UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS TYLER DIVISION

TEXAS MEDICAL ASSOCIATION et al.,

Plaintiffs,

Civil Action No. 6:22-cv-00372-JDK

v.

Lead Consolidated Case

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

BRIEF OF NINE PATIENT AND CONSUMER ADVOCACY ORGANIZATIONS AS AMICI CURIAE IN SUPPORT OF DEFENDANTS

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INTEREST OF AMICI CURIAE

Amici curiae The Leukemia & Lymphoma Society, ALS Association, Cancer Support Community, Cancer*Care*, Epilepsy Foundation, Families USA Action, Hemophilia Federation of America, National Multiple Sclerosis Society, and PIRG (Public Interest Research Group)) (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. Descriptions of *Amici* are included in the Appendix to this brief.

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 six Americans who have received a surprise medical bill.¹ Given the impact of surprise bills on those served by *Amici*, many *Amici* joined community principles for surprise billing reforms² and worked with Congress to develop the bipartisan, bicameral 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. Because the patients and consumers we serve have a strong interest in the outcome of this litigation, *Amici* respectfully submit this brief in support of Defendants.

¹ See 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.

² See ALS Ass'n et al., Surprise Medical Billing Principles (Feb. 2020) [Ex. A].

INTRODUCTION

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 No Surprises Act. 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. In prohibiting balance billing, the Act was designed to ensure that the benefits to patients who would otherwise have been harmed by surprise bills did 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, in turn, to reduce (or at least not increase) health insurance premiums and promote lower health care costs overall.³

Through the Final Rule, *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (Aug. 26, 2022) (the "Rule"), Defendants, the Departments of Health and Human Services, Labor, and Treasury (collectively, 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.⁴ In promulgating the Rule, the Departments followed this 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.

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

⁴ 87 Fed. Reg. at 52,627 & n. 32.

As advocates for patients and consumers, *Amici* strongly reject the assertion made by Plaintiffs and their *amici*—every one of which is a medical provider or provider trade association—that patients and consumers will be harmed by the Rule's IDR process. To the contrary, the Rule is consistent with the text and purpose of the No Surprises Act and will encourage more in-network participation by providers, leading to even more comprehensive coverage and reducing health care costs for patients and consumers.

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—including preventing abuses of the IDR process that would inflate health care costs for everyone. Many *Amici* were highly engaged with lawmakers and the Departments throughout the legislative and rulemaking processes. Based on their 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.

While Plaintiffs and their *amici* prefer a wholly unregulated IDR process that might yield them higher compensation in IDR disputes, 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 Plaintiffs' requested *vacatur* of the Rule would harm patients and consumers across the country, including those served by *Amici*, this Court should deny Plaintiffs' Motions for Summary Judgment, ECF Nos. 41, 42, and grant Defendants' Cross-Motion for Summary Judgment, ECF No. 63.

3

ARGUMENT

I. SURPRISE MEDICAL BILLS RESULT IN HIGHER OUT-OF-POCKET COSTS FOR PATIENTS AND INFLATED HEALTH COSTS THAT CONTRIBUTE TO INCREASED HEALTH INSURANCE PREMIUMS.

As Congress recognized in passing the No Surprises Act, surprise medical bills can impose "staggering" financial burdens on patients and their families.⁵ Patients receive out-ofnetwork bills through no fault of their own when they unknowingly receive care from a provider that is not in their insurance network. This is especially true in emergencies when patients often have no way to choose their hospital, physician, or air ambulance provider. Nor can they know whether certain specialists who may treat them during a visit to an in-network hospital—such as anesthesiologists or radiologists-are outside of their plan's network until after receiving a surprise bill. Patients with chronic or serious conditions, such as those with cancer, chronic respiratory disease, or at risk of a heart attack, face an elevated risk of receiving out-of-network bills from hospitals, doctors, and air ambulance providers.⁶ In barring providers from balance billing patients for these charges, the Act recognized the need for a streamlined IDR process to help resolve disputes about the payment of out-of-network bills. The Act required the Departments to establish procedures through the IDR process by which those disputes would be resolved in a fair and cost-effective manner. The Departments, in executing this responsibility through the Rule, have established common-sense procedures and safeguards to further these interests.

⁵ 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").

⁶ 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.

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

Surprise bills are common in both emergency and non-emergency situations and have resulted in significant out-of-pocket costs for directly affected patients and higher premiums for privately insured consumers.⁷ These surprise bills add up. A recent study found that Americans owed more than \$140 billion dollars in medical debt and that unpaid medical bills are the largest driver of that debt.⁸ Surprise bills can hit low-income consumers the hardest: more than one-fourth of adults are unable to pay their monthly bills or are one \$400 financial setback away from being unable to pay them in full.⁹ The added burden of an unexpected medical expense—which could total hundreds or thousands of dollars—can spell financial ruin for many families.

1. Emergency Care

A patient might receive a surprise bill in an emergency if the closest hospital is outside the patient's network, if the patient is seen by an out-of-network emergency room physician at an in-network hospital, or if the patient requires air ambulance transport to receive emergency care. According to one study, 18 percent of all emergency visits by patients in large employer plans in

⁷ See H.R. Rep. No. 116-615, pt. I, *supra* note 5, at 53 (summarizing the data on surprise billing 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").

⁸ Raymond Kluender *et al.*, *Medical Debt in the US, 2009-2020*, 326 J. Am. Med. Ass'n 250, 255 (2021), https://bit.ly/3KFqh23.

⁹ Bd. of Governors of Fed. Reserve Sys., *Economic Well-Being of U.S. Households in 2020* 4, 33 (May 2021), https://bit.ly/3FZzXkl.

2017 had at least one out-of-network charge that could result in a surprise bill.¹⁰ Another study estimated that one in five inpatient emergency room visits could lead to a surprise bill.¹¹

Critically ill or injured patients who require emergency transportation from air ambulance providers are even more likely to face surprise medical bills. While air ambulance services often reduce transport time for patients during life-threatening situations and are a critical component of successful treatment for individuals experiencing serious health events, those patients generally have no choice over 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.¹² There are many harrowing stories from patients who have received surprise five-figure bills for out-of-network air ambulance services.¹³ The risk that a patient might receive a surprise out-of-network bill from an air ambulance provider has also grown over time. Multiple studies confirm that the prices charged by air ambulance providers—and thus the out-of-network bills that these companies send to patients—have increased significantly. According to one study, the use of

¹⁰ Karen Pollitz *et al.* (Feb. 10, 2020), *supra* note 6.

¹¹ 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.

¹² See H.R. Rep. No. 116-615, pt. 1, supra note 5, at 52.

¹³ 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 Bills*, 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.

helicopter ambulances declined by 14.3 percent from 2008 to 2017 while the average price per trip more than doubled, rising 144 percent.¹⁴ Use of airplane ambulances remained steady during this time, even as the average price increased by 166 percent.¹⁵ Multiple studies have documented high and rapidly rising prices for air ambulance transport.¹⁶ These significant price increases are attributed at least in part to market concentration and greater private equity ownership of air ambulance providers.¹⁷ As 35 state insurance commissioners, including the commissioner of the Texas Department of Insurance, wrote to Congressional leaders, surprise billing for air ambulance services has for many providers become "a business model to prey on people during their most vulnerable time" by "pass[ing] on massive surprise bills to private market consumers and expect[ing] them to make up the claimed difference."¹⁸

2. Non-Emergency Care

Surprise bills also affect patients when they seek non-emergency care (such as surgery or maternity care) at in-network facilities. 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 lead to a surprise bill.¹⁹ Another study found that 20 percent of all patients who had an elective procedure—such as a hysterectomy, knee replacement, or heart surgery—with an in-network

 ¹⁴ John Hargraves & Aaron Bloschichak, *Air Ambulances – 10 Year Trends in Costs and Use*, Health Care Cost Inst. (Nov. 7, 2019), https://bit.ly/3GXKzSb.
 ¹⁵ Id.

¹⁶ 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.

¹⁷ See Loren Adler et al., High air ambulance charges concentrated in private equity-owned carriers, Brookings Inst. (Oct. 13, 2020), https://bit.ly/3ECnx4J.

¹⁸ Letter from Jon Godfread, Comm'r, N.D. Ins. Dep't, *et al.* to Hon. Bobby Scott *et al.* 2 (Nov. 7, 2019), bit.ly/3AkFfau.

¹⁹ Karen Pollitz et al. (Feb. 10, 2020), supra note 6.

primary surgeon at an in-network facility were still at risk of a surprise bill from an out-ofnetwork specialist.²⁰ Of these, potential surprise bills averaged more than \$1,200 for anesthesiologists and more than \$3,600 for surgical assistants.²¹ And 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 \$2,000.²²

B. Surprise Billing Increases Health Insurance Premiums and Overall Health Care Costs for Privately Insured Individuals.

In addition to higher out-of-pocket costs, surprise medical bills increase health care costs, which, in turn, increases premiums for those with private health insurance.²³ One study found that health care spending for people with employer-sponsored insurance would be reduced by 3.4 percent (about \$40 billion annually) if certain hospital-based specialists—anesthesiologists, pathologists, radiologists, and assistant surgeons—were unable to send surprise bills to patients.²⁴ Another study found that about 12 percent of health plan spending is attributable to ancillary and emergency services where providers commonly send surprise bills to patients, leading researchers to conclude that policies to address surprise bills could reduce premiums by 1

²⁰ 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 (2020), https://jamanetwork.com/journals/jama/article-abstract/2760735.

²¹ *Id*.

²² Kao-Ping Chua *et al.*, *Prevalence and Magnitude of Potential Surprise Bills for Childbirth*, JAMA Health F. (July 2, 2021), https://bit.ly/307GTpL.

²³ 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.

²⁴ Zack Cooper et al., Out-Of-Network Billing And Negotiated Payments For Hospital-Based Physicians, 39 Health Affairs 24, 24 (2020), https://bit.ly/3X8PpEB.

to 5 percent.²⁵ These studies make clear that, even if not all patients receive a surprise bill, everyone pays the price for this practice through higher health care costs and premiums.

When the No Surprises Act was considered in Congress, *Amici* consistently highlighted the link between premiums and out-of-pocket protections. One of the core principles adopted by coalitions of patient and consumer advocates was that new surprise billing protections should "ensure costs are not simply passed along to patients through higher premiums or out-of-pocket costs"²⁶ and "hold costs down."²⁷ Congress heeded this warning: In a joint statement announcing the bipartisan agreement that would become the Act, the chair and ranking members of the Senate HELP Committee and the House Committees on Energy and Commerce, Ways and Means, and Education and Labor explained that lowering health care costs was a high priority. These Congressional leaders noted that the "bipartisan, bicameral deal" would "protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers, without increasing premiums for patients."²⁸ The Congressional Budget Office confirmed this intent and estimated that the Act would reduce premiums by 0.5 to 1.0 percent.²⁹

Based on this history, there is no question that Congress' intent in passing the No Surprises Act was both to protect patients from surprise medical bills and lower health care costs.

²⁵ Erin L. Duffy et al., Policies to address surprise billing can affect health insurance premiums,
26 Am. J. Managed Care 401, 401-04 (2020), http://bit.ly/3tFMk1e.

²⁶ ALS Ass'n *et al.*, *supra* note 2, at 2.

²⁷ Letter from Families USA *et al.* to House Speaker Pelosi and House Minority Leader McCarthy, at 2 (July 10, 2019), https://bit.ly/3tQAra6; Letter from Families USA et al. to House Speaker Pelosi and Leaders McConnell, McCarthy, and Schumer (Nov. 12, 2019), https://bit.ly/3tWPCP9.

²⁸ S. Comm. on Health, Educ., Labor & Pensions, Congressional Committee Leaders Announce Surprise Billing Agreement (Dec. 11, 2020), https://bit.ly/3rSj1Ht.

²⁹ Cong. Budget Office, *Estimate for Divisions O Through FF H.R. 133, Consolidated Appropriations Act, 2021, Public Law No. 116-260, Enacted on December 27, 2020 3* (Jan. 14, 2021), http://bit.ly/3hK3BUu.

A key way that Congress codified that goal was by directing the Departments to establish a single uniform IDR process to resolve payment disputes between providers and payers.³⁰ A wholly unregulated IDR process without guidance or oversight by the Departments directly conflicts with the Act's statutory text and Congress's intent to rein in health care costs—and, in turn, help limit premiums for patients and consumers.

II. THE RULE WILL NOT HARM PATIENTS OR CONSUMERS, BUT WILL PROTECT THEM BY ENCOURAGING IN-NETWORK NEGOTIATIONS AND CONTROLLING HEALTH INSURANCE PREMIUMS.

The Rule, consistent with this Court's prior rulings and the Act's statutory text, 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.³¹ In issuing the Rule, the Departments responded to concerns shared by the public during the 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 in the form of higher premiums.

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.

Plaintiffs and their *amici* repeatedly assert that the Rule places a "thumb on the scale" for the qualifying payment amount, or QPA, relative to the other statutory factors. The Rule does no such thing. Rather, like the statute, the Rule requires certified IDR entities to consider all the relevant statutory factors, including the QPA, and to then "select the offer that the certified IDR

³⁰ 42 U.S.C. § 300gg-111(c)(2).

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

entity determines best represents the value of the qualified IDR item or service as the out-ofnetwork rate."³² The Rule also reasonably clarifies that an IDR entity may not double-count information already factored into the QPA.³³ In short, the IDR entity must consider each relevant statutory factor, but, as the Rule reasonably clarifies, they 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

Plaintiffs and their *amici* protest that the Rule's requirement that IDR entities only consider "credible" information is somehow unreasonable or prejudicial. But the Rule merely formalizes the assumption to ensure that IDR entities cannot consider non-credible information submitted by either party. Plaintiffs assert, incorrectly, that the Rule requires a credibility determination for all of the statutory factors except for the QPA. This too is belied by the text of

³² *Id*.

³³ *Id.* at 52,628–30.

³⁴ *Id*.

³⁵ *Id.* at 52,628–29.

³⁶ *Id.* at 52,629.

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, as Plaintiffs contend, 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 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, contrary to Plaintiffs' objections, 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 in an even-handed way. 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.

Plaintiffs' requested relief—a *vacatur* of the challenged provisions of the Rule and an instruction that would effectively bar Defendants from providing guidance or direction to

³⁷ *Id.* at 52,627.

³⁸ Id.

certified IDR entities—would result in an unpredictable and administratively burdensome IDR process. Arbitrators would 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 abovemarket payments to out-of-network providers.

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

Plaintiffs and their supporting *amici* argue 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 cannot justify a *vacatur* of the challenged provisions of the Rule.

First, 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 Evidence from other laws adopted in states, including Connecticut and New York, also shows out-of-network providers choosing to join payer networks after implementation of surprise billing reforms.⁴⁰ Conversely, a poorly-designed or unregulated IDR process will likely incentivize the use of arbitration over voluntary negotiations to resolve disputes or participation in health insurance networks. In the first year since the No Surprises Act's IDR process went into

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/3G1dSIG; 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.

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 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 nearly five-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 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.

Second, payers have legal and economic incentives to maintain robust provider networks. While the No Surprises Act does not include new standards that require payers to have adequate provider networks, many payers are subject to network adequacy requirements under existing federal and state laws.⁴⁴ Where legal requirements might not exist, insurers and plans have some market-based incentives to compete for business by offering products with provider networks that ensure access to a broad range of in-network care.⁴⁵ Strong network adequacy protections are key to ensuring access to care and help mitigate concerns raised by Plaintiffs and their *amici*.

⁴¹ See U.S. Dep't of Health & Hum. Servs., Centers for Medicare & Medicaid Servs., Center for Consumer Information & 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 See Justin Giovannelli *et al.*, *Regulation of Health Plan Provider Networks*, Health Affairs Health Policy Brief (July 28, 2016), https://bit.ly/32E9H1B.

⁴⁵ See Gary Claxton *et al.*, *Employer strategies to reduce health costs and improve quality through network configuration*, Peterson-KFF Health Sys. Tracker (Sept. 25, 2019), https://bit.ly/3G8MaUf.

Third, most providers and facilities do *not* balance bill patients for care. Fewer than half of the providers across medical specialties send out-of-network bills; of those that do, most do so less than 10 percent of the time.⁴⁶ The challenged provisions of the Rule will thus have very little impact on most providers.⁴⁷ Even if the Rule were to impact some types of specialty providers, hospitals and other facilities have strong financial incentives to ensure that they have sufficient staff for well-functioning emergency departments and operating rooms.⁴⁸ Experience suggests that facilities and hospital-based clinicians will ensure access to care by taking necessary actions like making higher payments to out-of-network clinicians.⁴⁹ Hospitals and other facilities will then negotiate with payers to secure higher in-network rates to account for these marginal costs.

CONCLUSION

The Rule is consistent with the text and purpose of the No Surprises Act and will benefit patients by implementing an IDR process that helps ensure lower health care costs for privately insured Americans. The Court should deny Plaintiffs' Motions for Summary Judgment and grant Defendants' Cross-Motion for Summary Judgment.

⁴⁶ Jean Fuglesten Biniek *et al.*, Health Care Cost Inst., *How often do providers bill out of network?* (May 28, 2020), https://bit.ly/3KRS8MA.

⁴⁷ See Kevin Kennedy et al., Health Care Cost Inst., Surprise out-of-network medical bills during in-network hospital admissions varied by state and medical specialty, 2016 (Mar. 28, 2019), https://bit.ly/3GcNVzr.

⁴⁸ See Chloe O'Connell *et al.*, *Trends in Direct Hospital Payments to Anesthesia Groups: A Retrospective Cohort Study of Nonacademic Hospitals in California 2019*, 131 Anesthesiology 534, 534-42 (2019), https://doi.org/10.1097/ALN.00000000002819.

⁴⁹ *See id.*

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Respectfully submitted,

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APPENDIX

Descriptions of *Amici Curiae*

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 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.

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.

A-1

CancerCare 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 *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.

A-2

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.

PIRG (Public Interest Research Group) 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.

CERTIFICATE OF SERVICE

I hereby certify that on November 16, 2022, I electronically filed the foregoing Brief of Nine Patient and Consumer Advocacy Organizations as *Amici Curiae* in Support of Defendants with the Clerk of Court and served the same on all counsel of record using the Court's CM/ECF electronic filing system.

<u>/s/ Joseph J. Wardenski</u> Joseph J. Wardenski Case 6:22-cv-00372-JDK Document 78-1 Filed 11/16/22 Page 1 of 4 PageID #: 853

Exhibit A

Surprise Medical Billing Principles (Feb. 2020)



Surprise Medical Billing Principles

"Surprise billing" or "balance billing" occurs when patients receive care from a provider outside of their insurance network, usually without their knowledge. The patient is then billed the difference between what the provider charged and what their insurer paid for the service.

Often, surprise bills are related to the receipt of emergency care –urgent and sometimes life-threatening situations where patients are not able to decide which facility or physician provides their care. Recent academic studies have found that approximately one out of every five emergency department visits involve care from an out-of-network provider.¹ However, surprise bills are not unique to the emergency setting. Another study found that the physician specialties most likely to send surprise bills are anesthesiology, interventional radiology, emergency medicine, pathology, neurosurgery, and diagnostic radiology.²

Surprise bills are an increasingly common occurrence for patients and consumers. They occur regardless of the type of health insurance and are rendered in almost all health care settings. Most consumers with health insurance expect their coverage will provide protection from unexpected, exorbitant medical bills for needed care; however, more than half (57%) of insured Americans have been caught off guard by a medical bill for care they thought would be covered by their insurance plan. Even among large employer plans, nearly one-in-ten elective inpatient procedures involved a potential surprise bill.³

¹ Cooper, Zack, Fiona Scott Morton. 2016. "Out-of-network emergency-physician bills—an unwelcome surprise." NEJM 2016; 375:1915-1918. https://www.nejm.org/doi/full/10.1056/NEJMp1608571.

² Bai G, Anderson GF. Variation in the Ratio of Physician Charges to Medicare Payments by Specialty and Region. JAMA. 2017;317(3):315–318. doi:10.1001/jama.2016.16230.

³ Garman, Christopher, Benjamin Chartock. 2017. "One in Five Inpatient Emergency Department Cases May Lead to Surprise Bills." Health Affairs. Vol 36. No. 1 https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0970.

Principles

Our 25 patient and consumer advocacy organizations believe that access to affordable, accessible and adequate health insurance is key to improving the health and wellbeing of all people living in the United States.⁴ As such, we believe that Congress should take strong and swift action to protect patients and consumers from surprise medical bills by passing legislation that meets the following principles:

- 1. Hold Patients Harmless: Any policy addressing surprise billing must ensure that patients are held financially harmless. When patients receive services from an out-of-network provider for which they have the reasonable expectation that the service was performed in-network (for example, services performed at an in-network facility, or services ordered by an in-network provider), the patient should incur no greater cost-sharing than if the service was performed by an in-network provider. Any such cost-sharing should accrue to in-network deductibles and out of-pocket caps. Any solution should also ensure costs are not simply passed along to patients through higher premiums or out-of-pocket costs.
- 2. Apply Protections to All Insurance Plans: Surprise billing protections should apply to all commercial health insurance plans, including individual, small group, large group, and self-insured plans as applicable.
- 3. **Apply Protections to All Surprise Bills for All Covered Services:** Protections should apply to all surprise bills, regardless of the amount of the bill. Protections should apply to devices that may be provided to a patient while in their provider's office. A surprise bill of any amount can be challenging to patients and their families.
- 4. **Apply Protections to All Care Settings**: Surprise billing protections should be applicable regardless of provider type or care setting. Policies should not limit these protections to just emergency services, hospital services, or certain types of specialists.
- 5. Require Transparency in Addition to Not Instead of Surprise Billing Protections: Increased transparency for patients is not a sufficient way for policymakers to address the problem of surprise billing. In the vast majority of surprise billing cases, the affected patient has little ability to seek an alternative in-network provider, even if given more information. While our organizations support greater transparency requirements for plans and providers, such requirements are insufficient to meaningfully protect patients from surprise bills.
- 6. Conduct Additional Research: Surprise billing can occur for a variety of reasons, including the inadequacy of a plan's provider network. Policymakers who enact surprise billing protections should also consider requiring data collection on the incidence of surprising billing to determine whether additional policies and protections are warranted (for example, enactment of more robust network adequacy requirements).
- 7. **Strengthen State Protections Instead of Weakening Them:** Any federal protections against surprise billing should set a floor to ensure that at least this level of protection exists in all states, but not pre-empt stronger state-level protections where these rules apply.

⁴ Consensus Healthcare Reform Principles: <u>https://www.heart.org/-/media/files/get-involved/advocacy/access-to-care/050819-healthcare-principles44logos.pdf?la=en&hash=413C07330CE837C8AEDF059454378C45B655594A</u>

8. Protecting Patients who Utilize Emergency Transportation: Our organizations are deeply concerned about the impact of balance billing practices on individuals who require emergency transportation. Emergency transportation services reduce transport time for patients during life threatening situations and are a critical component of successful treatment for individuals experiencing a serious health event. Patients in these situations have no choice over who provides care or how they are transported and are frequently balance billed as a result. Policymakers should craft policies that protect patients in all health care settings, including emergency transportation settings.

ALS Association

American Cancer Society Cancer Action Network American Diabetes Association American Heart Association American Kidney Fund American Lung Association Arthritis Foundation **COPD** Foundation **Cystic Fibrosis Foundation Epilepsy Foundation Family Voices** Hemophilia Federation of America Leukemia & Lymphoma Society Mended Little Hearts Muscular Dystrophy Association National Alliance on Mental Illness National Health Council National Hemophilia Foundation National Multiple Sclerosis Society National Organization for Rare Disorders National Patient Advocate Foundation Pulmonary Hypertension Association Susan G. Komen The American Liver Foundation WomenHeart: The National Coalition for Women with Heart Disease