past legitimate hope of a cure—and then to refer the almost-dead patients to AseraCare for enrollment for the sole purpose of shrinking AseraCare’s average length of stay and fraudulently increasing its Aggregate Cap amount, thereby disguising AseraCare’s fraudulent admission of other non-qualifying patients.

*Id.*

<sup>154</sup> *See* Kent Faulk, *Whistleblower Trial: Did AseraCare Hospice Bill Medicare for*

provisions mandated by the FCA—but not including the per-claim penalties required by the Act<sup>155</sup>—the DOJ sought more than \$200 million from AseraCare.<sup>156</sup> This figure incorporated the time period during which the fraudulent reimbursements allegedly occurred—just over four total years, between January 1, 2007 to December 31, 2008, and January 1, 2009 to February 28, 2011.<sup>157</sup>

#### D. *The Trial*

Adding to *AseraCare*'s intrigue has been its uncommon procedural history. In May of 2015, Chief Judge Bowdre bifurcated the trial,<sup>158</sup> separating the issue of falsity from a separate phase “on all other issues and claims, including the knowledge and damage elements of the [g]overnment’s claims.”<sup>159</sup> This first phase of the trial, which focused exclusively on the falsity requirement under the FCA, began on August 10, 2015.<sup>160</sup> This phase—which focused its analysis on 121 patients—ended in mid-

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*Patients Who Weren't About to Die?*, AL.COM (Aug. 9, 2015, 10:47 AM), [http://www.al.com/news/birmingham/index.ssf/2015/08/whistleblower\\_trial\\_were\\_non-d.html](http://www.al.com/news/birmingham/index.ssf/2015/08/whistleblower_trial_were_non-d.html).

<sup>155</sup> Those penalties were adjusted upwards as of August 2016. *See False Claims Act Penalties Double as of August 1, 2016*, NAT'L L. REV. (July 19, 2016), <http://www.natlawreview.com/article/false-claims-act-penalties-double-august-1-2016> (“As of August 1, 2016, False Claims Act civil penalties increase to between \$10,781.40 and \$21,562.80 per claim, plus three times the amount of damages that the federal government sustains because of the false claim.”).

<sup>156</sup> *See* Kent Faulk, *\$202 Million AseraCare Medicare Fraud Case Starts Aug. 3 DOJ Says*, AL.COM (July 10, 2015), [http://www.al.com/news/birmingham/index.ssf/2015/07/company\\_could\\_owe\\_more\\_than\\_2\\_0.html](http://www.al.com/news/birmingham/index.ssf/2015/07/company_could_owe_more_than_2_0.html). The \$202 million damages amount sought by the DOJ was the result of a random sample:

The DOJ came to that dollar amount through an analysis of random samples of 2,181 AseraCare patients for whom the company billed Medicare for at least 365 days of continuous hospice care. . . . More than half of the 233 cases in the random samples should have been deemed ineligible for hospice, the DOJ argued.

*Id.*

<sup>157</sup> *Id.*

<sup>158</sup> This was a controversial decision. *See* Peter S. Spivack, Stephanie L. Carman, & Natalie T. Sinicrope, *5 Important Lessons from AseraCare's FCA Case*, LAW360 (Mar. 9, 2016, 11:03 AM), <https://www.law360.com/articles/768839/5-important-lessons-from-aseracare-s-fca-case> (noting that the case was bifurcated into two phases—a phase one that focused on falsity, and a phase two that focused on intent and other FCA issues—and describing the decision and procedural posture of the case as “uncharted waters.”) Indeed, the *AseraCare* “court’s decision to bifurcate the trial was preceded—and likely influenced—by a controversial decision: to allow the government to use statistical sampling and extrapolation in its efforts to prove falsity and calculate potential damages.” *Id.*

<sup>159</sup> *AseraCare I*, 153 F. Supp. 3d 1372, 1377 (N.D. Ala. 2015).

<sup>160</sup> *Id.* at 1379.

October.<sup>161</sup> At the conclusion of the phase, the “jury answered . . . interrogatories and found that AseraCare submitted false claims for 104 of the patients during some or all of their hospice stay.”<sup>162</sup> Following the jury verdict, the court was prepared to move on to the subsequent phase of the trial, during which the jury was set to look at whether AseraCare violated the intent requirement under the FCA, specifically to “examine whether AseraCare knowingly submitted false claims.”<sup>163</sup>

But the *AseraCare* case did not proceed in this typical fashion. Following the jury’s decision in October, Chief Judge Bowdre issued a memorandum order in which she effectively overturned the jury’s findings due to incorrect jury instructions. This was followed by an even more stunning opinion in March of 2016. Both of these opinions are presented below.

### 1. The November 2015 Opinion

Less than two weeks after the jury returned a finding of falsity for 104 of the 121 patients examined in the *AseraCare* case, and in a surprising turn of events,<sup>164</sup> Chief Judge Bowdre ordered a new trial.<sup>165</sup> Granting *AseraCare*’s motion for a new trial because “she had given the jury ‘incomplete’ instructions before their deliberations in the first phase of the trial,”<sup>166</sup> Chief Judge Bowdre reopened the issue due to what amounted to a jury instruction error. According to a report about the case:

*AseraCare* attorneys last week had asked [Chief Judge] Bowdre for a new trial after she stated she realized she had committed ‘major reversible error’ in the jury instructions, according to a court document filed today by DOJ attorneys. [Chief Judge] Bowdre granted *AseraCare*’s motion on the ground that she had failed to provide the jury with a “sufficient legal standard for evaluating the case,” according to the document. Specifically, [Chief Judge] Bowdre said today that she had not included essential statements of the False Claims Act law in her jury instructions, including that claims are not false under that law when reasonable persons can disagree on whether the hospice care

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<sup>161</sup> See Kent Faulk, *AseraCare Hospice Trial with \$200 Million at Stake Gets Do-Over*, AL.COM (Oct. 26, 2015), [http://www.al.com/news/birmingham/index.ssf/2015/10/federal\\_judge\\_halts\\_aseracare.html](http://www.al.com/news/birmingham/index.ssf/2015/10/federal_judge_halts_aseracare.html).

<sup>162</sup> *AseraCare I*, 153 F. Supp. 3d at 1379.

<sup>163</sup> Lisa Schencker, *Hospice Company AseraCare Loses First Round of False Claims Trial*, MODERN HEALTHCARE (Oct. 15, 2015), <http://www.modernhealthcare.com/article/2015/10/15/NEWS/151019935>.

<sup>164</sup> Faulk, *supra* note 161 (quoting a practitioner as finding the reversal as “somewhat surprising”).

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

was properly billed to the government.<sup>167</sup>

Further, the Court filed a memorandum opinion on November 3, 2015, in which it formally granted AseraCare's motion for a new trial.<sup>168</sup> Chief Judge Bowdre candidly began the order by noting that, as the FCA "is still developing" and that "[m]any key issues remain undecided," the court had provided insufficient instructions to the jury.<sup>169</sup> In a nod to the rapidly-developing standards in medical necessity-based FCA cases, Chief Judge Bowdre emphasized the "uncharted" nature of the government's allegations in the case.<sup>170</sup>

Specifically, the Judge noted that, following the initial jury finding, the court "had serious questions as to whether the [g]overnment had proven an objective falsehood . . . ."<sup>171</sup> And, upon review, Chief Judge Bowdre felt that the instructions given did not convey the appropriately high standard that courts must impose on the government pursuing medical necessity-based fraud cases.<sup>172</sup> Specifically, Chief Judge Bowdre wrote that

the court became convinced that it committed reversible error in the instructions it provided to the jury. The court concluded that it should have advised the jury that (1) "the FCA requires 'proof of an objective falsehood,'" and (2) a mere difference of opinion, *without more*, is not enough to show falsity.<sup>173</sup>

Consequently, Chief Judge Bowdre noted that the "failure to instruct the jury on these key points of law was reversible error."<sup>174</sup>

Foreshadowing what was to come in 2016, the court noted that it was "convinced that the law is clear: a difference of opinion is not enough."<sup>175</sup> The court had told the jury that "a claim is 'false' if it is an assertion that is untrue when made or when used," and that "practices that may be improper,

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<sup>167</sup> *Id.*

<sup>168</sup> *AseraCare I*, 153 F. Supp. 3d 1372, 1377 (N.D. Ala. 2015).

<sup>169</sup> *Id.* at 1375 ("One of the undecided areas of law in the Eleventh Circuit is the legal standard for falsity in a case like this one, where the [g]overnment alleges that the hospice provider's medical records do not support its hospice eligibility certifications, and, therefore, the certifications are false. This case does not involve the types of false claims for which the legal standard is well-established: the hospice provider forged physicians' signatures, billed for services that it did not perform, or submitted claims for fictitious patients. In traversing this uncharted territory, the court has carefully considered each of the novel issues presented by this case, and has attempted to render its decisions in a way that aligns with the current state of the law. Nonetheless, the court misstepped. The court committed reversible error in failing to provide the jury with complete instructions as to what was legally necessary for it to find that the claims before it were false.").

<sup>170</sup> *Id.*

<sup>171</sup> *Id.* at 1381.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* (citations omitted).

<sup>174</sup> *AseraCare I*, 153 F. Supp. 3d at 1381.

<sup>175</sup> *Id.*

standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare.”<sup>176</sup> Again, the court noted its mistake: “[t]hese instructions, while correct statements, were incomplete. The instructions that the court gave did not fully advise the jury about the standard it must apply to find that AseraCare submitted false claims.”<sup>177</sup>

Finally, the court drew on past precedent to note that scientific judgments and medical opinions “about which reasonable minds may differ cannot be false.”<sup>178</sup> The fact that CMS relied upon the doctor’s certification for hospice, which features individual clinical judgment, bolstered Chief Judge Bowdre’s conclusion that the hospice certification statement is a judgment or opinion that does not lend itself well to the FCA’s falsity standard.<sup>179</sup> “This guidance from CMS,” the Chief Judge wrote, “shows that physicians applying their clinical judgment about a patient’s projected life expectancy could disagree, and neither physician would be wrong.”<sup>180</sup>

In effect, Chief Judge Bowdre’s conclusion on the FCA requirements in the November 2015 case cracked open a potentially radical defense for providers targeted by the FCA for a medical necessity-based fraud claim. This argument features the potentiality that if the provider can couch his or her disagreement with Medicare as a reasonable clinical disagreement, then the FCA—dependent upon falsity and intent—may be limited in application. Consequently, it seems, in this area, medical disagreement—as long as it is reasonable and supported—can serve to immunize providers from FCA enforcement.

## 2. The March 2016 Opinion

In a straightforward and striking opinion in the spring of 2016, Chief Judge Bowdre tossed the lawsuit, granting summary judgment in favor of AseraCare.<sup>181</sup> Put simply, Chief Judge Bowdre disagreed with the government’s characterization of the case. Responding to “[g]overnment claims that the medical records of the 123 patients at issue in this case do not contain ‘clinical information and other documentation that support [this] medical prognosis,’ and thus, AseraCare’s claims for those patients were

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<sup>176</sup> *Id.* at 1382 (citations omitted).

<sup>177</sup> *Id.*

<sup>178</sup> *Id.* at 1383.

<sup>179</sup> *Id.*

<sup>180</sup> *AseraCare I*, 153 F. Supp. 3d at 1384 (“The case law, the regulations, and even the testimony of the [g]overnment’s witnesses support the court’s conclusion that it should have instructed the jury that a mere difference of opinions among physicians, *without more*, is insufficient to show falsity under the False Claims Act.”).

<sup>181</sup> *United States v. AseraCare Inc. (AseraCare II)*, 176 F. Supp. 3d 1282, 1284 (N.D. Ala. 2016).

‘false,’” Chief Judge Bowdre noted that the case could be characterized by “conflicting views of physicians about whether the medical records support AseraCare’s certifications that the patients at issue were eligible for hospice care.”<sup>182</sup> Chief Judge Bowdre noted that “[w]hen hospice certifying physicians and medical experts look at the very *same* medical records and disagree about whether the medical records support hospice eligibility, the opinion of one medical expert *alone* cannot prove falsity without further evidence of an objective falsehood.”<sup>183</sup> Further, when it comes to the FCA, as she noted in the November 2015 opinion, “[a] mere difference of opinion between physicians, *without more*, is not enough to show falsity.”<sup>184</sup> Instead, “all that exists is a difference of opinion.”<sup>185</sup>

In her opinion, Chief Judge Bowdre seemed keenly aware of the potentially wide reach of the FCA, noting that “[t]he court [was] concerned that allowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of the certifying physicians.”<sup>186</sup> The court further noted that the certification—based upon the clinical expertise of a physician—was a vital component of the hospice certification process, and that enabling the government to prove falsity through a clinical disagreement would allow the government to “short-circuit” the falsity requirement within the FCA.<sup>187</sup> “If the court were to find that all the [g]overnment needed to prove falsity in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician,” the court found, “hospice providers would be subject to potential FCA liability any time the [g]overnment could find a medical expert who disagreed with the certifying physician’s clinical judgment. The court refuses to go down that road.”<sup>188</sup>

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<sup>182</sup> *Id.* at 1283 (citations omitted).

<sup>183</sup> *Id.*

<sup>184</sup> *Id.* The Court also noted that “AseraCare’s medical experts, as well as the certifying physicians, also reviewed the same medical records and found that they *did* support the [certifications of terminal illness] of the patients at issue. The court finds that contradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA as a matter of law.” *Id.* at 1286.

<sup>185</sup> *Id.* at 1285 (“When two or more medical experts look at the same medical records and reach different conclusions about whether those medical records support the certifying physicians’ [Certifications of Terminal Illness], all that exists is a difference of opinion. This difference of opinion among experts regarding the patients’ hospice eligibility *alone* is not enough to prove falsity, and the [g]overnment has failed to point the court to any *objective* evidence of falsity.” (emphasis in original)).

<sup>186</sup> *Id.*

<sup>187</sup> *AseraCare II*, 176 F. Supp. 3d at 1285.

<sup>188</sup> *Id.*

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Chief Judge Bowdre’s surprising March 2016 opinion became a focal point for the health law industry, with many in the provider community celebrating the decision.<sup>189</sup> Whether Chief Judge Bowdre’s holding stands, however, is still to be determined. The DOJ has filed an appeal in the *AseraCare* case that is pending before the Eleventh Circuit at the time of this writing,<sup>190</sup> and oral arguments were held in 2017.<sup>191</sup> Nevertheless, no matter the outcome of the appeal of the *AseraCare* case, the legal reasoning employed and the perspective of the FCA shared in the case by Chief Judge Bowdre has already had an impact on other courts’ treatment of the FCA and its falsity requirement, especially in cases alleging a lack of medical necessity.

#### V. HETEROGENEITY AS AN ANTAGONIST TO FRAUD

*AseraCare* was not the first—and certainly will not be the last—federal court case to apply a stringent falsity requirement to the detriment of relators in health care FCA cases. Noteworthy cases drew attention before *AseraCare*’s 2016 result, and at least two federal court decisions have relied on and extended the *AseraCare* conception of falsity under the FCA. The more recent of these two decisions—which was overturned by an appellate court in 2018—had, at the time, led practitioners to claim that the tie between the FCA and medical necessity was “increasingly tenuous,” clearly

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<sup>189</sup> See, e.g., Kathleen McDermott & Howard J. Young, *False Claims Act Trial Sets Precedent for Future Cases*, MORGAN LEWIS LAWFLASH (Apr. 1, 2016), <https://www.morganlewis.com/pubs/false-claims-act-trial-sets-precedent-for-future-cases> (noting that Chief Judge Bowdre’s decision “explains and resolves this important FCA legal issue with elegant and devastating simplicity, ensuring that the decision will be a strong and influential precedent[,]” and calling the case a “notable defeat for the government’s assertion of FCA liability against healthcare providers”); Michael L. Waldman & Eric A. White, *AseraCare Puts ‘False Claims’ Back in the False Claims Act*, BLOOMBERG BNA (July 18, 2016), <https://www.bna.com/aseracare-puts-false-n73014444927/> (calling the *AseraCare* decision a “possible common-sense reawakening”). Further, lawyers have noted that “[h]ealthcare providers are understandably frustrated to have legitimate clinical disagreements labeled as fraudulent practices with no nexus to actual false claims or any evidence of objective falsehood related to a claim.” McDermott & Young, *supra* note 189. See also Schencker, *supra* note 88 (“If a medical professional says, ‘Here are the criteria, and in my professional opinion, I believe this person is appropriate for hospice care,’ that, I believe, should constitute a barrier to fraud prosecution,” and noting that he “believes hospices shouldn’t face fraud liability just because another medical professional may reasonably disagree with it certifications.”) (quoting Mark Silberman, a partner at Duane Morris).

<sup>190</sup> See *AseraCare I*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015), *appeal docketed*, No. 16-13004 (11th Cir. 2016).

<sup>191</sup> See *False Claims Act Standard for Falsity of Medicare Hospice Claims Debated on Appeal*, LEXIS LEGAL NEWS, (Apr. 17, 2017), <https://www.lexislegalnews.com/articles/16507/false-claims-act-standard-for-falsity-of-medicare-hospice-claims-debated-on-appeal>.



“welcome news for health care providers.”<sup>192</sup> Nonetheless, the Tenth Circuit’s decision in 2018 has undoubtedly muddied the falsity analysis.<sup>193</sup>

A. *The Siblings and Progeny of AseraCare*

These cases are *U.S. ex rel. Morton v. A Plus Benefits, Inc.*,<sup>194</sup> decided in 2005 by the Tenth Circuit, *U.S. ex rel. Wall v. Vista Hospice Care*,<sup>195</sup> decided by the District Court for the Northern District of Texas in 2016, and *U.S. ex rel. Polukoff v. St. Mark’s Hospital*,<sup>196</sup> heard and decided by the District Court for the District of Utah in 2017, and overturned by the Tenth Circuit in 2018,<sup>197</sup> which demonstrates the instability of case law in this area. All three cases are summarized briefly below.

1. *U.S. ex rel. Morton v. A Plus Benefits, Inc.*

Eleven years before Chief Judge Bowdre’s opinion in *AseraCare*, a three-judge panel of the Tenth Circuit applied a similar analysis regarding the FCA’s falsity requirement.<sup>198</sup> In a case with unique facts, relators—parents of a prematurely-born infant who needed medical treatment—alleged that their private insurance plan wrongly denied coverage for treatment, and “directed” them to “file the claims with Medicaid.”<sup>199</sup> Therefore, because of the plan’s allegedly wrongful refusal, Medicaid covered the services, and the parents alleged that the statement constituted Medicaid fraud.<sup>200</sup> Due to the wrongful denial of coverage, they argued, the Medicaid program paid for services for which it should not have paid.<sup>201</sup>

The District Court dismissed the complaint due to its failure to allege a false or fraudulent claim, and the Tenth Circuit affirmed.<sup>202</sup> In its analysis,

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<sup>192</sup> See Rebecca C. Martin & Laura McLane, *The FCA and Medical Necessity: An Increasingly Tenuous Relationship*, MCDERMOTT WILL & EMERY: FCA UPDATE (Feb. 7, 2017), <http://www.fcaupdate.com/2017/02/the-fca-and-medical-necessity-an-increasingly-tenuous-relationship/> (“In cases where the FCA is used by the government and relators to monitor and attempt to punish allegedly ‘fraudulent’ conduct that, in reality, involves questions of physician judgment, *Polukoff*’s adoption of *AseraCare*’s logic gives added weight to arguments against liability premised on disagreements over clinical decision-making”).

<sup>193</sup> *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730 (10th Cir. 2018).

<sup>194</sup> *U.S. ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App’x. 980 (10th Cir. 2005).

<sup>195</sup> *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016).

<sup>196</sup> See *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, No. 2:16-cv-00304-JNP-EJF, 2017 WL 237615 (D. Utah Jan. 19, 2017), *rev’d*, 895 F.3d 730 (10th Cir. 2018).

<sup>197</sup> *Id.*

<sup>198</sup> See *Morton*, 139 F. App’x. at 980.

<sup>199</sup> *Id.* at 981.

<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

<sup>202</sup> *Id.* at 982.

the Tenth Circuit noted that the scienter and falsity showings required under the FCA were “inseparable.”<sup>203</sup> While taking a harder line on the FCA falsity requirement, and citing other FCA cases, the court noted that, to find FCA liability, what is required is an “objective falsehood,” and “a lie.”<sup>204</sup>

Rejecting the relators’ attempt to prove falsity, the court noted that “liability under the FCA must be predicated on an objectively verifiable fact.”<sup>205</sup> Further, the court noted that the clinical determination was not “susceptible to proof of truth or falsity” and that “not all clinical diagnoses and characterizations of medical care are intrinsically ambiguous,” but called the care at issue in the case “inherently ambiguous.”<sup>206</sup> As a result, the Tenth Circuit concluded that the plaintiffs’ challenge did not fall within the parameters of the FCA, and that the relators could not show the requisite falsity to maintain an FCA action.<sup>207</sup> Dismissal with prejudice by the District Court was appropriate, and the order was affirmed.<sup>208</sup> In a subsequent opinion, nonetheless, the Tenth Circuit has limited the application of this holding, “cabin[ing it] to the facts in that case.”<sup>209</sup>

## 2. United States ex rel. Wall v. Vista Hospice Care, Inc.

The relator in *Vista Hospice Care*, a social worker employed for two years by Vista Hospice (“Vista”), alleged that Vista had violated the Anti-Kickback Statute (AKS),<sup>210</sup> the FCA, and the Texas Medicaid Fraud

<sup>203</sup> *Id.*

<sup>204</sup> *Morton*, 139 F. App’x. at 982.

<sup>205</sup> *Id.* at 983 (The court also noted that “we are not prepared to conclude that in all instances, merely because the verification of a fact relies upon clinical medical judgments, or involves a decision of coverage under an ERISA plan, the fact cannot form the basis of an FCA claim.”).

<sup>206</sup> *Id.* at 983–84. The court quoted *Wang v. FMC Corp.*, noting “[t]he Act is concerned about ferreting out ‘wrongdoing,’ not scientific errors. What is false as a matter of science is not, by that very fact, wrong as a matter of morals.” 975 F.2d 1412, 1421 (9th Cir. 1992). The *Wang* court noted that “[t]he Act would not put either Ptolemy or Copernicus on trial.” *Id.*

<sup>207</sup> *Morton*, 139 F. App’x. at 984.

<sup>208</sup> *Id.*

<sup>209</sup> *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018).

<sup>210</sup> The Anti-Kickback Statute (AKS), a federal criminal anti-fraud statute, reads (in relevant part) as follows:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

Prevention Act (TMFPA),<sup>211</sup> alleging a scheme to wrongfully enroll and bill for hospice services for allegedly ineligible individuals.<sup>212</sup> In a decision written by Judge Barbara M.G. Lynn, the court granted Vista's motion for summary judgment for each claim, except for an allegation of retaliation.<sup>213</sup>

Notably for the instant analysis, Vista focused on the testimony of the relator's expert witness, Dr. Karl Steinberg, and in addition to seeking dismissal of the false claims allegations, Vista sought to strike the expert's testimony.<sup>214</sup> In a passage that bears a similarity to the analysis in *AseraCare*, Judge Lynn noted that "an FCA claim about the exercise of [clinical] judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis."<sup>215</sup> Further, the court provided examples of what would be sufficient.<sup>216</sup>

For example, a relator could present evidence that a certifying physician was not, in fact, exercising the physician's clinical judgment when certifying a patient, because the physician never reviewed the patient's medical condition nor saw the patient, or that the physician did not actually believe that if the patient's disease ran its normal course, the patient had a prognosis of six months or less. A testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough

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shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b) (2018).

<sup>211</sup> See TEX. HUM. RES. CODE ANN. §§ 36.001–36.132 (West 2015). The Texas Medicaid Fraud Prevention Act (TMFPA) is known as a state-level analog to the federal FCA. See, e.g., U.S. *ex rel.* Bates v. Dentsply Int'l, Inc., No. CIV.A. 12-7199, 2014 WL 4384503, at \*10 (E.D. Pa. Sept. 4, 2014) (noting that the "[r]elator has alleged violations of 28 state and municipal laws analogous to the federal False Claims Act," and citing the TMFPA allegations as one of the "analogous" state laws).

<sup>212</sup> United States v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at \*1 (N.D. Tex. June 20, 2016).

<sup>213</sup> *Id.* at \*27.

<sup>214</sup> *Id.* at \*1.

<sup>215</sup> *Id.* at \*17.

<sup>216</sup> *Id.*

to show falsity.<sup>217</sup>

Further, mirroring the concern that was later expressed in *AseraCare*, Judge Lynn painted the hypothetical that unknowing providers could find themselves targeted by the DOJ following a situation in which an expert reviewer disagreed with their clinical decisions.

If all that was necessary to prove falsity was to put up a medical expert to review medical records and provide an opinion at odds with that of the certifying physician, hospice providers would be subject to potential FCA liability “any time [a relator] could find a medical expert who disagreed with the certifying physician’s clinical judgment.” That situation would be directly at odds with the assurances given by CMS that doctors need not fear the exercise of their medical judgment as to the future course of a terminal patient.<sup>218</sup>

The court noted that the relator did not sufficiently allege causation, as he failed to draw a connection between the patients that were reviewed by the expert, Dr. Steinberg, and the claims for which Vista sought reimbursement.<sup>219</sup> Finding these deficiencies fatal to the relator’s claim, the court dismissed the false claims allegations based on the same reasoning as Judge Bowdre’s decision in *AseraCare*.<sup>220</sup>

### 3. United States ex rel. Polukoff v. St. Mark’s Hospital

Nearly one year after Chief Judge Bowdre’s decision in *AseraCare*, the District Court for the District of Utah granted a motion to dismiss with prejudice in *U.S. ex rel. Polukoff v. St. Mark’s Hospital*.<sup>221</sup> Another decision to grab the attention of the defense bar, in writing about the *St. Mark’s Hospital* case, attorney commentators have noted that the case represents another reminder of how a case like *St. Mark’s Hospital*, “in reality, involves questions of physician judgment,” and “gives added weight to arguments against liability premised on disagreements over clinical decision-making.”<sup>222</sup>

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<sup>217</sup> *Id.* (citations omitted).

<sup>218</sup> *Vista Hospice Care*, 2016 WL 3449833, at \*18 (citation omitted).

<sup>219</sup> *Id.* (“Although Relator has produced some evidence of the Defendants’ pressure on their employees to admit large numbers of hospice patients, and that a few employees falsified data on a few specified patient charts, a practice that could jeopardize the proper exercise of physician judgment, she has not tied that evidence to the patients whose charts Dr. Steinberg evaluated, nor to the submission of a single false claim. Relator concedes that she cannot do so.”).

<sup>220</sup> *Id.* at \*21.

<sup>221</sup> See *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, No. 2:16-cv-00304-JNP-EJF, 2017 WL 237615 (D. Utah Jan. 19, 2017), *rev’d*, 895 F.3d 730 (10th Cir. 2018).

<sup>222</sup> Martin & McLane, *supra* note 192.

In short, the relator in *St. Mark's Hospital* alleged that a cardiologist “performed unnecessary medical procedures and then billed the federal government for some of these procedures.”<sup>223</sup> Further, according to the relator’s allegations, Intermountain Healthcare, Inc. and Intermountain Medical Center (collectively referred to as “IHC”), and St. Mark’s Hospital (“St. Mark’s”), “fraudulently billed the government for costs associated with these unnecessary procedures.”<sup>224</sup> Specifically, the allegations focused on a procedure called “patent foramen ovale (PFO) closure,”<sup>225</sup> which is performed in an effort to prevent the patient from suffering a stroke.<sup>226</sup>

Importantly to the District Court and Judge Jill N. Parrish, the clinical expertise surrounding whether or not a PFO closure would prevent a patient from suffering a stroke was subject to shifting clinical opinion.<sup>227</sup> Specifically, as the court mentioned, both the American Heart Association (AHA) and the American Stroke Association (ASA) had changed their guidance documents in the last decade, and Medicare had no National Coverage Determination (NCD) for the procedure.<sup>228</sup> As a result, the court noted that no clear clinical consensus existed for the procedure.<sup>229</sup>

The relator’s argument centered on the fact that because the procedures must have been medically necessary and reasonable in order to be reimbursable by Medicare, and because the care could not have been medically necessary, the representation was false, and therefore, the cardiologist violated the FCA.<sup>230</sup> Citing the Tenth Circuit’s decision in *Morton* and the Northern District of Alabama’s 2016 decision in *AseraCare*, the District Court required proof that the “defendants knowingly made an objectively false representation to the government that caused the

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<sup>223</sup> See *St. Mark's Hosp.*, 2017 WL 237615, at \*1.

<sup>224</sup> *Id.* The court noted that the relator alleged that Dr. Sorensen fraudulently administered the procedure to patients, and that “the hospital defendants [through] their managing agents knew that Dr. Sorensen was performing allegedly medically unnecessary procedures in their facilities, but billed the government for costs associated with these procedures anyway.” *Id.* at \*6.

<sup>225</sup> *Id.* at \*1.

<sup>226</sup> *Id.* (“The foramen ovale is a small opening in the wall separating the two upper chambers of the heart found in a fetus as it develops in the womb. In about 75% of the population, the opening closes soon after birth. In the other 25% of the population, the opening never closes. Except in rare cases, this condition is asymptomatic. But an adult with a PFO has an increased risk of suffering a stroke because blood clots that would otherwise have lodged in the lungs during pulmonary circulation may instead leak through the PFO, enter the systemic circulatory pathway, and lodge in the brain. A PFO may be closed through a percutaneous surgical procedure.”).

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *St. Mark's Hosp.*, 2017 WL 237615, at \*1.

<sup>230</sup> *Id.* at \*8.

government to remit payment.”<sup>231</sup>

On that front, the court did not agree with the relator that the certification of the reasonableness and necessity of the PFO closures was “objectively false” under the meaning of the FCA.<sup>232</sup> In its most important passage:

[t]hese representations, however, cannot be proven to be objectively false. Opinions, medical judgments, and “conclusions about which reasonable minds may differ cannot be false” for the purposes of an FCA claim. Moreover, liability may not be premised on subjective interpretations of imprecise statutory language such as “medically reasonable and necessary.” Dr. Polukoff alleges that some of the PFO closures performed were medically unreasonable and unnecessary because they were performed on patients with an elevated risk of stroke but who had not yet suffered a stroke or to treat chronic migraines. But similar to the medical decisions at issue in *Morton*, these allegations are based on subjective medical opinions that cannot be proven to be objectively false.<sup>233</sup>

In attempting to show that the cardiologist administered care that was not medically necessary, and by implication, that the reimbursement sought for that care was false, Dr. Polukoff relied on the AHA/ASA standards to prove that the care was lacking in medical necessity.<sup>234</sup> But the court rejected the argument, noting that Medicare did not require compliance with the professional standard in order to reimburse for the care at issue.<sup>235</sup> For this argument, the court relied on the seminal *Mikes v. Straus* decision from the Second Circuit in 2001.<sup>236</sup> Consequentially, the court noted that “even if Dr. Polukoff could show that [the cardiologist] did not comply with the relevant AHA/ASA standards, this does not support a claim that [the cardiologist]’s certification that the PFO closures were medically necessary was objectively false.”<sup>237</sup>

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<sup>231</sup> *Id.* at \*8–9 (citing U.S. *ex rel.* *Morton v. A Plus Benefits, Inc.*, 139 F. App’x. 980, 982 (10th Cir. 2005); *AseraCare II*, 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016)).

<sup>232</sup> *St. Mark’s Hosp.*, 2017 WL 237615, at \*8–9.

<sup>233</sup> *Id.* at \*9 (citations omitted).

<sup>234</sup> *Id.* at \*10.

<sup>235</sup> *Id.* (citing *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011)).

<sup>236</sup> *Id.* The Court in *St. Mark’s Hospital* quoted arguably the most important sentence from *Straus*, noting that “[t]he term ‘medical necessity’ does not impart a qualitative element mandating a particular standard of medical care, and [the relator] does not point to any legal authority requiring us to read such a mandate into the form.” *Id.*

<sup>237</sup> *Id.* In a footnote, the court noted that the guidelines do not speak to whether or not the procedure was recommended to treat migraines, the treatment plan Dr. Sorensen was following. *See id.* at \*10 n.7. (“Although the 2006 and 2011 recommendations may give rise to a permissible inference that a prior stroke is a prerequisite to a PFO closure, the AHA/ASA never explicitly states that a patient with an elevated risk of strokes should not receive the

The court then noted that Medicare remained free—through the Secretary of Health and Human Services (HHS)—to establish a standard in this area of clinical practice through the national coverage determination (NCD) process to allay any confusion that exists within the provider community.<sup>238</sup> The court concluded by dismissing the claim with prejudice—denying the relator’s request of leave to amend his complaint—but not before a noteworthy rebuke of the relator’s attempted theory of liability.<sup>239</sup> In a sweeping passage, Judge Parrish noted that

[i]n the absence of an objective standard created by the government, Dr. Polukoff can only rely upon the subjective and ambiguous “reasonable and necessary” standard. Any attempt to prove that the defendants have violated this standard by seeking payment for PFO closures must necessarily rest on evidence of medical opinions and subjective standards of care rather than objectively false representations. But as the Tenth Circuit held in *Morton*, the punitive provisions of the FCA—including treble damages and attorney fees—cannot be applied absent an objectively false representation. Therefore, Mr. Polukoff’s FCA claims fail as a matter of law and the court dismisses all causes of action asserted against the defendants.<sup>240</sup>

Throughout this section, Judge Parrish seemed to call into question the validity of a substantial amount of FCA actions that had been maintained in recent years that hinged on the definition and understanding of medical necessity. Indeed, an FCA action that rests on a theory of liability that the care administered was not medically necessary is purportedly based upon “evidence of medical opinions and subjective standards of care.”<sup>241</sup> The decision seemed to immediately change the calculus for targeted parties, relators, and the United States government in litigating these cases and considering settlement.

But the Tenth Circuit reversed Judge Parrish’s decision in mid-2018.<sup>242</sup> Reversing and remanding the lower court, the Tenth Circuit found that medical necessity determinations *can* be false—adopting a broad reading of the FCA<sup>243</sup>—“if the procedure was not reasonable and necessary under the government’s definition of the phrase.”<sup>244</sup> Recognizing that “a broad

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procedure. In the absence of a clear prohibition, even if Dr. Sorensen had represented that he had complied with AHA/ASA guidelines, such a representation would not be objectively false.”)

<sup>238</sup> *St. Mark’s Hosp.*, 2017 WL 237615, at \*10.

<sup>239</sup> *Id.* at \*11–12.

<sup>240</sup> *Id.* at \*10.

<sup>241</sup> *Id.*

<sup>242</sup> U.S. *ex rel.* Polukoff v. St. Mark’s Hosp., 895 F.3d 730 (10th Cir. 2018).

<sup>243</sup> *Id.* at 742–43.

<sup>244</sup> *Id.* at 743.

definition of ‘false or fraudulent’ might expose doctors to more liability under the FCA,” the court pointed to the Supreme Court’s recent ruling in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, which highlighted the importance of proof of materiality and scienter in FCA cases.<sup>245</sup> Whether or not *Escobar* provides an important backstop in these cases, the decision illustrated the rolling legal standards in this area.

#### B. *The Problem of Reasonable Clinical Judgment*

As the *AseraCare* case waits on appellate resolution, recent case law shows that the application of the FCA to medical necessity-based fraud may be in the midst of a reorganization. Indeed, the government has entered into a litany of settlements in recent years with doctors, hospitals, and skilled nursing facilities that have resolved medical necessity-based fraud allegations.<sup>246</sup> These settled cases sent a strong message to the provider community that a failure to demonstrate or defend the medical necessity of an administered procedure or product constitutes a false claim. Care that is administered that is allegedly not medically necessary has—with few exceptions—been enough for the government to achieve FCA settlements.<sup>247</sup>

But those are settled cases, and within medical necessity-based cases that make it in front of a judge or jury, “most courts have acknowledged that

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<sup>245</sup> *Id.*

<sup>246</sup> See, e.g., Press Release, U.S. Dep’t of Justice Office of Pub. Affairs, Dignity Health Agrees to Pay \$37 Million to Settle False Claims Act Allegations (Oct. 30, 2014), <https://www.justice.gov/opa/pr/dignity-health-agrees-pay-37-million-settle-false-claims-act-allegations> (documenting the settlement of allegations “that 13 of [Dignity Health’s] hospitals in California, Nevada and Arizona knowingly submitted false claims to Medicare and TRICARE by admitting patients who could have been treated on a less costly, outpatient basis”); Press Release, U.S. Dep’t of Justice, Nation’s Largest Nursing Home Therapy Provider, Kindred/Rehabcare to Pay \$125 Million to Resolve False Claims Act Allegations (Jan. 12, 2016), <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-therapy-provider-kindredrehabcare-pay-125-million-resolve-false> (discussing an agreement settling allegations that companies “violated the False Claims Act by knowingly causing skilled nursing facilities (SNFs) to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary and skilled, or that never occurred”); *DOJ: Orthopedic Surgery Practice Agrees to Settle False Claims Act Allegations*, NEWS4JAX (Dec. 7, 2016), <http://www.news4jax.com/news/local/jacksonville/doj-orthopedic-surgery-practice-agrees-to-settle-false-claims-act-allegations> (documenting that, among other allegations, an orthopedic medical group “used and billed for ultrasound-guided injections routinely even in the absence of medical necessity”); Kurt Eichenwald, *Tenet Healthcare Paying \$54 Million in Fraud Settlement*, N.Y. TIMES: TIMESMACHINE (Aug. 7, 2003), <http://www.nytimes.com/2003/08/07/business/tenet-healthcare-paying-54-million-in-fraud-settlement.html> (noting that the settlement was entered into “to resolve government accusations that doctors at a hospital in Northern California conducted unnecessary heart procedures and operations on hundreds of patients” and that the “settlement is the largest in a case [at the time] involving what is known as medical necessity fraud, or billing government health programs for tests and treatments that the patient’s condition did not require”).

<sup>247</sup> See, e.g., Eichenwald, *supra* note 246.



‘liability under the FCA . . . must be predicated on an objectively verifiable fact.’”<sup>248</sup> This becomes a difficult challenge, especially when trying to determine whether “a statement or certification by a physician or other practitioner that a service or item is medically necessary objectively false, and what must the government or the relator allege and prove to establish a knowingly false certification or statement.”<sup>249</sup> Of course, the challenge involves the intersection between the “objective falsehood” requirement and the “subjective judgment on which medical experts, may, in many cases, reasonably disagree”—which often can be the hallmark of a medical necessity determination.<sup>250</sup>

As a result, like in *AseraCare*, if courts conclude that FCA claims based on reasonable opinions of medical necessity are not typically actionable—even if those decisions could be deemed negligent—well-settled FCA applications seem to be at risk.<sup>251</sup> Nonetheless, medical necessity statements can be “objective falsehoods” if they conflict with clearly known facts, are completely unsupportable, or depend upon false information that was knowingly submitted.<sup>252</sup>

Consequently, the predominant challenge of prosecuting a medical necessity-based fraud case becomes mapping an intent-based fraud statute onto the heterogeneous and complex world of clinical decision-making. If the DOJ focuses on the clinical care at issue—that is, that some care is medically necessary and that other care is fraudulent—then the clinical decisions that are somewhere between the poles on that continuum are hard to define. This challenge invites courts to opt for clear, simple rules in this foggy area—which explains the enticing cleanliness present in dismissing a medical necessity-based FCA claim due to a “mere” clinical disagreement between doctors.<sup>253</sup>

But, while simple, this may not fully represent the precedent, structure, and common usage of the FCA. It is an odd paradox to claim that, due to medical complexity, the DOJ would be unable to prove that a clinical decision lacks medical necessity in *any* case—i.e., that any clinical decision-maker is subject to yawning and unverifiable medical heterogeneity—but it seems that this conclusion may be the import of *AseraCare* and some of its

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<sup>248</sup> Michael W. Youtt, H. Victor Thomas, & Adam Robison, *The FCA and Fraudulent Opinions of Medical Necessity*, 32 A.B.A. GP SOLO, no. 6, Nov./Dec. 2015, at 74 (quoting *U.S. ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App’x. 980, 983 (10th Cir. 2005)).

<sup>249</sup> *Id.* at 75.

<sup>250</sup> *Id.* at 74.

<sup>251</sup> *Id.* 74–75 (“Courts have recognized that mere differences of scientific or medical opinions are not actionable under the FCA.”).

<sup>252</sup> *Id.* at 75.

<sup>253</sup> See *AseraCare I*, 153 F. Supp. 3d 1372 (N.D. Ala. 2015), *appeal docketed*, No. 16-13004 (11th Cir. 2016); *AseraCare II*, 176 F. Supp. 3d 1282, 1284 (N.D. Ala. 2016).

progeny. That is seemingly what defense counsel would have the enforcement regime resemble, which is, in effect, an unenforceable legal rule because of the helpless complexity and variability that accompanies medical practice. Nevertheless, this results in an under-inclusive rule altogether because some physicians do administer health services that are knowingly lacking in medical necessity, and billing for those services clearly constitutes fraud.

C. *Medical Necessity as Relevant to Intent*

Although most courts treat the question of whether or not care was administered that was lacking in medical necessity as an analysis that addresses the falsity of the claim submitted, one could make an argument that courts should instead fit the medical necessity question into the FCA's intent analysis. This is for a couple of main reasons.

First, billing for care that is lacking in medical necessity is billing for a false claim.<sup>254</sup> Within the Medicare program, it follows that Medicare defines what is medically necessary. It cannot be the case that care that is the result of clinical judgment *cannot* be false when a claim for reimbursement is submitted. Presumably, if Medicare's standard is outdated and irrational, then the provider who violates that standard and bills for the care *still* has submitted a false claim for purposes of falsity under the FCA. Indeed, when the provider bills for care that does not meet this standard, she cannot overcome the argument that, just because reasonable doctors may disagree over the standard, care administered and billed for is *not false* for purposes of FCA liability.

Now, whether or not American patients, taxpayers, and providers want a system that would produce such a result is a worthwhile and weighty question—a question that has been grappled with multiple times before.<sup>255</sup> It likely does not make sense to disempower American providers in that way, and, in fact, doing so may chill innovation and the organic development of the standard of care. If Medicare defines certain care as “non-medically necessary,” however, then billing for that care—under simple interpretative principles of the FCA—is false.

Of course, what makes this even worse for providers is that, like payers generally, under this regime, Medicare has the discretion to change the

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<sup>254</sup> See Youtt et al., *supra* note 20.

<sup>255</sup> See Isaac D. Buck, *Caring Too Much: Misapplying the False Claims Act to Target Overtreatment*, 74 OHIO ST. L.J. 463 (2013) [hereinafter Buck, *Caring Too Much*] (documenting the problems associated with using the FCA to prevent and punish claims of alleged overtreatment); Isaac D. Buck, *Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259 (2015) (placing overtreatment regulation into the scholarship of overenforcement).

standard of what is medically necessary, or not, as it sees fit. The result is a system of outdated clinical standards, or not, depending on which area of medicine the provider practices, and perhaps most importantly, a complex enforcement environment that often fails to notify providers who treat Medicare patients. What seems the most troubling about this system is Medicare's failure to adequately update its standards and, above all, its failure to notify providers—either before care is administered, or even after a bill is submitted, but well before any fraud investigation is opened—of what, exactly, that medical standard is. The problem, then, seems to be one of *notice*.

Nevertheless, a provider who submits a bill for care that is—in some way—not what Medicare believes it should pay, has submitted a “false” claim under the FCA. For sure, it is up to the DOJ to prove that the claim is “false,” but concluding that “reasonable” differences in clinical decision-making blocks the FCA from applying to these types of clinical judgments cannot be the rule. As the appellate brief in *AseraCare* mentions, “[t]he existence of competing expert testimony as to whether a Medicare claim is reimbursable [and if not, then false] does not mean the standard is incapable of objective evaluation and application.”<sup>256</sup> Adopting this new standard would cause FCA enforcement within the health care space—and a substantial number of enforcement actions and settlements—to grind to a halt.

Instead, it seems as though this is not a fight over falsity at all, but rather over the FCA's intent standard. It is definitely the case that the FCA's intent standard—defined as an act requiring either “actual knowledge,”<sup>257</sup> an act in “deliberate ignorance of the truth or falsity of the information,”<sup>258</sup> or an act in “reckless disregard of the truth or falsity of the information”<sup>259</sup>—is often a relatively small hurdle for prosecutors to leap. Nonetheless, there may be clinical decisions that could meet the FCA's falsity standard (assuming they conflict with Medicare's standards), but that would not constitute false *claims* because the clinical decisions could be negligent or even reasonable, given the clinical history of the patient or the typical practice of the provider.

Indeed, if the doctor has administered care that is “reasonable,” but, of course, not in compliance with Medicare's conception of medical necessity, then the provider has not met the intent standard under the FCA. Even if the

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<sup>256</sup> Brief for Appellant at 28, *United States v. GGNSC Admin. Servs.*, No. 16-13004 (11th Cir. Aug. 31, 2016).

<sup>257</sup> See 31 U.S.C. § 3729(b)(1)(A)(i) (2018).

<sup>258</sup> *Id.* § 3729(b)(1)(A)(ii).

<sup>259</sup> *Id.* § 3729(b)(1)(A)(iii). Courts have also noted that perhaps all that is required is gross negligence “plus.” See Buck, *Caring Too Much*, *supra* note 255, at 483 n.140 (listing cases).

provider was in some way negligent surrounding the clinical decision-making vis-à-vis the Medicare standard, this would still not meet the constraints of the FCA.<sup>260</sup> The intent standard kicks in to protect reasonable, and even *some* unreasonable, beliefs and submissions.

As the government argued in its appellant's brief to the Eleventh Circuit, the concepts of falsity and scienter, or intent, under the FCA were "conflated" by the district court in *AseraCare*.<sup>261</sup> After noting the court's conclusion that opinions and clinical judgments cannot constitute the falsity requirement under the FCA, the DOJ argued that "whether reasonable minds might have a good faith disagreement as to whether AseraCare's physician certifications were supported by medical documentation is a question that goes to whether AseraCare *knowingly* submitted false claims to Medicare, not whether those claims were false."<sup>262</sup> The DOJ brief goes on to argue that

[t]he district court was apparently concerned that False Claims Act liability might attach even if a certifying physician acted reasonably in believing that a patient was eligible for hospice services. But that concern is not properly addressed by altering the definition of what makes a claim "false" under the FCA. As the Supreme Court recently explained, there is no need to "adopt[] a circumscribed view of what it means for a claim to be false or fraudulent," because "concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.'"<sup>263</sup>

Finally, the Supreme Court's 2016 decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*,<sup>264</sup> provides some additional guidance on the question, emphasizing the importance of intent under the FCA. Even though the Court's analysis focused on the viability of the implied certification theory and on materiality under the FCA, the Court did provide interesting remarks on intent, highlighting its importance as a backstop to expansive liability.<sup>265</sup>

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<sup>260</sup> See Buck, *Caring Too Much*, *supra* note 255, at 483.

<sup>261</sup> Brief for Appellant, *supra* note 256, at 32.

<sup>262</sup> *Id.* at 32–33.

<sup>263</sup> *Id.* at 34 (citing *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, No. 15-7, slip op. at 13–14 (S. Ct. Apr. 19, 2016)).

<sup>264</sup> 136 S. Ct. 1989, 2002 (2016).

<sup>265</sup> See *id.* ("[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, 'concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.' Those requirements are rigorous.") (internal citation omitted).

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Why, exactly, this relatively narrow argument over where medical necessity belongs in the fraud enforcement context matters is because it likely hamstring the DOJ's ability to adequately regulate cases of demonstrated health care fraud. If courts conclude that doctors engaging in "reasonable" disagreements about care are allowed to bill and receive Medicare reimbursement for that care, then the legitimacy of the enforcement mechanism begins to crumble.

Like in the FDCA-FDA context mentioned earlier in this Article,<sup>266</sup> the *legal* question of whether or not fraud occurred then becomes hitched to the *scientific* question of whether or not the care was reasonable—or, in the FDCA context, the question of whether the marketing information was truthful. This builds uncertainty into the enforcement mechanism, and allows targeted physicians and professionals to appeal to Americans' special reverence for the medical community while allowing for a system to take hold that immunizes providers from suit based upon "reasonable" clinical disagreements. As a result, the FCA fully transforms into a negligence-based statute, immunizing providers who administer care that is not medically necessary, but "reasonable" nonetheless.

What is particularly noteworthy about this development is that it seems to be occurring in conjunction with strong, new value-based payment incentives that are taking hold within Medicare. As a result, the question of medical necessity appears to be migrating from a fraud standard to a reimbursement one. These changes are most prominently illustrated by the passage of the Medicare Access and CHIP Authorization Act (MACRA),<sup>267</sup> which is summarized immediately below.

#### VI. MOVING TO REIMBURSEMENT-BASED INCENTIVES

As has been the case in medical necessity-based fraud enforcement, actions like the one seen in the *AseraCare* case evince a deeper structural problem within American health care. That is, within American health care, both payers and patients are particularly vulnerable to medicine's dark inclinations that push the system toward excess. Laws and regulations in health care—sources of power one would expect to protect consumers and payers from overtreatment and excess medical costs—contain insufficient cost-sensitive provisions. And because providers own the relevant expertise, patients and payers are unable to evaluate and value the care they receive. Applied in industries beyond health care, this has been defined by

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<sup>266</sup> See discussion and accompanying notes *supra* pp. 7–9 and notes 18–30.

<sup>267</sup> See Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87.

economists and other scholars as the problem of “credence goods.”<sup>268</sup> Other scholars have referred to the challenge as the problem of the fraudulent expert.<sup>269</sup>

In the world of fraud and abuse enforcement, the credence goods problem makes it extraordinarily difficult for market-based consumer tools to work. As a result, and because consumers cannot adequately protect themselves (and their payers) from excess, the DOJ steps in to assist. And where the DOJ intervenes using the anti-fraud tools, the medical community often strikes back, arguing that the legal standard is outdated or unrealistic, and application of which would actually harm patients.<sup>270</sup>

After years of an enforcement regime that has been dominated by these arguments, it finally seemed as though Medicare had begun to turn the page with the passage of MACRA in 2015.<sup>271</sup> MACRA imposes a number of new efficiency-based metrics on providers and entities, and finally moves the overtreatment and efficiency arguments fully into reimbursement policy.

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<sup>268</sup> See, e.g., Abigail R. Moncrieff, *The Individual Mandate as Healthcare Regulation: What the Obama Administration Should Have Said in NFIB v. Sebelius*, 39 AM. J.L. & MED. 539, 546 (2013) (noting that the credence good problem constitutes a market failure in the health insurance marketplace, and defining a credence good as “one that consumers have a hard time evaluating both before and after consumption such that experience provides little if any help in determining one’s willingness to pay for future consumption—even from the same provider”).

<sup>269</sup> See, e.g., Nathaniel G. Hilger, *Why Don’t People Trust Experts?*, 59 J.L. & ECON. 293, 293 (2016) (suggesting that a conflict of interest exists because “these experts first diagnose the consumer’s condition, and then they treat the condition they have diagnosed”). Hilger suggests that consumers should be able to “observe experts’ cost functions,” and that without such observation, “honest treatment becomes impossible in a wide range of price-setting and market environments.” *Id.* at 294.

<sup>270</sup> First, the provider community powerfully argues for the hospice patients who may be adversely affected by “gun-shy” providers as a result of the government’s theory of liability. As seen in a brief filed by the American Medical Association, among other medical associations and societies, a powerful argument against tight application of the FCA in this context focuses on the concerns over the impact on health care access. See Brief for the American Medical Ass’n et al. as Amici Curiae Supporting Appellees, *United States v. GGNSC Admin. Servs.*, No. 2:12-cv-245 (11th Cir. 2016) (No. 16-13004). In attacking the government’s argument regarding falsity, the *amici* argued that the government’s argument was unreasonable, and

if accepted, the [g]overnment’s position would end up hurting the very people the Medicare hospice benefit is supposed to help: Fearing the prospect of litigation instigated by bounty-seeking relators, physicians may be reluctant to certify patients as terminally ill except in the most obvious of cases, leaving many deserving patients without the means to pay for hospice care. Because that is the opposite of what Congress intended, the [g]overnment’s position should be rejected, and the judgment of the District Court affirmed.

*Id.* at 6.

<sup>271</sup> Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87.

Assuming the shift occurs unchanged, new policy is able to fill the gap left by a receding medical necessity-based FCA enforcement. Instead of a hard law solution to these thorny issues of clinical heterogeneity and fraud, CMS seems poised to utilize reimbursement doctrine, and new value-based metrics, to target providers. Indeed, Medicare is in the midst of a sea change that will radically alter its ability to control costs.

MACRA constituted a fundamental shift for Medicare reimbursement policy. For the first time in decades, Congress radically changed the way Medicare pays its doctors under Part B<sup>272</sup>—that is, the part of the program that pays providers, and not hospitals, for the services they provide to its beneficiaries. Gone are the days of the Sustainable Growth Rate (SGR),<sup>273</sup> and the weak and ineffective pressure that it applied to providers in an attempt to control their costs.<sup>274</sup>

The “milestone”<sup>275</sup> passage of MACRA in April of 2015 repealed the SGR structure and ushered in “sweeping changes in physician value-based payment.”<sup>276</sup> “Representing a historic shift from traditional Medicare fee-for-service (FFS) reimbursement toward value-based payments for physician services,”<sup>277</sup> MACRA instantiates cost control and quality-based reimbursement throughout Medicare. Indeed, “it affects how Medicare pays

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<sup>272</sup> See *What Part B Covers*, MEDICARE.GOV, <https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html> (last visited Feb. 18, 2017).

<sup>273</sup> Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 541 n.103 (2013) (noting that the modern SGR was established in 1997); Wendy K. Mariner, *Health Insurance Is Dead; Long Live Health Insurance*, 40 AM. J.L. & MED. 195, 205 n.82 (2014) (“Medicare’s governing legislation requires CMS to set physician payment rates annually. The statutory formula for Sustainable Growth Rates has required reductions in payment rates since 2002, but Congress has postponed enforcement of those reductions annually.”).

<sup>274</sup> Richard Dolinar & S. Luke Leininger, *Pay for Performance or Compliance? A Second Opinion on Medicare Reimbursement*, 3 IND. HEALTH L. REV. 397, 401 (2006) (“The SGR system has been ineffective in controlling volume—the volume of physician services per beneficiary rose by almost twenty-two percent between 1999 and 2003 . . . .”); Briar Siljander & Jennifer L. Gross, *Assessing the Impact of the Medicare Access and CHIP Reauthorization Act: The Repeal of the SGR and Beyond*, 27 HEALTH LAW. 26, 26 (2015) (noting the “much-lauded repeal of the Medicare Sustainable Growth Rate [] methodology”); Bagley, *supra* note 273, at 542 (“Congress’s most assertive effort to counteract the incentives generated by a fee-for-service payment system—the global cap on Part B payments known as the SGR—has proven ineffective.”).

<sup>275</sup> *Quality Payment Program: Executive Summary*, U.S. DEP’T. OF HEALTH AND HUMAN SERVS.: CTRS. FOR MEDICARE AND MEDICAID SERVS. 4 (Oct. 14, 2016), <http://www.pecaa.com/wp-content/uploads/2016/04/QPP-Executive-Summary-of-Final-Rule.pdf> (“The MACRA marks a milestone in efforts to improve and reform the health care system.”).

<sup>276</sup> D. Scott Jones, *Physician Value-Based Payment Impacts All Physicians, 2016–2017*, 18 J. HEALTH CARE COMPLIANCE 11, 11 (2016).

<sup>277</sup> Charles B. Oppenheim & Kelly A. Carroll, *Looking Past MACRA’s Details: Key Long-Term Changes Ahead for Providers*, 10 J. HEALTH & LIFE SCI. L. 26 (2016).

all physicians and it will change how physicians consume and order services of other providers in an effort to improve quality and enhance cost effectiveness.”<sup>278</sup> This universal reform expands value-based reimbursement beyond the largely voluntary value-based alternative payment methods that currently exist.<sup>279</sup>

Its most audacious action institutes the Quality Payment Program (QPP).<sup>280</sup> According to CMS, this could impact more than a half-million providers, including physicians, physician assistants, nurse practitioners, and clinical nurse specialists.<sup>281</sup> Under the QPP, Medicare clinicians will be separated into one of two different reimbursement tracks. First, a smaller percentage of providers will participate in advanced alternative payment models (advanced APMs)—these include the Medicare Shared Savings Program and the Next Generation ACO Model.<sup>282</sup> Some of these advanced APMs will continue current voluntary alternative payment models.<sup>283</sup> Those who do not participate in an advanced APM will be enrolled in the Merit-Based Incentive Physician System (MIPS). Therefore, the balance of Medicare’s reimbursement change will take place under the MIPS program. Still, MIPS may be subject to a number of regulatory changes and delays as

<sup>278</sup> *Id.* at 29 (emphasis added).

<sup>279</sup> *See, e.g., Shared Savings Program*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/SharedSavingsProgram/> (last modified Aug. 10, 2018).

<sup>280</sup> *MACRA Quality Payment Program Overview*, U.S. DEP’T. OF HEALTH AND HUMAN SERVS.: CTRS. FOR MEDICARE AND MEDICAID SERVS. (Oct. 26, 2016), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf> [hereinafter *MACRA Quality Payment Program Overview*].

<sup>281</sup> *Id.* at 7 (those participating in Part B Medicare who bill the program more than \$30,000 annually and those who see more than 100 Medicare patients per year will be subject to the new reimbursement scheme). Newly-enrolled Medicare clinicians and those who participate in alternative payment methods, as well as those who do not meet the monetary and patient number cutoffs, are exempt from the reforms of MIPS. *Id.* *See also* Krista Teske, *Your Questions About the MACRA Final Rule—Answered*, ADVISORY BOARD (Jan. 31, 2017), <https://www.advisory.com/research/physician-practice-roundtable/members/expert-insights/2016/nine-faqs-on-provider-payment-under-macra> (“CMS estimates that approximately 712,000 clinicians will be affected by QPP changes in the first performance year (2017). However, not all clinicians will be subject to these changes.”).

<sup>282</sup> *MACRA Quality Payment Program Overview*, *supra* note 280, at 19; *see also* Oppenheim & Carroll, *supra* note 277, at 33 (“APMs include models such as accountable care organizations, patient-centered medical homes, and other models that have been evaluated by the Center for Medicare and Medicaid Innovation.”).

<sup>283</sup> *See Alternative Payment Models in the Quality Payment Program as of February 2018*, U.S. DEP’T. OF HEALTH AND HUMAN SERVS.: CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf> (last visited Feb. 19, 2017) (providing a chart for all advanced payment models and whether they qualify as an advanced APM under the new QPP).



it is implemented.

As of late 2017, under MIPS, a provider's reimbursement is affected by a composite score of four different criteria: quality, advancing care information, improvement activities, and cost.<sup>284</sup> During the first year, the quality data was scheduled to be weighted to make up sixty percent of the overall MIPS score, while improvement activities would make up fifteen percent, and advancing care information would make up the remaining twenty-five percent.<sup>285</sup> The cost metric is not included in the initial year of data collection; it begins in 2018.<sup>286</sup> By the 2019 performance year, however, cost will be weighted to make up thirty percent of the providers' overall MIPS score, and quality will drop from sixty to thirty percent.<sup>287</sup> Payment adjustments under MIPS will begin on January 1, 2019, as the first performance year has already concluded—it began on January 1, 2017.<sup>288</sup>

The four categories seek to encourage providers to administer high-quality care. Advancing care information seeks to protect patient health information, encourage electronic prescribing, provide patient electronic access, and promote the health information exchange.<sup>289</sup> Improvement activities ask providers to “attest to participation in activities that improve clinical practice,” like shared decision-making, patient safety efforts, care coordination, and increased access.<sup>290</sup> The quality performance category asks providers to select six of 271 possible quality measures, which includes one outcome measure or high-priority measure, on which to be measured.<sup>291</sup>

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<sup>284</sup> See *The Quality Payment Program Overview Fact Sheet*, U.S. DEP'T. OF HEALTH AND HUMAN SERVS.: CTRS. FOR MEDICARE AND MEDICAID SERVS. 9–10, [https://www.nyspsych.org/assets/docs/quality\\_payment\\_program\\_overview\\_fact\\_sheet.pdf](https://www.nyspsych.org/assets/docs/quality_payment_program_overview_fact_sheet.pdf) (last visited Feb. 19, 2017).

<sup>285</sup> *Id.*

<sup>286</sup> *Id.* at 10.

<sup>287</sup> See *Quality Payment Program Final Rule Summary*, AM. SOC'Y FOR RADIATION ONCOLOGY 4, [https://www.astro.org/uploadedFiles/\\_MAIN\\_SITE/Daily\\_Practice/Medicare\\_Payment\\_Initiatives/MACRA/Content/MACRAFinalRuleSummary.pdf](https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Medicare_Payment_Initiatives/MACRA/Content/MACRAFinalRuleSummary.pdf) (last visited Feb. 18, 2017). In the 2018 performance year, cost constitutes ten percent of the overall MIPS score, while quality drops from a weighted value of sixty percent to fifty percent. *Id.*

<sup>288</sup> *The Merit-Based Incentive Payment System: Advancing Care Information and Improvement Activities Performance Categories*, U.S. DEP'T. OF HEALTH AND HUMAN SERVS.: CTRS. FOR MEDICARE AND MEDICAID SERVS. 14 (Dec. 13, 2016), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MIPS-ACI-and-IA-presentation.pdf>.

<sup>289</sup> *Id.* at 20.

<sup>290</sup> *Id.* at 27.

<sup>291</sup> *The Merit-Based Incentive Payment System: Quality and Cost Performance Categories*, U.S. DEP'T. OF HEALTH AND HUMAN SERVS.: CTRS. FOR MEDICARE AND MEDICAID SERVS. 18 (Jan. 12, 2017), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/QPP-MIPS-Quality-and-Cost-Slides.pdf>.

And although the cost criterion does not enter the calculus until 2018, CMS has provided guidance for developing cost measures as well.<sup>292</sup> Its focus is on efficiency.<sup>293</sup>

MIPS penalties and bonuses will be phased in. In 2019, the first payment program year, penalties and bonuses will be limited to four percent adjustments of the provider's overall Medicare Part B reimbursement.<sup>294</sup> But by 2022 and after, the top penalties and bonuses could grow to nine percent.<sup>295</sup> Because MACRA "locks provider payment rates at near zero growth,"<sup>296</sup> and requires general budget neutrality, "such that the increase in charges resulting from positive adjustments equals the estimated decrease in charges resulting from negative MIPS adjustments,"<sup>297</sup> the bonuses that providers receive for positive adjustments could be as high as three times the penalties. Although it will not be known until the total numbers of positive adjustments are known, this general neutrality requirement means that bonuses could be as high as twenty-seven percent in 2022.<sup>298</sup>

Finally, given the undeniable fluidity that defines the current state of American health law and policy, it is worthwhile to consider whether the changes brought by MACRA and MIPS should be considered to be permanent. At least one consultant had noted that, while Congressional Republicans clearly intended to repeal and replace the Patient Protection and Affordable Care Act (ACA) in 2017, this "sentiment does not carry over to QPP" due to its strong support, its budgetary upside, and bipartisan interest in securing the future financial stability of Medicare.<sup>299</sup> Even though the repeal and replace effort did not succeed, the ACA has nonetheless been impacted by policy changes and enforcement priorities. Still, the Trump administration seems poised to limit and remake the MIPS program for 2019.<sup>300</sup>

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<sup>292</sup> *Id.* at 26–31 (noting the "five essential components" of establishing cost measures).

<sup>293</sup> *Id.*

<sup>294</sup> *How Payments, Penalties Will Change Post-SGR*, AM. MED. ASS'N.: AMA WIRE (July 2, 2015), <https://wire.ama-assn.org/ama-news/how-payments-penalties-will-change-post-sgr> [hereinafter *How Payments, Penalties Will Change Post-SGR*].

<sup>295</sup> *Id.*

<sup>296</sup> Teske, *supra* note 281.

<sup>297</sup> Oppenheim & Carroll, *supra* note 277, at 32.

<sup>298</sup> *Understanding Medicare's Merit-Based Incentive Payment System (MIPS)*, AM. MED. ASS'N., <https://www.ama-assn.org/practice-management/understanding-medicare-s-merit-based-incentive-payment-system-mips> (last visited Feb. 18, 2017); *see also How Payments, Penalties Will Change Post-SGR*, *supra* note 294.

<sup>299</sup> *See* Teske, *supra* note 281.

<sup>300</sup> *See* Steven Porter, *Expect Big MIPS Changes Under 2019 Quality-Reporting Proposals*, HEALTHLEADERS (July 16, 2018), <https://www.healthleadersmedia.com/clinical-care/expect-big-mips-changes-under-2019-quality-reporting-proposals>.

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*A FAREWELL TO FALSITY*

51

## VII. CONCLUSION

Like the larger health care delivery and administrative industry, the FCA—as it applies to medical necessity-based fraud cases in the United States—has entered a period of major uncertainty. While courts recognize new theories of falsity under the FCA, reimbursement-based tools are becoming more prominent. The FCA’s losses may be the reimbursement scheme’s gains. Nonetheless, the inability to use the FCA to regulate medical practice that is based upon a controversial conception of medical necessity may have real consequences for the future of health care fraud and abuse regulation—and, undoubtedly, on both the quality that American patients receive and the prices they pay.