No. 20-371

IN THE

Supreme Court of the United States

CARE ALTERNATIVES,

Petitioner,

v.

UNITED STATES OF AMERICA; STATE OF NEW JERSEY EX. REL. VICTORIA DRUDING; BARBARA BAIN; LINDA COLEMAN; RONNI O'BRIEN,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF *AMICI CURIAE* HOSPICE, HEALTH CARE, AND PHYSICIAN ORGANIZATIONS IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICI CURIAE*[1]

The **National Hospice and Palliative Care Organization (NHPCO)** is the oldest and largest membership organization in the country representing the entire spectrum of non-profit and for-profit hospice and palliative care programs and professionals in the United States. It represents over 4,000 hospice locations and more than 60,000 hospice professionals, caring for the vast majority of the nation's hospice patients. As such, it is committed to improving end-of-life care with the goal of creating an environment in which individuals and families facing serious illness, death, and grief will experience the best care that humankind can offer.

The **National Association for Home Care & Hospice (NAHC)** is a not-for-profit trade association representing the interests of nearly 6,000 home- and community-based health care providers throughout the nation, including hospices, home health agencies, and home care companies. The hospice members include non-profit, proprietary, public, and government-based entities. Since its inception in 1982, NAHC has directly participated in legislative and regulatory matters involving the Medicare hospice benefit along with numerous matters before the courts.

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[1] All parties were timely notified and consented to the filing of this brief. Nobody other than *amici* authored this brief in any part or funded its preparation or filing.

The **American Medical Association (AMA)** is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state and in every medical specialty.

The **American Academy of Hospice and Palliative Medicine (AAHPM)** is the professional organization for physicians specializing in hospice and palliative medicine. AAHPM's more than 5,500 members also include nurses and other health and spiritual care providers who are committed to improving the care and quality of life of patients with serious illness, as well as their families and caregivers. Since 1988, AAHPM has been dedicated to expanding access of patients and families to high-quality palliative and end-of-life care and advancing the discipline of hospice and palliative medicine through professional education and training, development of a specialist workforce, support for clinical practice standards, research, and public policy.

The **American Health Care Association (AHCA)** is a nationwide association of long-term and post-acute care providers that provide essential care to approximately one million individuals in over 14,000 not-for-profit and proprietary member facilities. AHCA advocates to government, business leaders, and the general public for quality care and services for frail, elderly, and disabled Americans. AHCA is committed to developing necessary and reasonable public policies that balance economic and regulatory principles to support quality care and quality of life.

SUMMARY OF THE ARGUMENT

The Court should grant certiorari to honor Congress's decision to defer to physicians' clinical judgment, to resolve a circuit split threatening gross disparities in hospice care provision, and to ensure Medicare's hospice benefit remains accessible to those who need it most. Left in place, the decision below and the circuit split it creates will inject retrospective second-guessing into the patient-physician relationship and arbitrarily restrict access to cost-effective end-of-life care—all without any foothold in statutory text.

Hospice care, which has time and again been shown to improve patient quality of life while reducing overall Medicare spending, is a critical part of our health care system. Focusing on caring, not curing, hospice care involves an interdisciplinary team working together to manage pain and symptoms, deliver therapies and counseling, and provide support to patients and their families at the end of life.

Both the number of individuals accessing hospice care and the number of hospice providers have continuously increased. Most hospice patients are Medicare beneficiaries. To be eligible for the Medicare hospice benefit, patients must be "terminally ill," meaning they have a "medical prognosis" that their "life expectancy is 6 months or less." 42 U.S.C. §§ 1395f(a)(7), 1395x(dd)(3)(A). Even for experienced hospice physicians, predicting life expectancy comes with inherent uncertainty and requires the exercise of clinical judgment.

To that end, Medicare pays for an individual's hospice care when a hospice physician certifies "that the individual is terminally ill . . . based on the physician's or medical director's *clinical judgment regarding the normal course of the individual's illness* . . . ." *Id.* § 1395f(a)(7) (emphasis added). Congress carefully adopted this statutory framework, which squarely bases the condition for payment on good-faith, reasonably supported clinical judgments of hospice physicians made at the time care is provided. The framework reflects the medical reality that reasonable physicians can reach different terminality determinations, with neither being wrong. At the same time they have consistently affirmed the centrality of hospice physicians' clinical judgment, Congress and CMS have adopted complementary measures—such as a requirement to evaluate patients face-to-face—to reinforce best practice. Congress has also created financial safeguards, including fixed rates and payment caps, to limit the government's payment obligations. Hospice care, in fact, typically saves money as compared to conventional per-service medical care.

Contrary to statutory text and medical reality, the decision below disregards Congress's decision to entrust the terminality determination to hospice physicians' clinical judgment. The Third Circuit concluded that a factfinder can second-guess a terminality determination and find it "false" under the False Claims Act *even if* the hospice physician exercised clinical judgment as required by statute. According to the Third Circuit, differing *post hoc* opinions about whether a patient was, in fact, terminally ill create a jury question regarding falsity. This holding opens a square circuit split with the Eleventh Circuit's recent decision on the same issue in *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019). *See* Pet. for Writ of Cert. 15–19.

The decision below and the circuit split it creates will lead to detrimental consequences for hospices, physicians, and patients. To start, the decision will complicate compliance with the Medicare payment statute. For multistate hospice providers operating on both sides of the circuit split, setting consistent internal policy may be nearly impossible. Knowing that treble damages, statutory penalties, and reputational harm accompany False Claims Act liability, these providers are more likely to craft reactionary organization-wide policies to comply with the Third Circuit's erroneous decision, extending legal error beyond its jurisdictional bounds.

So too will the decision below negatively affect hospice physicians' approaches to accepting patients and providing care. Fearing retrospective second-guessing of their clinical judgment, physicians may be reluctant to certify a patient as terminally ill unless the patient is nearly certain to die within six months. Other physicians, in turn, may hesitate to refer potential patients to hospice.

As a result, the decision below will restrict patient access to important care. Not only does the decision threaten access in jurisdictions that follow its rule, but the circuit split also could cause inter-circuit disparities. Even though Medicare sets a nationwide standard, similarly situated patients might experience different access to care based solely on where they happen to live.

As the average age of Americans increases and the demand for hospice care escalates, negative consequences flowing from the Third Circuit's decision will only intensify. By threatening to limit the availability of the Medicare hospice benefit, the decision could deprive millions of terminally ill individuals and their families of hospice care's undisputed benefits. It will encourage reliance on other forms of care that cost the health care system—and the government—more money. And it will do all this in defiance of statutory text and without medical justification.

ARGUMENT

I. Hospice care is an important and increasingly used part of our health care system, as Congress and CMS have recognized.

Improving quality of life while saving money, hospice offers compassionate end-of-life care for millions of Americans. Since the early 1980s, Medicare has paid for hospice care for terminally ill patients with a life expectancy of six months or less. Predicting life expectancy, however, comes with inherent uncertainty and requires the exercise of clinical judgment. For that reason, Congress has carefully tied Medicare payment to the reasonable, good-faith clinical judgment of hospice physicians actually treating Medicare beneficiaries. At the same time, Congress has structured the hospice payment model to save Medicare money.

A. Hospice care improves quality of life for millions of Americans, most of whom are Medicare beneficiaries.

Every year, millions of Americans turn to hospice care. *See, e.g.*, Nat'l Hospice & Palliative Care Organization, *NHPCO Facts and Figures*, 6–11, 22 (Aug. 20, 2020), https://bit.ly/3gTXpmx [hereinafter NHPCO]; Isaac D. Buck, *A Farewell to Falsity: Shifting Standards in Medicare Fraud Enforcement*, 49 Seton Hall L. Rev. 1, 11 (2018). Unlike conventional medicine, hospice care "focuses on caring, not curing." NHPCO, *supra*, at 2. Studies have repeatedly shown that hospice care is associated with reduced symptom distress, improved patient experience, and high patient and family satisfaction. *See* Ruth Kleinpell et al., *Exploring the Association of Hospice Care on Patient Experience and Outcomes of Care*, 9 BMJ Supportive & Palliative Care 13 (2019); Amy S. Kelley et al., *Hospice Enrollment Saves Money for Medicare and Improves Care Quality Across a Number of Different Lengths of Stay*, 32 Health Affairs 552 (2013). Indeed, hospice care "greatly improve[s] the quality of care for patients and their families near the end of life." Kelley, *supra*.

Depending on a patient's circumstances, hospice care can be delivered at the patient's home, in a freestanding hospice facility, at an assisted living facility, at a nursing home or long-term care facility, or in a hospital. NHPCO, *supra*, at 2–3. Regardless of setting, hospice care is provided by an interdisciplinary team "consist[ing] of the patient's personal physician, hospice physician or medical director, nurses, hospice aides, social workers, bereavement counselors, clergy or other spiritual counselors, trained volunteers, and speech, physical, and occupational therapists, [as] needed." *Id.* at 3. Working together, the hospice team provides a patient with virtually all needed care, from pain and symptom management, to psychosocial and spiritual counseling, and everything in between. *See* 42 C.F.R. § 418.3. The length of time any particular patient remains enrolled in hospice care can vary greatly—from a few days, to a few weeks, to multiple months. *See* NHPCO, *supra*, at 12–14. Although primarily used by elderly individuals, hospice care is available to (and used by) all age groups. *Id.* at 9.

With more and more individuals and their families accessing hospice for end-of-life care, the number of hospice organizations has also steadily increased. *See* Buck, *supra*, at 11. As of 2018, over 4,600 Medicare-certified hospice providers were operating—a 13.4% increase since 2014. NHPCO, *supra*, at 20. Hospice providers vary in size, from fewer than 50 patients to over 500 per day. *See id.*

Finally, the vast majority of hospice patients are Medicare beneficiaries. In 2018, 1.55 million Medicare beneficiaries were enrolled in hospice care at some point during the year. *Id.* at 6. That same year, over 50% of all Medicare decedents—those who died while on Medicare—were relying on hospice care at the end of their lives. *Id.* at 7. In 2001, that number was only 19%. Buck, *supra*, at 11. These numbers highlight how Medicare beneficiaries are increasingly choosing to rely on this important service to meet their health care needs at the end of life.

B. Congress and CMS have carefully designed the Medicare hospice benefit to account for the inherent uncertainty in predicting end of life.

The Medicare statute sets forth conditions for payment of health care services. *See* 42 U.S.C. § 1395f(a). Under the subsection devoted to hospice care, Medicare pays if "the individual's attending physician" and "the medical director" "certify in writing . . . that the individual is terminally ill . . . based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness . . . ." *Id.* § 1395f(a)(7).[2] As a medical matter, hospice care is intended to provide "caring, not curing" treatment and comfort for terminally ill individuals. *See* NHPCO, *supra*, at 2. It thus makes sense that Medicare pays for hospice care only for patients who are "terminally ill," 42 U.S.C. § 1395f(a)(7), meaning they have a "medical prognosis" that their "life expectancy is 6 months or less," *id.* § 1395x(dd)(3)(A).

Yet "[b]ecause death is a probabilistic event, its exact timing cannot be predicted with certainty." David Hui, *Prognostication of Survival in Patients with Ad-*

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[2] For the first 90-day hospice benefit period, both the "attending physician" *and* "the medical director" or "physician member of the interdisciplinary group" must certify. 42 U.S.C. § 1395f(a)(7). For subsequent benefit periods, only the medical director or physician member of the interdisciplinary group must certify. *Id.*

vanced Cancer: Predicting the Unpredictable?, 22 Cancer Control 489, 491 (2015); *see United States v. AseraCare, Inc.*, 938 F.3d 1278, 1282 (11th Cir. 2019). All hospice patients present with their own unique circumstances and conditions that impact the overall prediction. Moreover, substantial portions of hospice patients die of dementia, respiratory diseases, and other causes for which "the art and science of predicting prognosis" is particularly uncertain. Diane E. Meier, *Increased Access to Palliative Care and Hospice Services: Opportunities to Improve Value in Health Care*, 89 Milbank Q. 343, 355 (2011); *see* NHPCO, *supra*, at 11. This lack of certainty means physicians acting in good faith exercising clinical judgment can arrive at divergent predictions that are equally valid and supportable. *See AseraCare, Inc.*, 938 F.3d at 1296–98.

When crafting payment conditions for hospice care, Congress accounted for that inherent uncertainty. This is reflected in statutory text, which empowers the "physician's clinical judgment" to "dictate[] eligibility" "as long as it represents a reasonable interpretation of the relevant medical records." *Id.* at 1294; *see* 42 C.F.R. § 418.22(b)(2).

What the text lays bare, statutory and regulatory history reinforce. Congress had originally limited Medicare beneficiaries to 210 days of covered hospice care. Recognizing the scientific uncertainty in predicting life expectancy, Congress repealed the 210-day limit in 1989. *See* Pub. L. 101-234; 70 Fed. Reg. 70532, 70533 (Nov. 22, 2005). Medicare now covers hospice care for eligible beneficiaries for as long as they remain terminally ill.

Then in 1997, to further reflect how predicting life expectancy "will never be an exact science," 142 Cong. Rec. S9582 (Aug. 2, 1996) (statement of Sen. Breaux), Congress added a "sort of good faith defense" for providers submitting claims, *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (Gorsuch, J.); *see* 42 U.S.C. §§ 1395pp, 1395pp(g)(2); Pub. L. 105-33, § 4447. Section 1395pp protects "providers who didn't know and couldn't have reasonably been expected to know that their services weren't permissible when rendered" from "hav[ing] to repay the amounts they received from CMS." *Caring Hearts*, 824 F.3d at 970. Subsection (g)(2) explicitly covers hospice claims based on terminality determinations. This "sort of good faith defense," *id.*, provides some financial protection for hospices, which must assume a significant financial burden for their patients based on an inherently inexact terminality determination. Together with the 1989 repeal of the 210-day limit, this 1997 change underscores Congress's deliberate choice to entrust the terminality determination to hospice physicians' clinical judgment.

So too does CMS's "rulemaking commentary signal[] that well-founded clinical judgments . . . be granted deference." *AseraCare, Inc.*, 938 F.3d at 1295; *see, e.g.*, 79 Fed. Reg. 50451, 50470 (Aug. 22, 2014); 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013); 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010). CMS, in fact, explicitly rejected a proposal to define certification requirements, thereby "remov[ing] any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness." 73 Fed. Reg. 32088, 32138 (June 5, 2008).

CMS also understands that a terminal prognosis is far from a guarantee of death within six months. Rather, Medicare beneficiaries are hospice-eligible when their clinical status is "*more likely than not* to result in a life expectancy of six months or less." 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013) (emphasis added). That a patient has the "good fortune to live longer than predicted by a well-intentioned physician," Correspondence from Nancy-Ann Min DeParle, HCFA Administrator (date-stamped Sept. 12, 2000), "is not cause to terminate benefits," CMS, *Medicare Benefit Policy Manual*, CMS Pub. 100-02, Ch. 9, § 10, https://go.cms.gov/3leRkDV [hereinafter CMS, *MBPM*]. CMS has thus assured physicians that "[t]here is *no risk*" in "certifying an individual for hospice care that" the physician honestly "believes to be terminally ill." CMS, *Hospice Care Enhances Dignity And Peace As Life Nears Its End*, CMS Pub. 60AB, Transmittal AB-03-040, https://bit.ly/2DB9JtY (emphasis added).

As Congress and CMS have emphasized the centrality of clinical judgment, they have also adopted complementary measures to fortify hospice physician accountability. In 2009, CMS mandated that physicians include an attested "narrative explanation of the clinical findings that supports a life expectancy of 6 months or less" as part of a patient's certification. 42 C.F.R. § 418.22(b)(3); *see* 74 Fed. Reg. 39413 (Aug. 6, 2009). This narrative "must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients." *Id.* § 418.22(b)(3)(iv). Then in 2011, Congress and CMS began requiring hospice physicians (or employed hospice nurse practitioners) to have face-to-face encounters with patients anticipated to reach their third hospice benefit period. 42 U.S.C. § 1395f(a)(7)(D)(i); 42 C.F.R. § 418.22(b)(4). Information from these face-to-face encounters is then shared with the relevant practitioner before certification.

C. Hospice care saves the Medicare system money.

To be sure, hospice care has been a "quickly growing piece of the Medicare budget." Buck, *supra*, at 10. In 2018, patients collectively received 114 million days of Medicare-paid hospice care. NHPCO, *supra*, at 12, 18. At $19.2 billion dollars, this expenditure represented a 7.2% increase over the prior year. *Id.* Per hospice patient, Medicare spent $12,200 on average. *Id.* at 18.

Yet at the same time, hospice care saves the health care system—and hence, the government—money. By its very structure, the Medicare hospice payment model makes sure hospices take responsibility for virtually all end-of-life care, while providing overall cost-savings to the Medicare trust. *See* 76 Fed. Reg. 47301, 47302 (Aug. 4, 2011). To start, Medicare pays hospice providers an all-inclusive per-diem rate. 42 C.F.R. § 418.302. Payment is made at one of four predetermined rates for each day that a Medicare beneficiary is under the care of a hospice. 42 C.F.R. § 418.302; CMS, *Medicare*

Claims Processing Manual, CMS Pub. 100-04, Ch. 11, § 30.1, https://go.cms.gov/33veboE. The per-diem payment covers all hospice-care services, including skilled nursing services, physicians' administrative services, medical social services, physical and occupational therapy, home health aide, counseling, on-call services, medical equipment, and prescription drugs—all depending on the individual needs of the patient. *Id.* § 418.202; *see also* 83 Fed. Reg. 20934, 20948 (May 8, 2018).

Two payment caps further limit the government's obligations. These caps limit the amount and cost of care that any individual hospice agency provides in a single year. *See* 42 C.F.R. §§ 418.302(f), 418.308, 418.309; *see also* CMS, *MBPM*, *supra*, Ch. 9, § 90. One cap limits the number of days of inpatient care an agency may provide to not more than 20 percent of its total patient care days. 42 C.F.R. § 418.302(f). The other cap sets an aggregate dollar limit on the average annual payment per beneficiary a hospice provider can receive. *Id.* § 418.309. This aggregate cap limits the total payments that any individual hospice can receive in a cap year to an allowable amount based on an annual per-beneficiary cap amount and the number of beneficiaries served. *Id.* § 418.309; *see also* CMS, *MBPM*, *supra*, Ch. 9, § 90. Providers exceeding the cap must repay the excess. 42 C.F.R. § 418.308(d). Together, these caps protect the government against paying hospices above a certain dollar amount.

Hospice care also saves the government money *as compared to* conventional, per-service care. *See, e.g.*, Abt Associates, *Analysis of Medicare Pre-Hospice Spending and Hospice Utilization* (2015), https://go.cms.gov/34l48ln. Absent hospice care, the government would be called upon to pay for conventional per-service medical care *and also* "whatever palliative services are needed to manage [the patient's] terminal illness" such as durable medical equipment, pharmacy, radiology, labs, and therapies. 142 Cong. Rec. S9582 (Aug. 2, 1996) (statement of Sen. Breaux).

Several studies, moreover, have shown that hospice care can result in substantial cost savings to the Medicare program. *See, e.g.*, Brian W. Powers et al., *Cost Savings Associated with Expanded Hospice Use in Medicare*, 18 J. Palliative Med. 400 (2015); Christopher W. Kerr et al., *Cost Savings and Enhanced Hospice Enrollment with a Home-Based Palliative Care Program Implemented as a Hospice-Private Payer Partnership*, 17 J. Palliative Med. 1328 (2014); Ziad Obermeyer et al., *Association Between the Medicare Hospice Benefit and Health Care Utilization and Costs for Patients with Poor-Prognosis Cancer*, 312 J. Am. Med. Ass'n 1888 (2014); Kelley, *supra*; Donald H. Taylor Jr. et al., *What Length of Hospice Use Maximizes Reduction in Medical Expenditures Near Death in the US Medicare Program?*, 65 Social Science & Medicine 1466 (2007). These savings result from reduced use of hospital services at the end of life, which can also improve quality of life. *See* Kelly, *supra*.

II. The decision below and the circuit split it creates will negatively affect hospice care and detrimentally limit patient access.

The "clinical judgment" standard for Medicare hospice payment is both wise and workable. Its reasonable latitude affords *amici*'s member providers and physicians the confidence they need to truly serve all patients at the end of life, consistent with prevailing medical practice. Ensuring that Medicare beneficiaries can continue to access hospice care as the law intended depends on a faithful reading of Congress's decision to condition payment on a good-faith exercise of clinical judgment. To instead require physicians to always make an illusory "best" or "correct" terminality determination—from an after-the-fact perspective, when even *then* multiple determinations have clinical support—would depart from the reality of real-time medical practice. It would burden hospice physicians with a nearly impossible standard, chilling their willingness to accept patients. Congress did not impose such a standard—but the Third Circuit did.

A. Contrary to statutory text and medical reality, the decision below enables improper second-guessing of hospice physicians' clinical judgment.

The Medicare payment statute entrusts the terminality determination to hospice physicians' good-faith clinical judgment. *See* Pet. for Writ of Cert. 3–7, 27–32. To that end, "[n]othing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment." *AseraCare*, 938 F.3d at 1296. Not only does the statutory text ineluctably require this interpretation, but it also makes sense given the nature of hospice care and the uncertainty endemic to predicting life expectancy.

The Third Circuit's decision departs from statutory text and, in so doing, clashes with medical reality. Whereas Congress entrusted the terminality determination to hospice physicians' clinical judgment, the decision below permits actors *other than hospice physicians* to second-guess terminality determinations after the fact. To be sure, a factfinder can decide *whether* a hospice physician exercised clinical judgment reasonably and in good faith. *See id.* at 1297. Yet as long as the answer to that question is yes, statutory text precludes the factfinder from second-guessing the terminality *determination* any further.

Indeed, statutory text reflects the medical reality that two reasonable hospice physicians can reach different terminality determinations, both "based on . . . clinical judgment," 42 U.S.C. § 1395f(a)(7), with neither being wrong. But the Third Circuit's decision demands that a terminality determination be the *best*, as evaluated after the fact by paid experts and ultimately a lay factfinder. In so doing, the decision imposes a true/false binary that does not exist in the actual practice of medicine. It pressures a factfinder to answer the wrong question. Yet because "the [hospice] physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records," *AseraCare*, 938 F.3d at 1294, the factfinder's only question should be: "Did the hospice physician exercise clinical judgment?" By openly charting a contrary course, the Third Circuit interposed paid experts, judges, and juries in between patient and physician in a way that Congress rejected.[3]

Finally, although the Third Circuit's decision below arose in the hospice context, its reasoning is not so limited: standards dependent on reasonable clinical judgment pervade the Medicare program. *See, e.g.*, 42 C.F.R. § 412.3(d)(1)(i); 42 C.F.R. § 409.44(b)(3)(iii); 59 Fed. Reg. 56116, 56166 (Nov. 10, 1994); CMS, *MBPH*, ch. 7, § 20.3. Whether for hospice care or other treatment, the Medicare program recognizes that treating physicians "are best suited to evaluate each patient and determine whether a treatment is reasonable and necessary for that individual patient." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489 (3d Cir. 2017).

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[3] None of this is to suggest that hospice physicians' actions are wholly immunized from scrutiny under the False Claims Act. But "in order to properly state a claim under the FCA in the context of hospice reimbursement, a plaintiff alleging that a patient was falsely certified for hospice care must identify facts and circumstances surrounding the patient's certification that are inconsistent with the proper exercise of a physician's clinical judgment." *AseraCare*, 938 F.3d at 1297.

B. The decision below and the resulting circuit split threaten detrimental consequences for hospice providers, physicians, and patients.

The Medicare program, including the hospice benefit, is intended to create a national standard for uniform payment of health care services across all domestic boundaries. *See Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 134 (2d Cir. 2002) ("Medicare is . . . administered, for the most part, by intermediaries, who must apply a uniform set of standards established by federal law."); *see also, e.g.*, *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989) ("[F]ederal statutes are generally intended to have uniform nationwide application."); *Meyer v. Health Mgmt. Assocs., Inc.*, 841 F. Supp. 2d 1262, 1270 (S.D. Fla. 2012) ("[T]he federal government unquestionably has a strong interest in uniformity and consistency of federal [Medicare] law.") (quotation omitted) (second alteration in original).

The circuit split resulting from the decision below undermines national uniformity. It creates different standards—and hence, different incentives and different consequences—in different geographical areas. These differences, however, bear no relation to the purposes of hospice care or to its practice. They are arbitrary and threaten to cause detrimental consequences for hospice providers, physicians, and patients. Given hospice care's ever-increasing use and importance, *see supra* Part I.A, these consequences can impact millions of individuals and their families.

First, the decision below and the resulting circuit split will cause problems for hospice providers attempting to comply with the Medicare payment statute. Many hospice providers are large and have a presence in several states (and multiple federal circuits). AseraCare, for instance, "[o]perate[s] approximately sixty hospice facilities across nineteen states and admit[s] around 10,000 patients each year." *AseraCare*, 938 F.3d at 1282.

In jurisdictions following statutory text and *AseraCare*, hospice providers can align their internal policies with how their physicians practice. By contrast, in jurisdictions following the Third Circuit's standard of retrospective review for the "correctness" of terminality determinations, hospice providers cannot operate the same way. They know their physicians can exercise clinical judgment reasonably and in good faith *but still* be subject to second guessing. These providers will thus reflexively and defensively "adopt more internal review practices of all physician judgments." Melissa E. Najjar, *When Medical Opinions, Judgments, and Conclusions Are "False" under the False Claims Act: Criminal and Civil Liability of Physicians Who Are Second-Guessed by the Government*, 53 Suffolk U. L. Rev. 137, 157 (2020). "Requiring each and every judgment to undergo a process of review," however, "will delay patient care and increase costs." *Id.* For providers with physicians and patients on *both* sides of the circuit split, setting policy at the organization level could be nearly impossible. Yet there is no reason why good-faith clinical judgment should be dispositive *here* but not *there*—especially when medical standards and Medicare statutory text remain the same.

Hospice providers well-know of the False Claims Act's hard hammer. "[E]ssentially punitive in nature," *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000), the False Claims Act exposes providers to treble damages, statutory penalties, attorneys' fees, and other consequences, including severe reputational harm and debarment from government programs. Although the decision below enables atextual second-guessing of hospice *physicians'* determinations, False Claims Act liability ultimately flows to hospice *provider organizations*. Under the Third Circuit's regime, not only does the hospice ultimately not get paid for services rendered, but it also becomes subject to the False Claims Act's punitive enhancements.

As the demand for (and supply of) hospice care has increased, so too has opportunistic litigation against hospice providers. *See* U.S. Dep't of Justice, *Fraud Statistics* (2018), https://bit.ly/3lMuCUM; *See generally* Buck, *supra*; Am. Bar Ass'n, *Deputy AG Rod Rosenstein to Speak at ABA Conference on Civil False Claims Act and Qui Tam Enforcement* (June 6, 2018), https://bit.ly/34x7HXf. This litigious trend has generated legal uncertainty that is unsustainable for providers and physicians and unfair to patients. Expanding the scope of potential liability, as the Third Circuit did below, will only encourage more *qui tam* lawsuits. Such risk may cause hospice providers to adopt unduly conservative or reactionary policies for accepting patients that are driven by litigation risk rather than medical science. For administrative uniformity and to mitigate risk, hospice providers operating on both sides of the circuit split will likely gravitate toward the new norms demanded by the Third Circuit. Even if the decision below is only *law* in limited areas, hospice providers may themselves transport its detrimental consequences beyond its jurisdictional bounds.

In addition, the patchwork of approaches resulting from the circuit split may encourage forum shopping by *qui tam* relators. The False Claims Act authorizes venue "in any judicial district in which the defendant *or*, in the case of multiple defendants, any one defendant can be found, resides, transacts business, *or* in which any [proscribed] act . . . occurred." 31 U.S.C. § 3732(a) (emphases added). With this generous venue provision and the broad geographic footprint covered by many False Claims Act disputes, relators will often be able to find a reason to file suit within the Third Circuit against many a would-be defendant.

Finally, the circuit split threatens to exacerbate an already significant—but less visible—burden on providers. Under the False Claims Act, the Department of Justice liberally serves civil investigative demands (CIDs) in response to *qui tam* suits filed under seal. These CIDs often involve extensive discovery, last several years, and cost providers hundreds of thousands of dollars. The less certain the law, the more protracted CIDs tend to be—and the more likely providers capitulate through burdensome settlements regardless of merit. The circuit split here will contribute more legal uncertainty, thereby forcing more settlements in unmeritorious investigations. Further percolation of the circuit split is thus unnecessary and potentially harmful.

Second and relatedly, the decision below may negatively affect hospice physicians' approach to providing care and accepting patients. Physicians respond to legal changes that increase or decrease their threat of liability. *See, e.g.*, Ronen Avraham & Max M. Schanzenbach, *The Impact of Tort Reform on Intensity of Treatment: Evidence from Heart Patients*, 39 J. of Health Economics 273 (2015) (finding that changes in tort liability affect treatment patterns); Jeffrey Clemens & Joshua D. Gottlieb, *Do Physicians' Financial Incentives Affect Medical Treatment and Patient Health?*, 104 Am. Econ. Rev. 1320 (2014) (finding that "financial incentives significantly influence physicians' supply of health care" and that "reimbursement changes lead physicians to adjust treatment patterns"); Michael Frakes, *Defensive Medicine and Obstetric Practices*, 9 J. of Empirical Legal Studies 457 (2012) (finding that changes in tort liability affect treatment patterns). Evidence further shows that whereas uniform legal standards correlate with uniform practice standards, fractured legal standards correlate with fractured practice standards. *See* Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules*, 103 Am. Econ. Rev. 257 (2013).

Despite statutory text setting a payment standard in line with medical reality, the decision below raises the specter of False Claims Act liability even for terminality determinations based on clinical judgment. "[B]ecause even good faith medical opinions may become scrutinized and deemed false," physicians may forgo their best clinical judgment and "become reluctant" to certify a patient as terminally ill unless the patient is *nearly certain* to die within six months. Najjar, *supra*, at 157; *see also* 79 Fed. Reg. at 50470; *see also* 55 Fed. Reg. 50831, 50831–32 (Dec. 11, 1990) (describing how physicians were "discourage[d] . . . from certifying terminal illness" when the law "seemed to require certainty of prognosis"). Some hospice physicians, moreover, practice across jurisdictional lines. The circuit split dissonantly asks those physicians to conform their medical practice to multiple divergent legal standards, one of which is inconsistent with medical reality.

Third, as a direct result of its negative effects on hospice provider and physician behavior, the decision below will detrimentally affect patient access to care. Most hospice patients are Medicare beneficiaries whose eligibility hinges on an inexact, discretionary terminality determination. To mitigate the legal risk of potential False Claims Act scrutiny, providers and physicians may become more conservative in their terminality determinations than the practice of hospice medicine alone would demand. This, in turn, could limit *access* to hospice care for Medicare beneficiaries. These access effects could further compound as referring physicians become discouraged by hospice provider rejections. The Third Circuit's decision, like other cases imposing questionable False Claims Act standards, "ha[s] the potential to chill access to and quality of healthcare," particularly for "the nation's most vulnerable and fragile populations." Najjar, *supra*, at 157.

Not only does the decision threaten access to care within the Third Circuit, but the split it creates also threatens to spawn perverse disparities across the country. Individuals living in jurisdictions following the Third Circuit's precedent may have more restricted access to Medicare-covered hospice care than individuals living in other jurisdictions. Patients will thus receive different care not because of differences in medical condition, but because of where they happen to live. *Cf.* Michaelle Huckaby Lewis et al., *The Locality Rule and the Physician's Dilemma Local Medical Practices vs the National Standard of Care*, 297 J. Am. Med. Ass'n 2633 (2007) (discussing drawbacks of location-specific legal standards for medical care). Indeed, the decision below may arbitrarily keep many out of hospice altogether, causing needless suffering and denying those patients the benefits of hospice care.

Individuals who would medically benefit from hospice care, moreover, generally cannot use the power of exit to relocate to a more favorable jurisdiction. It is exceedingly difficult for most terminally ill individuals to move even short distances, much less to a different state. (That is among the reasons why most hospice care is provided in a patient's own home.) And even if a patient could exit to a more favorable jurisdiction, a difficult choice might follow: stay where you are with family, friends, and a familiar surrounding *but forgo* *hospice care*; or move to a different jurisdiction *but leave behind everything else at the end of life*.

* * *

Hospice care is a critical, growing, and cost-effective component of our health care system—as is the Medicare hospice benefit relied on by millions. The need for hospice care will only accelerate as American population demographics trend older. The Court should grant certiorari to resolve a circuit split creating arbitrary distinctions, to correct a textually unsupported and medically incoherent rule, and to ensure the Medicare hospice benefit is not unjustifiably curtailed to the detriment of those who need it most.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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