No. 25-3542

IN THE United States Court of Appeals FOR THE SIXTH CIRCUIT

IN HOME HEALTH, LLC, Plaintiff-Appellant,

v.

ROBERT F. KENNEDY, JR., Defendant-Appellee.

Appeal from the U.S. District Court for the Northern District of Ohio, No. 3:24-cv-00281, Hon. Jack Zouhary

AMICUS BRIEF OF
THE NATIONAL ALLIANCE FOR CARE AT HOME, INC. AND
AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE, INC.
IN SUPPORT OF APPELLANT AND REVERSAL

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UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Case I	Circuit Number: <u>25</u>	-3542	Case Name:	In Home Heal	lth, LLC v. Robe	ert F. Kenne
Name	of counsel:	William A. Dombi	& Jason E. Bring	(admission pe	ending)	
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This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

6th Cir. R. 26.1 DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

(a) Parties Required to Make Disclosure. With the exception of the United States government or agencies thereof or a state government or agencies or political subdivisions thereof, all parties and amici curiae to a civil or bankruptcy case, agency review proceeding, or original proceedings, and all corporate defendants in a criminal case shall file a corporate affiliate/financial interest disclosure statement. A negative report is required except in the case of individual criminal defendants.

(b) Financial Interest to Be Disclosed.

- (1) Whenever a corporation that is a party to an appeal, or which appears as amicus curiae, is a subsidiary or affiliate of any publicly owned corporation not named in the appeal, counsel for the corporation that is a party or amicus shall advise the clerk in the manner provided by subdivision (c) of this rule of the identity of the parent corporation or affiliate and the relationship between it and the corporation that is a party or amicus to the appeal. A corporation shall be considered an affiliate of a publicly owned corporation for purposes of this rule if it controls, is controlled by, or is under common control with a publicly owned corporation.
- (2) Whenever, by reason of insurance, a franchise agreement, or indemnity agreement, a publicly owned corporation or its affiliate, not a party to the appeal, nor an amicus, has a substantial financial interest in the outcome of litigation, counsel for the party or amicus whose interest is aligned with that of the publicly owned corporation or its affiliate shall advise the clerk in the manner provided by subdivision (c) of this rule of the identity of the publicly owned corporation and the nature of its or its affiliate's substantial financial interest in the outcome of the litigation.
- (c) Form and Time of Disclosure. The disclosure statement shall be made on a form provided by the clerk and filed with the brief of a party or amicus or upon filing a motion, response, petition, or answer in this Court, whichever first occurs.

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

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Name	of counsel:	William A. Dombi	& Jason E. Bring (admission pending)	
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			. Dombi en Gregory LLP bi@agg.com	

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Table of Contents

1.	INT	ERESTS OF AMICI	1
II.	STA	ATEMENT OF AMICI	3
III.	SUN	MMARY OF ARGUMENT	4
IV.	ARO A. B.	GUMENT Death is impossible to predict accurately The Negative Impacts of the Rulings Below	8
	C.	1. Patients	13 21 23
		 The physician is the "central figure" in the assessment of patients and patients' needs Congress recognized that terminal prognosis is not a perfect science 	
V.	COI	NCLUSION	34
CEF	RTIFI	CATE OF COMPLIANCE	35

TABLE OF AUTHORITIES

ı	age(s)
Cases	
United States ex rel. Anderson v. Curo Health Servs. Holdings, Inc., 2022 U.S. Dist. LEXIS 49561 (M.D. Tenn. Mar. 21, 2022)	27
Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019)	32
Exec. Dir. ex rel. Carey v. Sebelius, 698 F. Supp. 2d 436 (D. Vt. 2010)	28
Caring Hearts Pers. Home Servs. v. Burwell, 824 F.3d 968 (10th Cir. 2016)31	., 32, 33
Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261 (1990)	17
Cypress Home Care, Inc. v. Azar, 326 F. Supp. 3d 307 (E.D. Tex. 2018)	32
Hospice of E. Texas v. Sec'y of HHS, 2025 U.S. Dist. LEXIS 62035 (E.D. Tex. Feb. 21, 2025)	, 32, 33
United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. 2019)	, 28, 29
Statutes	
42 U.S.C. § 1395	, 33, 34
Other Authorities	
42 C.F.R. § 418.3	13
42 C.F.R. § 418.21	8
42 C.F.R. § 418.22	, 20, 27

42 C.F.R. § 418.24	14, 15
42 C.F.R. § 418.25	7, 27
42 C.F.R. § 418.54	7, 27
42 C.F.R. § 418.64	7, 27
42 C.F.R. § 418.100	24
42 C.F.R. § 418.102	2, 27, 29
42 C.F.R. § 424.535	22
70 Fed. Reg. at 70532	26
70 Fed. Reg. at 70539	26
73 Fed. Reg. at 32088, 32138	29
75 Fed. Reg. at 70448	30
78 Fed. Reg. at 48234, 48247	28, 29
79 Fed. Reg. at 50452, 50470	29
79 Fed. Reg. at 50456, 50469	29
American Medical Association, Code of Medical Ethics Opinion 5.5	18
Amy J. Frontz, Review of Hospices' Compliance with Medicare Requirements, HHS OGI WORK PLAN, A-02-18- 01001 (May 2021)	28
Amy S. Kelley & R. Sean Morrison, <i>Palliative Care for the Seriously Ill</i> , 373(8) N. ENGL. J. MED. 747–755 (Aug. 20, 2015)	16
Arif H. Kamal et al., Policy Changes Key to Promoting Sustainability and Growth of the Specialty Palliative Care Workforce, 38(6) HEALTH AFFAIRS, 916–924 (June 2019)	23

Barbara Gage et al., Important Questions for Hospice in the Next Century, HHS (March 2000)	17
Christina Chu et al., <i>Prognostication in palliative care</i> , 19(4) CLIN MED (LOND) 306–310 (Jul. 2019)	10
CMS MEDICARE BENEFIT POLICY MANUAL ("MBPM"), Ch. 9, § 10 (Mar. 20, 2025)	8, 15, 21
COMMITTEE ON CARE AT THE END OF LIFE, Approaching Death: Improving Care at the End of Life 30 (Marilyn J. Field & Christine K. Cassel eds., 1997)	20
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Melissa D. Aldridge et al., Association Between Hospice Enrollment and Total Health Care Costs for Insurers and Families, 2002–2018, 3 JAMA HEALTH FORUM e215104 (Feb. 11, 2022)	19
NORC AT THE UNIVERSITY OF CHICAGO, Value of Hospice in Medicare (March 2023)	14, 25
Pamela S. Harris et al., Can Hospices Predict Which Patients Will Die within Six Months?, 17(8) J PALLIAT MED. 894-98 (2014 Aug)	
Paul A. Glare & Christian T. Sinclair, <i>Palliative Medicine Review: Prognostication</i> , 11(1) J. PALLIAT. MED. 84 (2008)	8
Randi Dolin et al., Factors Driving Live Discharge from Hospice: Provider Perspectives, 53 J. PAIN & SYMPTOM MGMT.	1 0
1050–56 (June 2017)	10

Sara Mandelli et al., How palliative care professionals deal with predicting life expectancy at the end of life: predictors and accuracy, 29(4) SUPPORT CARE CANCER 2093–2103	
(Apr. 2021)	10
Sheila Poole & Ariel Hart, Jimmy Carter Delivered a Positive Message About Hospice Care, MOREHOUSE SCHOOL OF	
Medicine (Jan. 1, 2025)	9
Stephen R. Connor et al., Comparing Hospice and	
Nonhospice Patient Survival Among Patients Who Die	
Within a Three-Year Window, 33(3) J. PAIN & SYMPTOM	
Mgmt. 238–246 (2007),	13

I. INTERESTS OF AMICI

The National Alliance for Care at Home, Inc. ("Alliance") is a not-for-profit trade association representing the interests of nearly 10,000 home and community-based health care providers throughout the nation, including most hospices that serve Medicare-enrolled patients. These hospice members include non-profit, proprietary, public, and government-based entities. The Alliance, along with its predecessor organizations, has actively and directly participated in legislative and regulatory matters involving the Medicare hospice benefit along with numerous matters before the courts. Members of the Alliance rely upon its support and direction to achieve compliance with Medicare standards of coverage of hospice care. The source of the Alliance's authority to file is its Chief Executive Officer ("CEO").

American Academy of Hospice and Palliative Medicine, Inc. ("AAHPM" and, together with the Alliance, the "Amici") is the professional organization for physicians specializing in hospice and palliative medicine. AAHPM's more than 5,000 members also include nurses, social workers, pharmacists, and other health and spiritual care providers who are committed to improving the care and quality of life of

patients with serious illnesses, 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 source of AAHPM's authority to file is its Executive Committee.

The issues presented here are vital to the Alliance and AAHPM members. The Medicare program enables these hospices to provide the critical end-of-life care on which their patients and the Medicare program rely. Hospice patients are among the most vulnerable patient population as they are embracing a palliative care modality of service, foregoing curative care, and accepting their end of life. The hospice journey requires patients, their families, their physicians, and their hospice to trust each other in the process of choosing hospice over curative alternative care. Accepting death is one of the most difficult decisions in life.

The ability of a patient's physician to predict the time of death is extremely complex and far from perfect. Physicians need to rely on

objective and subjective clinical information along with their personal professional experience. Patients need to be able to trust the physician's assessment of their terminal illness. Hospices need to be able to trust that assessment as well and not fear second-guessing by non-clinician auditors who have never treated the patient. Here, the Court is presented with these central issues that are at the core of hospice care. The impact of those issues cannot be overstated. The Amici submit this memorandum to the Court as the voice of their members with respect to those crucial issues. The Amici recommend that the Court reverse the judgment below and recognize that hospice patients and their hospices should be able to trust the treating physician's assessment of a patient's terminal status.

II. STATEMENT OF AMICI

Pursuant to Federal Rule of Appellate Procedure 29(E), no party's counsel authored this brief, in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. And no person—other than the amicus curiae, its members, or its counsel—contributed money that was intended to fund preparing or submitting this brief.

III. SUMMARY OF ARGUMENT

The Court should reverse the decision below. That reversal should specifically recognize that a treating physician's assessment of a patient's life expectancy is entitled to deference in the absence of clear and objective clinical evidence that the assessment is unreliable and inaccurate. In doing so, the Court will conform its judgment to the carefully constructed structure of the Medicare hospice benefit that puts the attending physician and/or the hospice's medical director (who is also a physician) as the central figure in determining whether a patient meets the life expectancy requirement under 42 U.S.C. §§ 1395f(a)(7) and 1395x(dd)3)(A).

Reaching precise prognosis of the specific life expectancy of an individual has evaded medical science for many years. While some tools have emerged that are helpful, their accuracy falls far short of perfect. These tools and the guidelines issued by Medicare recognize the imprecision of terminal illness prognostication and that individual patients are unique in that respect. Studies have shown that it is essential to permit those physicians who have the daunting task of evaluating life expectancy under the Medicare hospice benefit to be able

to rely upon their experience and subjective patient assessment beyond the standardized tools. Certifying terminal illness is not simply a series of checked boxes.

The Court's careful consideration of this matter is essential given the significant impact that the decision below would have on hospice patients and their families along with the hospices that care for them and the Medicare program that serves over 67 million people. Individuals with a terminal illness face one of life's most complex decisions—do they continue to pursue the possibilities attendant to curative care, or do they choose end-of-life care focused on palliation and comfort through hospice care? In reaching that decision, the Medicare program sets a structure that relies upon a physician's evaluation of the patient's unique condition, which is guided by that physician's experience, along with the learnings available through medical science. More importantly, the patient must have full trust in the physician. Injecting the potential for an Administrative Law Judge (ALJ) to substitute his opinion after the fact as to whether an individual is terminally ill with a life expectancy of six months or less will have the natural and foreseeable effect of blocking access to palliative care when it is most needed. Trust between physician

and patient will diminish. Hesitancy for physicians to offer hospice care will grow. Patients will seek extended "curative" care without the real possibility of a cure, with such care creating both a loss of better care and higher care costs that do not occur in hospice. Hospices and physicians will react, chilled by the increased threat of retroactive payment denials, and avoid timely admission of patients, particularly those with chronic disease where the trajectory of a terminal illness is least known. Ultimately, the Medicare program itself suffers as delayed or denied hospice care costs Medicare through lost hospice savings.

The ruling of the ALJ, affirmed by the District Court, contradicts the carefully constructed framework of the hospice benefit enacted by Congress and implemented by the U. S. Department of Health and Human Services ("HHS") through the Centers for Medicare and Medicaid Services ("CMS"). That framework places the treating physician "at the center of the [hospice] eligibility inquiry." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1293 (11th Cir. 2019). Under 42 U.S.C. § 1395f(a)(7)(A), a physician must certify the patient is terminally ill and eligible for the hospice benefit. HHS/CMS has carried out this requirement through a series of rules that cover hospice conditions of

participation, (42 C.F.R. § 418.102), a patient's admission to hospice (42 C.F.R. § 418.25), the hospice patient's assessment (42 C.F.R. § 418.54), and the hospice services provided to the patient (42 C.F.R. § 418.64). The imprecise science of longevity prognostication also led Congress to extend hospice coverage to an infinite number of benefit periods, 42 U.S.C. § 1395d(a)(4), along with a limitation of liability when the hospice "did not know and could not have reasonably known" that Medicare would later determine the patient did not meet its terminal illness standard. 42 U.S.C. § 1395pp. The ALJ erroneously decided that this knowledge standard could never be met because Medicare published sufficient guidance in its rules and policy issuances, a position which defies logic given that Medicare has acknowledged the complexity of a terminal illness prognosis and the need for evaluating each patient uniquely. Overall, Amici support the in-depth legal arguments presented by Appellant.

Finally, Amici recommend that the Court reverse the judgment below and set out a standard that provides that an ALJ give deference to the treating physician's prognosis in the absence of objective clinical evidence that contradicts that prognosis, which permits the ALJ to reach

such a conclusion with the aid of expert physician testimony to present an applicable contradictions in the record evidence.

IV. ARGUMENT

A. Death is impossible to predict accurately.

"But of that day or hour no one knows . . . "1 A key question in health care therefore remains, "Doctor, how long do I have?" When structuring the hospice benefit, Congress vested physicians with the heavy, subjective task of offering prognostications of their patients' terminal trajectories over the following six months. 42 U.S.C. § 1395f(a)(7)(A)(i). But recognizing that death is impossible to predict accurately, Congress also authorized unlimited renewals of the hospice benefit, with no cap on how long patients can remain on service. See id. at A(ii); see also 42 C.F.R. § 418.21 (allowing "[a]n unlimited number of subsequent 60—day periods") (emphasis added); CMS MEDICARE BENEFIT POLICY MANUAL ("MBPM"),

¹ *Matthew* 24:36.

Paul A. Glare & Christian T. Sinclair, *Palliative Medicine Review: Prognostication*, 11(1) J. PALLIAT. MED. 84, 84 (2008), https://journals.sagepub.com/doi/pdf/10.1089/jpm.2008.9992.

Ch. 9, § 10 (Mar. 20, 2025) ("The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.").3

Despite significant advances in healthcare science, the ability to predict the life expectancy of patients with advanced illness remains an exceedingly difficult undertaking for even the most experienced clinicians and even the most notable of patients. For example, former President Jimmy Carter entered hospice at the age of 98 and lived almost two more years on the service. Therefore, while the science of life expectancy has improved somewhat, it still falls far short of the precision necessary for accurately determining terminality and, thus, eligibility for the Medicare hospice benefit, as at least "13.4% of patients survived more than 6 months after hospice admission." For some conditions, such as stroke,

Available at: https://www.cms.gov/regulations-and-guidance/guidance/guidance/manuals/downloads/bp102c09.pdf.

See Sheila Poole & Ariel Hart, Jimmy Carter Delivered a Positive Message About Hospice Care, Morehouse School of Medicine (Jan. 1, 2025), https://www.msm.edu/RSSFeedArticles/2025/January/President-Jimmy-Carter.php (President Carter elected hospice on February 18, 2023, and lived approximately 22 months before passing away on December 29, 2024).

Pamela S. Harris et al., Can Hospices Predict Which Patients Will Die within Six Months? 17(8) J PALLIAT MED. 894-98 (2014 Aug), https://pmc.ncbi.nlm.nih.gov/articles/PMC4118712/.

the probability of six-month mortality ranged as low as 32.6%.⁶ According to another study, even using every assessment tool available to hospices to predict terminality, clinicians underestimate remaining life span by 20%.⁷

Thus, as Congress instructed, even with the availability of assessment tools and other prognosis-related evaluation techniques, certifying physicians must still revert to their independent "clinical judgment" based on their own experiences with individual patients. 42 U.S.C. § 1395f(a)(7)(A)(i). This makes perfect sense, as available tools for prognosticating death fall far short of success.8

So, the question in this case and others boils down to the following: "If there are no objective tools for accurately predicting death and Congress has vested physicians with exclusive authority for prognosing

 $^{^6}$ Id.

Sara Mandelli et al., *How palliative care professionals deal with predicting life expectancy at the end of life: predictors and accuracy*, 29(4) SUPPORT CARE CANCER 2093–2103 (Apr. 2021), https://pubmed.ncbi.nlm.nih.gov/32865674/.

Christina Chu et al., *Prognostication in palliative care*, 19(4) CLIN MED (LOND) 306–310 (Jul. 2019) https://pubmed.ncbi.nlm.nih.gov/31308109/ ("although clinician predictions are known to be inaccurate, very few existing prognostic tools have consistently been shown to provide a superior performance").

terminality, how can an ALJ substitute his judgment for that of the certifying physician without strong—if not overwhelming—testimony from other equally qualified physicians that the prognosis was erroneous?" The clear answer is that ALJs (lawyers) are *not* qualified to substitute their judgment for the clinical judgment of physicians.

The reality of an end-of-life prognosis is that it is not a series of checkboxes or a scoring system that takes a simple plug in of data. It is about a real person under the care of skilled clinicians specializing in providing hospice care.

The Amici recommend that the Court reverse the judgment below as inconsistent with the law and not supported by substantial evidence. The ALJ chose to disregard the certification of terminal illness by the patients' treating physicians along with the confirming certifications of the hospice Medical Director. In doing so, the ALJ created the risk that patients at the end of life will be wrongly denied appropriate access to palliative care at a time when they need it the most.

Hospices will face continual threats that they will be retroactively denied Medicare payment for the care provided and the Medicare

program will lose out on the significant savings brought to the program through timely use of hospice care.

In considering this matter, the Amici ask the Court, consistent with Congress's directive when establishing the hospice program, to apply a standard of deference to the treating physicians and medical directors' judgment on the terminal status of their patients. That deference should be balanced with a standard that permits an ALJ to reject those judgments only when there is clear and convincing objective evidence contrary to the certifications of terminal status.

ALJs have the tools and resources available to review hospice appeals properly without substituting a nonmedical opinion for that of the physicians who know the patients best. Additionally, an ALJ has the full power to secure expert physician testimony to assist in analyzing the record evidence.

Patients at the end of life who are considering forfeiting curative care coverage under Medicare and accepting an impending death with palliative care deserve this approach to the hospice benefit. The hospice provider that extends care to these patients deserves the same.

B. The Negative Impacts of the Rulings Below

The ALJ's ruling, as adopted by the District Court, will impose significant negative consequences on *patients*, *providers*, and the Medicare *program* writ large.

1. Patients

a. Restrictive interpretation deprives patients of palliative care when it is most needed.

Hospice care is not merely a reimbursement category—it is a humane alternative to aggressive curative treatment at the end of life. CMS regulations define hospice services as a "comprehensive set of services" intended to manage pain and symptoms while addressing emotional and spiritual needs. See 42 C.F.R. § 418.3.

When an ALJ retroactively redefines eligibility, hospices are deterred from admitting borderline or non-cancer diagnoses—precisely the patients who often benefit most from palliative interventions. Hospice enrollment significantly improves quality of life, symptom control, and even length of life, while reducing costs to Medicare. A 2023

Stephen R. Connor et al., Comparing Hospice and Nonhospice Patient Survival Among Patients Who Die Within a Three-Year Window, 33(3) J. Pain & Symptom Mgmt. 238–246 (2007), https://www.jpsmjournal.com/article/S0885-3924(06)00724-X/fulltext.

study concluded that hospice care saves the Medicare program approximately \$3.5 billion annually while improving patient comfort and reducing family distress. ¹⁰ Thus, a restrictive ALJ interpretation harms both patient welfare and fiscal efficiency—outcomes Congress explicitly sought to avoid when creating the hospice benefit.

b. The ALJ decision undermines one of life's most difficult choices: whether to forgo curative care.

The decision to elect hospice care—relinquishing curative treatment in favor of comfort—is among the most profound and emotionally weighty decisions an individual can make. HHS recognized this gravity by requiring that patients sign a written election statement affirming their understanding that hospice care is palliative, not curative. See 42 C.F.R. § 418.24(b). The regulation assumes that this choice is made in reliance on the physician's certification and the government's good faith that hospice services will be honored. When ALJs retroactively deny claims by second-guessing medical judgment,

NORC AT THE UNIVERSITY OF CHICAGO, Value of Hospice in Medicare (March 2023), $\frac{\text{https://www.norc.org/content/dam/norc-org/pdf2023/Value%20of%20Hospice%20in%20Medicare_Final%20Re-port.pdf}.$

they betray that trust. The chilling effect is not abstract—it alters behavior.

c. Deference to clinical judgment is required to preserve program integrity and patient dignity.

The regulatory framework already incorporates multiple safeguards to ensure medical necessity—requiring certification by both the attending and hospice medical director, face-to-face recertifications, and documentation of clinical decline. See 42 C.F.R. §§ 418.22, 418.24; MBPM Ch. 9, §§ 20.1–20.2.11 The role of the ALJ is to assess whether these procedures were followed, not to retroactively substitute medical opinion. Thus, a physician's reasonable clinical judgment, not the auditor's retrospective view, must govern eligibility determinations. See AseraCare, 938 F.3d at 1297 (physician's reasonable, sincerely held prognosis cannot be deemed false based merely on later expert disagreement).

Available at: $\frac{https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c09.pdf}{ance/manuals/downloads/bp102c09.pdf}\,.$

d. The ALJ's restrictive decision will force the use of "curative" care even when treating physicians deem the patient terminal.

A restrictive ALJ interpretation that denies payment unless death occurs within an arbitrarily short timeframe effectively forces providers and families back toward curative medicine, contrary to both statutory intent and medical ethics. As the *New England Journal of Medicine* has observed, when hospice enrollment is delayed, patients are often exposed to more invasive treatments and ICU-type care, inconsistent with their preferences.¹² Such outcomes undermine the cost-saving and humane goals of the hospice program.

e. Restrictive coverage standards will trigger confusion for patients and families.

When ALJs reinterpret eligibility standards inconsistently or retrospectively, families experience profound confusion and distress. They are told by their physician and hospice team that their loved one qualifies for comfort care, only to be informed months later that Medicare "disagrees." These retrospective reversals are destabilizing. A 2000 study commissioned by HHS found that "the structure of the Medicare benefit

Amy S. Kelley & R. Sean Morrison, *Palliative Care for the Seriously Ill*, 373(8) N. ENGL. J. MED. 747–755 (Aug. 20, 2015), <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC4671283/</u>.

and its eligibility requirements may discourage access to hospice care for certain groups of dying persons, particularly those for whom accurate prognoses are difficult to make."¹³ When patients and families cannot rely on the representations of their treating professionals and government-approved hospices, confidence in the Medicare system itself erodes.

f. Restrictive interpretations harm the patientphysician relationship and compromise ethical medical judgment.

End of life decision-making occupies a unique ethical space deserving of respect and deference. See Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 281 (1990) (it is a "deeply personal decision of obvious and overwhelming finality"). When ALJs second-guess hospice certifications based on retrospective document review, they insert bureaucratic oversight into the most intimate domain of medicine.

Physicians who see their clinical judgments repeatedly overturned or second-guessed by auditors and administrative adjudicators become increasingly hesitant to recommend hospice, even when it is medically

Barbara Gage et al., *Important Questions for Hospice in the Next Century*, HHS (March 2000), https://aspe.hhs.gov/reports/important-questions-hospice-next-century-1.

appropriate. Regulatory constraints contribute to hesitancy in admission decisions. Physicians describe CMS audits as creating "an industry fraught with fear and uncertainty." The ethical consequences are profound: when clinicians cannot freely counsel patients without fear of reprisal, the core principles of beneficence and autonomy are undermined. See American Medical Association, Code of Medical Ethics Opinion 5.5 (counseling that decisions near the end of life must balance compassion, respect for patient autonomy, and sound clinical judgment). 16

g. Restrictive interpretations will increase patient financial burdens through higher out-of-pocket costs for curative care.

ALJ rulings that unduly restrict hospice eligibility force dying patients back into a fee-for-service system ill-suited to their clinical and financial realities. Hospice enrollment substantially lowers health care costs for both insurers and families, with out-of-pocket expenditures in

Randi Dolin et al., Factors Driving Live Discharge from Hospice: Provider Perspectives, 53 J. Pain & Symptom Mgmt. 1050–56 (June 2017), https://www.jpsmjournal.com/article/S0885-3924(17)30091-X/fulltext .

¹⁵ *Id*.

Available at: $\frac{https://code-medical-ethics.ama-assn.org/ethics-opin-ions/medically-ineffective-interventions}{ions/medically-ineffective-interventions}.$

the last month of life approximately \$670 lower for hospice enrollees compared to non-hospice beneficiaries.¹⁷ Likewise, older Americans incur an average of \$9,530 in out-of-pocket costs in the last year of life, underscoring the magnitude of the financial burden when hospice is foregone.¹⁸ Thus, denying appropriate hospice access not only undermines the goals of care—comfort, dignity, and reduced medical intrusion—but also exposes families to substantial and avoidable financial hardship.

h. The ALJ's restrictive approach will harm patients with chronic diseases.

The ALJ's restrictive reasoning also discriminates against beneficiaries suffering from non-cancer, chronic terminal conditions. For patients with serious chronic diseases, "a result of [advances in medicine] has been the emergence of serious chronic diseases as a major pathway

See Melissa D. Aldridge et al., Association Between Hospice Enrollment and Total Health Care Costs for Insurers and Families, 2002–2018, 3 JAMA HEALTH FORUM e215104 (Feb. 11, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2788935.

See Eric French et al., End-of-Life Medical Expenses, 18-18 FED. RESERVE BANK OF RICHMOND WORKING PAPERS 1–38 (Nov. 19, 2018), https://www.researchgate.net/publication/330895642_End-of-Life_Medical_Expenses.

toward death."¹⁹ Yet because such diseases often follow a fluctuating trajectory rather than a linear decline, auditors and ALJs often misinterpret temporary stabilization as evidence of non-terminal status.

Unlike physicians, regulators "may not understand the uncertainty inherent in projecting survival." The Medicare prognosis provision "implies a degree of precision that does not exist," creating a chilling effect on appropriate referrals of terminally ill beneficiaries that is especially pronounced in patients dying of chronic conditions whose courses are "difficult to predict." This is a fundamental clinical misunderstanding that HHS sought to prevent by vesting eligibility determinations in the treating physician's reasonable medical judgment rather than administrative hindsight. See 42 C.F.R. § 418.22(b).

Eileen Fox et al., Evaluation of Prognostic Criteria for Determining Hospice Eligibility in Patients with Advanced Lung, Heart, or Liver Disease, 282 JAMA 1638-45 (2000), https://jamanetwork.com/journals/jama/fullarticle/192058.

Committee on Care at the End of Life 30 (Marilyn J. Field & Christine K. Cassel eds., 1997), $\frac{\text{https://www.ncbi.nlm.nih.gov/books/NBK233605/pdf/Bookshelf_NBK233605.pdf}}{\text{https://www.ncbi.nlm.nih.gov/books/NBK233605/pdf/Bookshelf_NBK233605.pdf}}.$

²¹ *Id.* at 169.

2. Providers

a. The Chilling Effect on Hospice Providers When Physician Judgment Is Undermined

Predicting the exact course of a patient's final illness—a "prognosis"—is inherently uncertain. MBPM, Ch. 9, § 10 ("Predicting of life expectancy is not always exact."). Hospice providers are not fortune tellers; they are caregivers guided by medical science, compassion, and the physician's best clinical assessment at the time of certification. When, however, auditors retroactively overturn those judgments—years after the care has been delivered—hospice providers face a paralyzing "chilling effect" that threatens the very access to care the Medicare statute was designed to protect. They distort the statutory framework of relying on a good faith prognosis (a prognostication about future events) and impose a hindsight standard that no clinician can meet.

b. Retrospective denials will force providers to limit access.

When government reviewers supplant contemporaneous clinical judgment with retrospective disagreement, the chilling effect is immediate and severe. Physicians, aware that their prognoses may later be second-guessed by non-treating reviewers, may hesitate to certify even clearly eligible patients. Hospices, facing the risk of massive repayment

liability, may decline to admit appropriate beneficiaries. The resulting deterrent effect deprives terminally ill patients of the timely palliative care Congress sought to guarantee.

Retroactive denials compel hospices to divert limited resources from patient care to years-long appeals and defensive documentation. Such a regime replaces compassion with risk aversion, transforming a benefit designed to comfort the dying into one that punishes those who serve them.

c. Restrictive standards will discourage physicians from serving as hospice medical directors due to fear of sanctions, revocation, or exclusion.

Every hospice is required by law to designate a physician medical director responsible for oversight of clinical operations and certification of terminal prognosis. See 42 C.F.R. § 418.102(b). These individuals serve to ensure that each patient's eligibility is reviewed and documented in good faith. But under a regime where ALJs freely substitute their own judgment for that of certifying physicians, medical directors are exposed to personal and professional jeopardy—including potential disciplinary action, revocation of billing privileges, civil monetary penalties, or

exclusion from the Medicare program if a later auditor or ALJ disagrees with their prognosis. See, e.g., 42 C.F.R. § 424.535(a)(21).

The hospice program already faces significant shortages of board-certified physicians and other qualified clinicians, particularly in rural and underserved regions, with predictions of a "workforce valley" on the near horizon. When the oversight environment becomes punitive rather than educational, the result is a chilling effect: experienced hospice medical directors hesitate to assume certification responsibilities, and recruitment of new physicians slows. If left unchecked, decisions like the ALJ's at issue here will further erode the pool of willing and competent hospice physicians, impairing both access to and quality of end-of-life care.

3. Medicare Program

The ALJ's restrictive interpretation threatens the financial solvency and structural integrity of the hospice program. When ALJs replace the physician prognostication standard with a retrospective

Arif H. Kamal et al., *Policy Changes Key to Promoting Sustainability and Growth of the Specialty Palliative Care Workforce*, 38(6) HEALTH AFFAIRS, 916–924 (June 2019), https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.00018.

accuracy requirement, they destabilize the financial underpinnings of the program itself. The hospice model depends on actuarial predictability. Providers must invest in interdisciplinary staff, medication inventories, durable medical equipment, and on-call coverage based on expected reimbursement. Retroactive denials—often years after services are rendered—produce catastrophic recoupments that no reasonable business model can absorb.

If the ALJ's restrictive reasoning proliferates, hospices will face systemic financial uncertainty, reducing their ability to accept high-risk patients, expand service areas, or maintain 24-hour coverage. Smaller non-profit and rural hospices—already operating on narrow margins—are especially vulnerable. The resulting attrition would directly undermine Medicare's statutory duty to ensure "reasonable access" to hospice services in all geographic regions. See 42 C.F.R. § 418.100(e). Thus, the financial instability created by retrospective denial regimes is not an isolated administrative consequence—it threatens the solvency, credibility, and long-term validity of the entire hospice delivery system envisioned by Congress.

As discussed earlier, the data demonstrate that the Medicare hospice benefit is a fiscally efficient and cost-saving component of the Medicare program. By comparing traditional Medicare fee-for-service decedents who used hospice to a carefully weighted comparison group of non-hospice users in their final year of life, NORC found that hospice users incurred 3.1 percent lower total costs of care in the last 12 months of life.²³

These findings are significant in a policy context. The hospice benefit redirects patients away from more intensive, higher-cost end-of-life interventions and toward comfort-focused care—in effect substituting lower-cost hospice services for the "usual care" modality. By replacing costly hospital and ICU interventions with coordinated, home-based care that aligns with patients' goals, the Medicare hospice benefit stands as an efficient, taxpayer-responsible program that advances both economic stewardship and human dignity at the end of life.

²³ See n. 10, supra.

C. Rulings below contradict the carefully constructed framework of hospice established by Congress and HHS.

1. The physician is the "central figure" in the assessment of patients and patients' needs.

"The language of the statute and implementing regulations makes plain that the clinical judgment of the patient's attending physician ... lies at the center of the eligibility inquiry." *AseraCare, Inc.*, 938 F.3d at 1293. "It is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill." 70 Fed. Reg. 70532, 70539 (Nov. 22, 2005).

a. Certification of eligibility is in the physician's hands.

One example of the physician's central role is the fact that Congress requires a *physician* to certify that a patient is eligible for hospice care. 42 U.S.C. § 1395f(a)(7)(A); see also 70 Fed. Reg. at 70539. Specifically, the physician must certify that the patient is "terminally ill" with life expectancy of six months or less. 42 U.S.C. § 1395f(a)(7)(A) (citing 42 U.S.C. § 1395x(dd)(3)(A)). In addition, recertifications are required for subsequent benefits periods, ensuring ongoing physician involvement. *Id.* Indeed, HHS has ensured that physicians are involved throughout the hospice process, including regarding the hospice's Medicare conditions of

participation (42 C.F.R. § 418.102), a patient's admission to hospice (42 C.F.R. § 418.25), the hospice patient's assessment (42 C.F.R. § 418.54), and the hospice services provided to the patient (42 C.F.R. § 418.64).

b. Recent face-to-face requirements reaffirm the physician's importance.

Starting in 2011, hospice physicians are required to have a "face-to-face" encounter with each hospice patient whose total stay across all hospices is anticipated to reach the third benefit period. 42 C.F.R. § 418.22(a)(4). The "purpose" of the face-to-face requirement—to allow the physician to "gather clinical findings to determine continued eligibility for hospice care"—is an acknowledgement of the physician's key role in hospice care. *Id.*; *United States ex rel. Anderson v. Curo Health Servs. Holdings, Inc.*, No. 3:13-cv-00672 (Lead); No. 3:20-cv-00168 (Member), 2022 U.S. Dist. LEXIS 49561, at *8 (M.D. Tenn. Mar. 21, 2022).

c. Physician assessments are entitled to deference and are not constrained by formulaic check boxes.

"CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference." *AseraCare*, 938 F.3d at 1295. "CMS stated: 'We believe that the certifying physicians have the best clinical experience, competence and judgment to make the determination

that an individual is terminally ill." Id. (quoting 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013)). This "is consistent with Congress and CMS's prior acknowledgement of the hospice physician's central role and the complexities and uncertainties involved in prognostication." Amy J. Frontz, Review of Hospices' Compliance with Medicare Requirements, HHS OGI WORK PLAN, A-02-18-01001 (May 2021). "The recognition of the hospice physician's central role, both by CMS and the court in AseraCare, is consistent with other cases requiring 'extra weight' or deference be given to a treating physician's contemporaneous informed opinion unless there is a reasoned basis for declining to do so." *Id.*; see also Exec. Dir. ex rel. Carey v. Sebelius, 698 F. Supp. 2d 436, 441, 443 (D. Vt. 2010) (noting that an ALJ must "give some extra weight to a treating physician's opinion, or supply a reasoned basis for declining to do so" and reversing the Secretary's decision, in part, because the ALJ failed to do so).

"Congress and CMS 'were careful to place the physician's clinical judgment at the center of the inquiry' rather than impose a more rigid set of criteria for eligibility determinations that would have minimized the role of clinical judgment." *Hospice of E. Texas v. Sec'y of HHS*, No. 5:23cv136-RWS-JBB, 2025 U.S. Dist. LEXIS 62035, at *68–69 (E.D. Tex.

Feb. 21, 2025) (quoting *AseraCare*, 938 F.3d at 1301).²⁴ In fact, "CMS has considered and expressly declined to impose defined criteria that would govern the physician's exercise of judgment." *Id.* at *69 (citing 73 Fed. Reg. 32088, 32138 (June 5, 2008)). "Rather, the certification of terminal illness is based in the unique clinical picture of the individual" 78 Fed. Reg. at 48247; *see also* 42 C.F.R. § 418.102(b) (requiring that physician's certification narrative "must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients").

2. Congress recognized that terminal prognosis is not a perfect science.

"CMS has repeatedly emphasized that [p]redicting life expectancy 'is not an exact science." *AseraCare*, 938 F.3d at 1295 (quoting 75 Fed. Reg. at 70372, 70448 (Nov. 17, 2010)); *see also* 79 Fed. Reg. 50452, 50470 (Aug. 22, 2014) (recognizing "the challenges in prognostication"). This is because all hospice patients present with their own "unique physical condition[s]" and circumstances that impact the overall condition. 79 Fed. Reg. at 50456, 50469; *see also Hospice of E. Texas*, 2025 U.S. Dist. LEXIS

The report and recommendation was adopted, 2025 U.S. Dist. LEXIS 59830 (Mar. 31, 2025).

62035, at *111 ("In fact, CMS's pronouncements and the LCDs repeatedly acknowledge the complexity of prognosticating a terminal illness"). Moreover, a substantial portion of hospice patients die of causes for which predicting life expectancy is especially uncertain. *See, e.g.*, 75 Fed. Reg. at 70448 (noting that certain conditions have "less predictable trajectories" and so physicians are free to use "any disease-specific scores or scales that can help them in predicting life expectancy").

Therefore, "[w]hile there is no question that clinical judgments must be tethered to a patient's valid medical records, it is equally clear that the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding." *AseraCare*, 938 F.3d at 1295. This is why "the LCD guidelines are just one pathway to establishing a terminal diagnosis and do not need to be met to demonstrate hospice eligibility." *Hospice E. Tex.*, 2025 U.S. Dist. LEXIS 62035, at *111.

a. Benefit periods are infinite.

In recognition of the difficulties in predicting life expectancy, the number of Medicare hospice benefit periods are unlimited if a physician

continues to recertify the patient as terminally ill. See 42 U.S.C. § 1395d(a)(4) (allowing benefits for "hospice care with respect to the individual during up to two periods of 90 days each and an unlimited number of subsequent periods of 60 days").

b. Limitation of Liability

Given the inherent challenges of prognosis, Congress has also expressly limited liability where claims are disallowed. 42 U.S.C. § 1395pp. Or, as more colorfully put: "In seeming recognition of the complexity of the Medicare maze, Congress there indicated that providers who didn't know and couldn't have reasonably been expected to know that their services weren't permissible when rendered generally don't have to repay the amounts they received from CMS. A sort of good faith affirmative defense, if you will." *Caring Hearts Pers. Home Servs. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016).

Notably, Section 1395pp also applies to hospices so that, "if a hospice did not know and could not have reasonably known that CMS would ultimately determine that a particular hospice patient was not terminally ill, then CMS shall nonetheless pay the hospice for the services

rendered to that patient." *Hospice of E. Tex.*, 2025 U.S. Dist. LEXIS 62035, at *106–07.

Knowledge that payment would not be made can be based on (1) written guidelines from CMS, (2) Federal Register publications of coverage decisions, and (3) local medical community standards. *Cypress Home Care, Inc. v. Azar*, 326 F. Supp. 3d 307, 317 (E.D. Tex. 2018) (citing 42 C.F.R. § 411.406(e)).

However, while CMS provides manuals, bulletins, and written guidelines, "[i]t would be unfair to expect a hospice to correctly predict how an ALJ would always rule in this uncertain and complicated area [i.e., predicting life expectancy] based simply on the receipt of non patient-specific material from CMS." Hospice of E. Tex., 2025 U.S. Dist. LEXIS 62035, at *109. Moreover, CMS "estimates that it issues literally thousands of new or revised guidance documents (not pages) every single year," and even back in 2016 there were already "about 37,000 separate guidance documents ... on CMS's website—and even that doesn't purport to be a complete inventory." Caring Hearts, 824 F.3d at 970. Rightly so, the Supreme Court has rejected HHS's use of such sub-regulatory guidance as a basis for denying claims. See Azar v. Allina Health Servs.,

139 S. Ct. 1804, 1810-11 (2019) (dismantling the notion that subregulatory agency actions can wield the force of law without undergoing the rigorous procedural safeguards of notice and comment).

Aside from the daunting task of keeping up with the torrent of new guidance—a task that CMS itself often fails to accomplish²⁵—the restrictive ALJ ruling here did not even specify which guidelines supposedly provided notice of payment denial. Such cursory denials lead to disastrous consequences. After all, where an ALJ can rely on CMS guidelines to find the provider had notice of the potential payment denial but fail to specify which guidelines purportedly provided such notice, then Section 1395pp will "rarely, if ever, be applied" because "[a]ny hospice seeking reimbursement presumably has received information from CMS." Hospice of E. Tex., 2025 U.S. Dist. LEXIS 62035, at *109.

Instead, where a "[h]ospice makes a pretty good case for the reasonableness of its belief that the beneficiaries' hospice eligibility was necessary based on the reasonable clinical judgment of its skilled hospice physicians," Section 1395pp should apply. *Id.* at *114; *see also id.* at *116

²⁵ See Caring Hearts, 824 F.3d at 970 (finding that CMS was "confused about its own law").

(finding that hospice should not have been subjected to recoupment under Section 1395pp).

V. CONCLUSION

For the foregoing reasons, the Court should reverse the judgment below and set out a standard that provides that an ALJ give deference to the treating physicians' prognosis in the absence of objective clinical evidence that contradicts that prognosis.

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Case: 25-3542 Document: 25 Filed: 11/12/2025 Page: 45

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Dated: November 11, 2025

/s/_ WILLIAM A. DOMBI