No. 23-40217

In the United States Court of Appeals for the Fifth Circuit

Texas Medical Association; Tyler Regional Hospital, L.L.C.; Doctor Adam Corley, *Plaintiffs–Appellees*,

v.

United States Department of Health and Human Services; Department of Labor; Department of the Treasury; Xavier Becerra, Secretary, U.S. Department of Health and Human Services; Julie A. Su, Acting Secretary, U.S. Department of Labor; Janet Yellen, Secretary, U.S. Department of Treasury, *Defendants–Appellants*.

Lifenet, Incorporated; East Texas Air One, *Plaintiffs–Appellees*,

v.

United States Department of Health and Human Services; Xavier Becerra, Secretary, U.S. Department of Health and Human Services; United States Department of the Treasury; Janet Yellen, Secretary, U.S. Department of Treasury; United States Department of Labor; Julie A. Su, Acting Secretary, U.S. Department of Labor; United States Office of Personnel Management; Kiran Ahuja, *Defendants–Appellants*.

On Appeal from the United States District Court
for the Eastern District of Texas, Tyler Division

BRIEF OF THE LEUKEMIA & LYMPHOMA SOCIETY AND TEN OTHER PATIENT AND CONSUMER ADVOCACY ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Texas Medical Association et al. v. United States Department of Health and Human Services et al. (No. 23-40217)

The undersigned counsel for *Amici Curiae* certifies that the following listed persons and entities, in addition to those listed in the briefs of the parties and other *amici curiae*, have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici Curiae on this Brief
The Leukemia & Lymphoma Society
The ALS Association
Cancer*Care*
Cancer Support Community
Epilepsy Foundation
Families USA Action
Hemophilia Federation of America
The Mended Hearts, Inc.
National Multiple Sclerosis Society
National Patient Advocate Foundation
U.S. PIRG

Counsel for Amici Curiae on this Brief
Joseph J. Wardenski
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The eleven *Amici Curiae* organizations on this brief are non-profit organizations that have no parent corporations. No publicly traded corporation has any ownership interest in any of the *Amici Curiae*.

Dated: July 19, 2023

/s/ Joseph J. Wardenski
Joseph J. Wardenski
Counsel for Amici Curiae on this Brief

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae The Leukemia & Lymphoma Society, The ALS Association, Cancer*Care*, Cancer Support Community, Epilepsy Foundation, Families USA Action, Hemophilia Federation of America, The Mended Hearts, Inc., National Multiple Sclerosis Society, National Patient Advocate Foundation, and U.S. PIRG (collectively, "*Amici*"), are patient and consumer advocacy organizations that represent or work on behalf of millions of patients and consumers across the country, including those facing serious, acute, and chronic health conditions.[2]

The Leukemia & Lymphoma Society ("LLS") is the world's largest voluntary health agency dedicated to fighting blood cancer and ensuring that the more than 1.3 million blood cancer patients and survivors in the United States have access to the care they need. LLS's mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and to improve the quality of life of patients and their families. LLS advances

[1] All parties have consented to the filing of this brief.

[2] Under Federal Rule of Appellate Procedure 29(a)(4)(E), *Amici* certify that no party's counsel authored this brief in whole or in part, that no party or party's counsel contributed money intended to fund the preparation or submission of the brief, and that no person (other than *Amici*, their members, and their counsel) contributed money intended to fund the preparation or submission of the brief.

that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated health care, regardless of the source of their coverage.

The ALS Association is the only national nonprofit organization fighting ALS on every front. The mission of The ALS Association is to discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest. By leading the way in global research, providing assistance for people with ALS through a nationwide network of chapters, coordinating multidisciplinary care through certified clinical care centers, and fostering government partnerships, The Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure.

Cancer*Care* is the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer.

The Cancer Support Community ("CSC"), as the largest professionally led nonprofit network of cancer support worldwide, is dedicated to ensuring that all people impacted by cancer are empowered

by knowledge, strengthened by action, and sustained by community. CSC delivers more than $50 million in free support and navigation services to cancer patients and their families. CSC also conducts cutting-edge research on the emotional, psychologic, and financial journey of cancer patients and advocate at all levels of government for policies to help individuals whose lives have been disrupted by cancer.

The Epilepsy Foundation is the leading national and voluntary health organization that speaks on behalf of more than 3.4 million Americans with epilepsy and seizures. Uncontrolled seizures can lead to disability, injury, or death. Epilepsy medications are the most common use for seizure treatment and is a cost-effective treatment for controlling and/or reducing seizures. So, making access to quality, affordable, physician-directed care, and effective coverage for epilepsy medications critically vital for people living with epilepsy.

Families USA Action is a 501(c)(4) social welfare organization with the mission of creating a system that delivers the best health and health care for all people in the United States. On behalf of health care consumers, working people, and patients, Families USA Action has led the No Surprises: People Against Unfair Medical Bills campaign since

2019, and has advocated for legislation and rulemaking that fully protect consumers from surprise bills while ensuring health care costs do not inflate overall. The organization's work on these issues emerged from consumers' reports of unaffordable surprise billing, and from reports by consumer advocates of their inability to address these issues in the past.

Hemophilia Federation of America ("HFA") is a community-based, grassroots advocacy organization that assists, educates, and advocates for people with hemophilia, von Willebrand disease, and other rare bleeding disorders. Bleeding disorders are serious, life-long, and expensive. HFA seeks to ensure that individuals affected by bleeding disorders have timely access to quality medical care, therapies and services, regardless of financial circumstances or place of residence.

The Mended Hearts, Inc. is a community-based, international nonprofit whose mission is to inspire hope and improve the quality of life for heart patients and their families through ongoing peer-to-peer support, education, and advocacy. Cardiovascular disease is the leading cause of death in men and women, and congenital heart disease is the number one birth defect. Patients and their families, across the

lifespan, require access to lifelong care, low-cost medications, and affordable health coverage to reduce the burden of disease and improve the quality of life.

The National Multiple Sclerosis Society mobilizes people and resources so that the nearly one million people affected by multiple sclerosis ("MS") can live their best lives while the Society works to stop MS in its tracks, restore what has been lost, and end MS forever.

National Patient Advocate Foundation is the advocacy affiliate of the Patient Advocate Foundation, a national charitable organization that provides direct assistance and support service for patients and families coping with complex and chronic conditions. The Foundation works to improve equitable health care access and mitigate distressing financial and other burdens these populations often experience.

U.S. PIRG is a not-for-profit organization that advocates for the public interest, working to win concrete results on real problems that affect millions of lives, and standing up for the public against powerful interests when they push the other way. It employs grassroots organizing and direct advocacy for the public on many different issues

including healthcare, preserving competition, and protecting consumer welfare.

Amici are committed to ensuring that all Americans have a high-quality health care system and access to comprehensive, affordable health insurance to prevent disease, manage health, cure illness, and ensure financial stability. Many patients served by *Amici* are among the one in five insured Americans who have received a surprise medical bill.[3] Given the impact of surprise bills on those served by *Amici*, many *Amici* joined community principles for surprise billing reforms[4] and worked with Congress to develop the bipartisan No Surprises Act of the 2021 Consolidated Appropriations Act (the "No Surprises Act" or the "Act"), Pub. L. No. 116-260, 134 Stat. 1182 (2020) (codified at 42 U.S.C. § 300gg-111). With these community principles as our guide, many *Amici* were heavily engaged throughout the legislative process leading to the Act's passage and Defendants' rulemaking to implement the Act.

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[3] *See* Karen Pollitz *et al.*, *US Statistics on Surprise Medical Billing*, 323 J. Am. Med. Ass'n 498 (2020), https://jamanetwork.com/journals/jama/fullarticle/2760721; Lunna Lopes *et al.*, Kaiser Family Found., *Data Note: Public Worries About And Experience With Surprise Medical Bills* (Feb. 28, 2020), https://bit.ly/3r9Qiz2.

[4] *See* ALS Ass'n *et al.*, *Surprise Medical Billing Principles* (Feb. 2020), *available at* https://bit.ly/44xLg0f.

Amici submit this brief to assist the Court in understanding the nature and extent of the harms that surprise billing has caused to patients and consumers—harms that the No Surprises Act was designed to address. Based on *Amici*'s experiences advocating for patients and consumers during the legislative and rulemaking processes, *Amici* are uniquely positioned to explain why common-sense regulation of the independent dispute resolution ("IDR") process by the federal agencies statutorily charged with implementing the law is necessary to fulfill the Act's central purpose of reducing individual and overall health care costs for consumers.

Because the patients and consumers we serve have a strong interest in the outcome of this litigation, *Amici* submit this brief in support of Defendants-Appellants and request that this Court reverse the district court's decisions below.

SUMMARY OF ARGUMENT

Effective implementation of the No Surprises Act is necessary to reduce the financial burden of illness on patients and help contribute to longer, healthier lives. Protecting patients from surprise medical bills is at the heart of the Act. Through the Act, Congress prohibited out-of-

network providers from sending surprise balance bills to patients for hospital-based care and air ambulance services. But the Act goes further: not only does it ban surprise bills in these contexts, but it also incorporates various consumer protections designed for the express purpose of keeping individual and overall health care costs down. The Act further protects consumers by curbing escalating costs associated with out-of-network health care.

By prohibiting balance billing by out-of-network providers, the Act directly shields patients from the often-catastrophic out-of-pocket expenses resulting from surprise bills and ensures that the benefits to patients who would otherwise have been harmed by surprise bills do not come at the expense of other health care consumers. The Act required the Departments to establish an independent dispute resolution ("IDR") process to resolve payment disputes between out-of-network providers and payers for medical services that would previously have been billed directly to patients in the form of surprise bills. The IDR process was expressly designed to provide a consistent and transparent process to resolve these disputes with two interrelated goals: to prevent abuse of this IDR process and to reduce (or at least not increase) health

insurance premiums and cost-sharing and promote lower health care costs overall.[5]

Through the Final Rule, *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (Aug. 26, 2022) (the "Rule"), Defendants-Appellants the U.S. Department of Health and Human Services *et al.* (the "Departments") have heeded their statutory duty under Section 103 of the No Surprises Act to institute uniform procedures for certified IDR entities to follow to resolve payment disputes.[6] In promulgating the Rule, the Departments followed the district court's directives and carefully considered the thousands of public comments in establishing common-sense and consistent procedures to ensure a workable, predictable IDR process.

Amici submit this brief to assist the Court in understanding the nature and extent of these harms to patients and consumers caused by surprise billing that the No Surprises Act was designed to address. Many *Amici* were highly engaged with lawmakers and the Departments throughout the legislative and rulemaking processes. Based on their

[5] *See* Letter from Sen. Murray & Rep. Pallone to Hon. Xavier Becerra, Sec'y of Health & Hum. Servs. (Jan. 7, 2022), https://bit.ly/3qTHv45.

[6] 87 Fed. Reg. at 52,627 & n.32.

experience advocating for patients and consumers during the legislative process leading to the passage of the No Surprises Act and the Departments' rulemaking processes, *Amici* are uniquely positioned to explain to the Court why the Rule is consistent with the text and purpose of the No Surprises Act. The Rule will encourage more in-network participation by providers, leading to better access to affordable care and reducing health care costs for patients and consumers.

The critical need for a uniform, predictable IDR process is underscored by the extraordinarily high number of potential payment disputes that may rely on the process. In just the first 11 months after the No Surprises Act took effect—from January 2022 to November 2022—the Act protected patients from an estimated 9 million surprise bills.[7] The first goal of the Act—protecting individual patients from surprise bills—is being met. But each of those millions of avoided surprise bills may result in disputed out-of-network payment amounts that, if not resolved voluntarily between providers and payers, may be

[7] *See* Am.'s Health Ins. Plans, *No Surprises Act Prevents More than 9 Million Surprise Bills Since January 2022* (November 16, 2022), https://bit.ly/3K43P46.

subject to the IDR process. Indeed, in the first year after the Act took effect, over 334,000 payment disputes were submitted through the federal IDR portal, far exceeding the government's predicted volume of disputes.[8] Uniform procedures and safeguards to govern the IDR process—such as those contained in the Rule—are essential to curb potential abuse of the IDR process, prevent wildly inconsistent outcomes in payment disputes, and mitigate the resulting inefficiencies and associated health care costs that would ultimately be borne by consumers through higher insurance premiums and cost-sharing.

The Departments have acted reasonably and within their statutory authority in setting reasonable, uniform procedures that offer transparency and predictability to IDR entities as they fulfill their statutory obligations. Because the district court's *vacatur* of the Rule has harmed and will continue to harm patients and consumers across the country, including those served by *Amici*, we respectfully request that the Court reverse the decision below.

[8] *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Federal Independent Dispute Resolution Process–Status Update* 1 (Apr. 27, 2023) ("CMS IDR Status Update"), https://bit.ly/3rzL566.

ARGUMENT

I. SURPRISE MEDICAL BILLS RESULT IN HIGHER OUT-OF-POCKET COSTS FOR PATIENTS AND INFLATED HEALTH COSTS THAT HARM ALL CONSUMERS.

Before the No Surprises Act, surprise medical bills imposed "staggering" financial burdens on patients and their families.[9] Before the Act, patients routinely received surprise balance bills when they unknowingly received care from an out-of-network provider. Surprise bills were especially common in emergency situations, where patients often have no way to choose their hospital, physician, or air ambulance provider. But even for non-emergency hospital-based services, patients often received surprise bills when, unbeknownst to them, they received care from out-of-network specialists—such as anesthesiologists or radiologists—during a visit to an in-network hospital. Patients with chronic or serious conditions—such as those with cancer, chronic respiratory disease, or at risk of a heart attack—faced an elevated risk

[9] *See* H.R. Rep. No. 116-615, pt. 1, at 52 (2020) (describing stories of patients harmed by surprise medical bills and noting that "[t]he financial liability imposed on patients by surprise medical bills can be staggering").

of receiving out-of-network bills from hospitals, doctors, and air ambulance providers.[10]

A. Surprise Medical Bills for Hospital-Based Care and Air Ambulance Services by Out-of-Network Providers Harmed Millions of Patients and their Families.

Before the No Surprises Act, surprise bills were common and resulted in significant out-of-pocket costs for patients, as well as higher health insurance premiums for all consumers.[11] Before the Act took effect, Americans owed more than $140 billion dollars in medical debt; unpaid medical bills were the largest driver of that debt.[12] Surprise bills hit low-income consumers the hardest: over a quarter of adults could not pay their monthly bills or were one $400 financial setback away

[10] *See* Karen Pollitz *et al.*, *Surprise bills vary by diagnosis and type of admission*, Peterson-KFF Health Sys. Tracker (Dec. 9, 2019), https://bit.ly/3o5ZouG; Karen Pollitz *et al.*, *An examination of surprise medical bills and proposals to protect consumers from them*, Peterson-KFF Health System Tracker (Feb. 10, 2020), https://bit.ly/3KLJ1gF.

[11] *See* H.R. Rep. No. 116-615, pt. 1, *supra* note 9, at 53 (summarizing surprise billing data and noting that the cost of inflated payment rates from certain provider specialties "are directly felt through higher out-of-pocket expenses and exorbitant surprise bills for out-of-network care, as well as by all consumers who share in rising overall health care costs through higher premiums").

[12] Raymond Kluender *et al.*, *Medical Debt in the US, 2009-2020*, 326 J. Am. Med. Ass'n 250, 255 (2021), https://bit.ly/3KFqh23.

from being unable to pay them in full.[13] These unexpected medical expenses spelled financial ruin for many families.

Surprise bills were particularly common in emergency care settings. Many patients received surprise bills when the closest hospital was out-of-network or if the patient was seen by an out-of-network provider at an in-network hospital. One study found that 18 percent of all emergency visits by patients in large employer plans in 2017 had at least one out-of-network charge that could have resulted in a surprise bill.[14] Another study estimated that one in five inpatient emergency room visits could lead to a surprise bill.[15]

Critically ill or injured patients who require emergency transportation from air ambulance providers were even more likely to face surprise medical bills. While air ambulance services are often a critical component of successful treatment for individuals experiencing serious health events, those patients generally have no choice over

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[13] Bd. of Governors of Fed. Rsrv. Sys., *Economic Well-Being of U.S. Households in 2020* 4, 33 (May 2021), https://bit.ly/3FZzXkl.

[14] Karen Pollitz *et al., An examination of surprise medical bills and proposals to protect consumers from them* (Feb. 10, 2020), *supra* note 10.

[15] Christopher Garmon & Benjamin Chartock, *One In Five Inpatient Emergency Department Cases May Lead To Surprise Bills*, 36 Health Affairs 177, 177-81 (2017), https://doi.org/10.1377/hlthaff.2016.0970.

whether to use an air ambulance or who provides that service. Consequently, nearly 70 percent of air ambulance transports are likely to be out-of-network.[16] There are many harrowing stories from patients who have received surprise five-figure bills for out-of-network air ambulance services.[17] The prices charged by air ambulance providers for helicopter and airplane transports—and the resulting out-of-network bills sent to patients—increased significantly in the years leading to the passage of the No Surprises Act.[18] According to one study, the use of helicopter ambulances declined by 14.3 percent from 2008 to

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[16] *See* H.R. Rep. No. 116-615, pt. 1, *supra* note 9, at 52.

[17] *See, e.g.*, Julie Appleby, *The case of the $489,000 air ambulance ride*, NPR (Mar. 25, 2022), http://bit.ly/3A34kX5; Jen Christensen, *Sky-high prices for air ambulances hurt those they are helping*, CNN (Nov. 26, 2018), https://cnn.it/3KzcPN8; Christina Caron, *Families Fight Back Against Surprise Air Ambulance Bills*, N.Y. Times (Apr. 17, 2020), https://nyti.ms/3qRBgh6; Anna Almendrala, *The Air Ambulance Billed More Than The Lung Transplant Surgeon*, NPR (Nov. 6, 2019), https://n.pr/3GWrksd; Sarah Kliff, *A $52,112 Air Ambulance Ride: Coronavirus Patients Battle Surprise Bill*s, N.Y. Times (Oct. 13, 2020), https://nyti.ms/3Iwrffs; Celia Llopis-Jepsen, *A Kansan's $50k Medical Bill Shows That You Don't Always Owe What You're Charged*, KCUR (May 26, 2020), https://bit.ly/3Isp2Bt; Alison Kodjak, *Taken For A Ride: M.D. Injured In ATV Crash Gets $56,603 Bill For Air Ambulance Trip*, NPR (Sept. 25, 2018), https://n.pr/35g4DBq; Rachel Bluth, *In Combating Surprise Bills, Lawmakers Miss Sky-High Air Ambulance Costs*, Kaiser Health News (June 14, 2019), https://bit.ly/3fMJC35.

[18] *See id.*; Ge Bai *et al.*, *Air Ambulances With Sky-High Charges*, 38 Health Affairs (July 2019) (Abstract), https://bit.ly/33HmVeg; Fair Health, Inc., *Air Ambulance Services in the United States: A Study of Private and Medicare Claims* (Sept. 28, 2021), https://bit.ly/3tYAO2m.

2017 while the average price per trip more than doubled, rising 144 percent.[19] Although the use of airplane ambulances remained steady, the average price increased by 166 percent over that same period.[20] These significant price increases were partly due to market concentration and greater private equity ownership of air ambulance providers.[21] Indeed, a bipartisan group of 35 state insurance commissioners told Congress that balance billing for air ambulance services had become "a business model to prey on people during their most vulnerable time."[22]

Surprise bills also affected patients in non-emergency contexts at in-network hospitals. Among patients in large employer plans, 16 percent of in-network hospital stays in 2017 included at least one out-of-network charge that could have led to a surprise bill.[23] Another study found that 20 percent of all patients who had an elective procedure with

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[19] John Hargraves & Aaron Bloschichak, *Air Ambulances – 10 Year Trends in Costs and Use*, Health Care Cost Inst. (Nov. 7, 2019), https://bit.ly/3GXKzSb.

[20] *Id*.

[21] *See* Loren Adler *et al.*, *High air ambulance charges concentrated in private equity-owned carriers*, Brookings Inst. (Oct. 13, 2020), https://bit.ly/3ECnx4J.

[22] Letter from Jon Godfread, Comm'r, N.D. Ins. Dep't, *et al.* to Hon. Bobby Scott *et al.* 2 (Nov. 7, 2019), https://bit.ly/3AkFfau.

[23] Karen Pollitz *et al.* (Feb. 10, 2020), *supra* note 10.

an in-network primary surgeon at an in-network facility—such as a hysterectomy, knee replacement, or heart surgery—remained at risk of surprise bills from out-of-network specialists who treated them during those visits.[24] Of these, potential surprise bills averaged more than $1,200 for anesthesiologists and more than $3,600 for surgical assistants.[25] Over 18 percent of families with in-network childbirths in 2019 potentially received a surprise bill for maternal or newborn care, with one-third of these families facing potential surprise bills exceeding $2,000.[26]

B. Before the No Surprises Act, Surprise Billing Increased Health Insurance Premiums and Overall Health Care Costs for Privately Insured Individuals.

Surprise medical bills also increased overall health care costs, which were passed along to consumers through increased health insurance premiums.[27] A 2020 study found that health care spending

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[24] Karan R. Chhabra *et al.*, *Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery with In-Network Primary Surgeons and Facilities*, 323 J. Am. Med. Ass'n 538, 538-47 (Feb. 11, 2020), https://bit.ly/3Q477bA.

[25] *Id.*

[26] Kao-Ping Chua *et al.*, *Prevalence and Magnitude of Potential Surprise Bills for Childbirth*, JAMA Health F. (July 2, 2021), https://bit.ly/3o7GTpL.

[27] *See* Erin Duffy *et al.*, Brookings Inst., *Surprise medical bills increase costs for everyone, not just for the people who get them* (Oct. 2, 2020), https://brook.gs/3FWoXnQ.

for people with employer-sponsored insurance would have decreased by 3.4 percent (about $40 billion annually) if certain hospital-based specialists—anesthesiologists, pathologists, radiologists, and assistant surgeons—had been barred from sending surprise bills.[28] Another study concluded that because approximately 12 percent of health plan spending is attributable to ancillary and emergency services—settings where surprise bills were commonplace—policies to address surprise bills could reduce premiums for all consumers by 1 to 5 percent.[29] These studies make clear that all consumers, not just patients who received surprise bills, paid the price for surprise billing through higher health care costs and premiums.

C. The No Surprises Act Was Designed to Ban Surprise Bills and Protect Consumers from Escalating Health Care Costs Associated with Out-of-Network Care.

In barring providers from balance billing patients for these charges, Congress established statutory mechanisms in the Act to enable providers and payers to resolve disputes over the payment of

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[28] Zack Cooper *et al.*, *Out-Of-Network Billing And Negotiated Payments For Hospital-Based Physicians*, 39 Health Affairs 24, 24 (Dec. 16, 2019), https://bit.ly/3X8PpEB.

[29] Erin L. Duffy *et al.*, *Policies to address surprise billing can affect health insurance premiums*, 26 Am. J. Managed Care 401, 401-04 (Sep. 11, 2020), http://bit.ly/3tFMk1e.

out-of-network bills without directly involving patients. Congress established the IDR process—and empowered the Departments to implement it through regulation—to further Congress' parallel goals of protecting individual patients from surprise bills and ensure that the Act would not impose higher health care costs on consumers.

During the legislative process leading to the Act's passage, patient and consumer advocates, including many *Amici*, urged Congress to design surprise billing protections in a manner that would "ensure costs are not simply passed along to patients through higher premiums or out-of-pocket costs."[30] The Act, as passed, reflected Congress' endorsement of these goals. In December 2020, the chairs and ranking members of the Senate and House committees that negotiated the legislation touted the "bipartisan, bicameral deal" that would "protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers, without increasing premiums for patients."[31]

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[30] ALS Ass'n *et al.*, *supra* note 4, at 2.

[31] S. Comm. on Health, Educ., Labor & Pensions, *Congressional Committee Leaders Announce Surprise Billing Agreement* (Dec. 11, 2020), https://bit.ly/3rSj1Ht.

To further these goals, the Act established a streamlined independent dispute resolution ("IDR") process to resolve payment disputes and required the Departments to establish IDR procedures to ensure that disputes would be resolved in a uniform, fair, predictable, and cost-effective manner.

II. THE RULE WILL PROTECT PATIENTS OR CONSUMERS BY ENCOURAGING IN-NETWORK NEGOTIATIONS AND CONTROLLING HEALTH INSURANCE PREMIUMS.

Through the Rule, the Departments have exercised their obligations under the Act to establish reasonable guardrails to prevent abuse of the IDR system, promote predictability, and protect patients and consumers.

A. The Common-Sense, Uniform IDR Procedures Established by the Rule Fulfill the Statutory Purposes of Preventing Abuse of the IDR Process and Reducing Health Care Costs.

The Rule requires certified IDR entities to consider all permissible information in determining which party's offer most closely approximates the value of the item or service at issue.[32] The Departments responded to concerns shared by the public during the

[32] 87 Fed. Reg. at 52,645 (§ 54.9816–8(c)(4)(ii)(A)), 52,649 (§ 2590.716–8), 52,652 (§ 149.510).

rulemaking process and established a reasonable, uniform process designed to limit variability in payment determinations, reduce gamesmanship or abuse of the IDR process, and in turn, control the escalation of health care costs that would ultimately be passed on to patients and consumers. The important guardrails established by the Rule include (1) ensuring that IDR entities do not double-count statutory factors that might favor one party to a payment dispute over another, and (2) emphasizing that IDR entities may only consider credible information in reaching their determinations. Notwithstanding Plaintiffs-Appellees' objections to these common-sense protections, these protections are consistent with the statutory text and necessary to ensure the IDR process results in even-handed, predictable outcomes and the resulting benefits to patients and consumers.

First, the Rule recognizes that one of the statutory factors—the qualifying payment amount, or QPA—is already calculated based on various factors, including several of the other statutory factors. Thus, the Rule also reasonably clarifies that an IDR entity may not double-count information already factored into the QPA.[33] Simply put, an IDR

[33] *Id.* at 52,628–30.

entity must consider each relevant statutory factor, but can do so only once.[34] To allow favorable information to be counted twice would tip the scale toward one party or the other, leading to higher or lower IDR determinations depending on which party is favored.

It is well within the Departments' statutory mandate to ensure that IDR entities even-handedly weigh all relevant information. In response to numerous public comments cautioning against double-counting, the Departments carefully explain in the Rule's preamble how certain factors—such as patient acuity or the complexity of furnishing the item or service—are already part of the QPA calculation.[35] *Amici* agree with the Departments that, without the guidance in the Rule, IDR entities might give more weight to potentially redundant information than is due or required by the statute, potentially resulting in artificial inflation of health costs that would ultimately be borne by consumers.[36]

[34] *Id.*

[35] *Id.* at 52,628–29.

[36] *Id.* at 52,629.

Second, the argument posited by Plaintiffs-Appellees below that the Rule's requirement that IDR entities only consider "credible" information is somehow unreasonable or prejudicial makes little sense and is inconsistent with the Act. The Rule merely formalizes the assumption that IDR entities cannot consider non-credible information submitted by either party. Plaintiffs-Appellees have asserted, incorrectly, that the Rule requires a credibility determination for all of the statutory factors except for the QPA. This too is contradicted by the text of the Rule and its preamble. As the Departments explain, "to the extent that the QPA is calculated in a manner that is consistent with the detailed rules issued under the July 2021 interim final rules, and is communicated in a way that satisfied the applicable disclosure requirements, the QPA will meet the credibility requirement that applies to the additional information . . . ."[37] The Departments have not exempted the QPA factor from the credibility requirement; rather, by incorporating the specific requirements and protections for the QPA into the Rule, they are ensuring that the credibility requirement be met. Thus, under the Rule, the IDR entity must consider all credible

[37] *Id*. at 52,627.

information related to the parties' offers, thereby ensuring that the ultimate payment amount is "reasonable," as the Act requires.

B. An Unregulated IDR Process Would Burden Patients and Families with Higher Premiums, Frustrating a Central Purpose of the No Surprises Act.

At base, the Rule formalizes the statutory requirements and provides clear guidance to IDR entities on how to fulfill these requirements. It does not, as Plaintiffs-Appellees have suggested in this case, tip the scale in favor of any one factor. Rather, it establishes a procedural and evidentiary framework to ensure a predictable, consistent, and fair process for balancing these factors. As the Departments explain, "[a]bsent clear guidance on a process for evaluating the different factors, there would be no guarantee of consistency in how certified IDR entities reached determinations in different cases."[38] The Departments' efforts to avoid wildly inconsistent determinations—and the potential abuse of the IDR system that might occur as a result—is a reasonable exercise of their statutory authority to regulate the IDR process.

[38] *Id.*

The district court's *vacatur* of the challenged provisions of the Rule, if not reversed, will likely result in an unpredictable and administratively burdensome IDR process for the millions of payment disputes resulting from the ban on surprise bills for patients. IDR entities would continue to be left without a clear, consistent way to resolve payment disputes. Both providers and payers would lose the uniform expectations that the Rule's IDR process establishes, leading to less predictable outcomes and increasing the overall likelihood of above-market payments to out-of-network providers.

C. The Rule's IDR Procedures Will Likely Promote More In-Network Care and Reduce Out-of-Pocket Costs and Premiums for Consumers.

Plaintiffs-Appellees have argued that the Rule will jeopardize access to care and harm patients by forcing providers to accept lower rates or reducing access to in-network care. But these so-called harms are nonexistent or significantly overblown and do not justify the district court's *vacatur* of the challenged provisions of the Rule.

Evidence from states with existing protections against surprise billing suggests that a well-designed IDR process that does not incentivize the overuse of arbitration can lead to higher rates of

participation of in-network providers. In California, for example, in-network service provision rose and remained high after implementation of the state's law in 2017.[39] After surprise billing protections were adopted in other states, out-of-network providers have chosen to join payer networks at increasing rates.[40] Conversely, a poorly-designed or unregulated IDR process will likely incentivize the use of arbitration to resolve disputes, while a well-regulated and predictable process will encourage voluntary negotiations to resolve such disputes and increase participation in health insurance networks by providers in specialties that have until now tended not to be in-network providers.

In the first year since the No Surprises Act's IDR process went into effect—largely without the benefit of clear, consistent processes or guidance from the Departments because of the litigation over the prior interim final rules—the use of IDR has been substantially higher than

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[39] *See* Loren Adler *et al.*, Brookings Inst., *California saw reduction in out-of-network care from affected specialties after 2017 surprise billing law* (Sept. 26, 2019), https://brook.gs/3KQ8cyz.

[40] *See* Loren Adler *et al.*, Brookings Inst., *Changes in emergency physician service prices after Connecticut's 2016 surprise billing law* (Sept. 23, 2021), https://brook.gs/3G1dSlG; N.Y. Dep't of Fin. Servs., *New York's Surprise Out-Of-Network Protection Law Report on the Independent Dispute Resolution Process* 8 (Sept. 2019), https://bit.ly/3g6pkFP.

predicted.[41] A recent HHS report found that, in just the first six months following the launch of the federal IDR portal, more than 90,000 disputes were initiated—a four-fold increase from initial predictions.[42] HHS noted that the cost and time burdens on the IDR entities of managing these disputes, and on the disputing parties, has been significant.[43] Between April 15, 2022, and March 31, 2023, over 334,000 payment disputes were submitted through the federal IDR portal, a number 14 times higher than initial predictions.[44]

These costs will ultimately be borne by consumers. A clearer, transparent process with more predictable results, like the one the Departments have now set forth in the Rule, would incentivize dispute resolution before the IDR process and minimize these additional costs.

CONCLUSION

The Rule is consistent with the text and purpose of the No Surprises Act: the Departments have exercised their statutory

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[41] *See* U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Ctr. for Consumer Info. & Ins. Oversight, *Calendar Year 2023 Fee Guidance for the Federal Government Independent Dispute Resolution Process under the No Surprises Act* 5 (Oct. 31, 2022), https://bit.ly/3DTgmn5.

[42] *Id.*

[43] *Id.*

[44] CMS IDR Status Update, *supra* note 8, at 1.

obligations under the Act to implement an independent dispute resolution process that will balance the interests of providers and insurers while ensuring that patients and consumers are not exposed to higher health care costs. Through the Rule, the Departments have reasonably exercised their authority to establish uniform, predictable procedures and guardrails to promote the Act's twin purposes of protecting individual patients from surprise bills and all protecting all consumers from rising health care costs. *Amici* respectfully request that this Court reverse the judgment of the district court.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). It contains 5,314 words, calculated using Microsoft Word's word-count feature, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(f).

2. This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5)–(6). It has been prepared using Microsoft Word in a proportionally spaced typeface, Century Schoolbook, with text in 14-point typeface and footnotes in a 12-point typeface.

DATED: July 19, 2023

/s/ Joseph J. Wardenski
Joseph J. Wardenski

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2023, I served a copy of the foregoing Brief of The Leukemia & Lymphoma Society and Ten Other Patient and Consumer Advocacy Groups as *Amici Curiae* in Support of Defendants-Appellants and Reversal with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the Court's CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the electronic filing.

Dated: July 19, 2023

/s/ Joseph J. Wardenski
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