UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION,
AMA Plaza
330 N. Wabash Ave., Suite 39300
Chicago, IL 60611,

AMERICAN HOSPITAL ASSOCIATION,
155 N. Wacker Dr.
Chicago, IL 60606,

RENOWN HEALTH,
50 W. Liberty Street, 11th Floor
Reno, NV 89501,

UMASS MEMORIAL HEALTH CARE, INC.,
One Biotech Park
365 Plantation Street
Worcester, MA 01605,

STUART M. SQUIRES, M.D.,
447 Shawcraft Road
Fayetteville, NC 28311,

and

VICTOR F. KUBIT, M.D.,
17 Clearwater Point Drive
Sanford, NC 27332,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201,

Civ. Action No. _____

U.S. OFFICE OF PERSONNEL MANAGEMENT,
1900 E Street NW
Washington, DC 20415,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

U.S. DEPARTMENT OF LABOR,
200 Constitution Avenue NW
Washington, DC 20210,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210,

U.S. DEPARTMENT OF THE TREASURY,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

and

JANET YELLEN, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs American Medical Association ("AMA"), American Hospital Association ("AHA"), Renown Health, UMass Memorial Health Care, Inc. ("UMass Memorial Health"), Stuart M. Squires, M.D., and Victor F. Kubit, M.D., by and through their attorneys, bring this action for declaratory and injunctive relief against defendants the United States Department of Health and Human Services, Department of Labor, Department of the Treasury, Office of

Personnel Management, and the current heads of those agencies in their official capacities, and allege as follows:

INTRODUCTION

1. This is an action under the Administrative Procedure Act to set aside specific and limited provisions of an interim final rule issued by the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management (collectively, the "Departments") in violation of their statutory authority. The rule, titled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("September Rule"), implements provisions of the No Surprises Act, Pub. L. 116-260 (the "Act").[1] The Act was passed on December 27, 2020, as part of the Consolidated Appropriations Act, 2021, and its requirements generally go into effect on January 1, 2022.

2. The AMA and AHA strongly support Congress's goal of protecting patients from surprise billing. For years, the AMA and AHA consistently advocated for a patient-first solution to surprise billing—namely, one that would shield patients from unexpected medical bills, while enabling physicians and hospitals ("providers"), on the one hand, and group health plans or commercial health insurance issuers ("insurers"), on the other, to determine fair payment among themselves.[2] The compromise set forth in the No Surprises Act did just that. It both protected

[1] The Act made parallel amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. These Departments, along with the Office of Personnel Management ("OPM") (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the September Rule.

[2] *See, e.g.*, Letter from AMA to Chairman Neal and Ranking Member Brady on Surprise Medical Billing (Feb. 7, 2019), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTER

patients from surprise medical bills and established an independent dispute resolution ("IDR") process in which patients would be removed from the middle of negotiations between providers and insurers. In so doing, the Act adopted an intentionally balanced approach that did not skew towards either providers or insurers.[3] The Departments' implementation of the Act in the September Rule, however, deviates from Congress's balanced design in a critical respect: the Rule places a heavy thumb on the scale during the independent arbitration process in a way that directly conflicts with the statutory text. The Departments reached this atextual result, moreover, without first providing notice or receiving the benefits of the public's views, as the law requires.

3. The No Surprises Act was the result of "a long-fought and negotiated bipartisan and bicameral compromise to protect patients by ending surprise billing." 166 Cong. Rec. H7290, H7291 (Dec. 21, 2020). A critical component of that compromise is the Act's IDR process. It protects patients from surprise medical bills by limiting the amount a patient can be billed by a provider who is not in the network supplied by their insurer. That limit is the amount of cost-sharing the patient would pay to a provider in their insurer's network. Providers not in the network are required to negotiate reasonable payment directly with the patient's insurer. If that negotiation is unavailing, the Act provides for binding "baseball-style" arbitration before a certified arbitrator (or, as the Act calls it, an "IDR entity"). The provider and insurer submit to the arbitrator the

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S%2F2019-2-7-Surprise-Billing-Ways-and-Means-Signon.pdf; Letter from AHA to Chairman Neal et al. on Surprise Medical Billing (Dec. 13, 2020), https://www.aha.org/system/files/media/file/2020/12/AHA-Letter-No-Surprises-Act_12-13-20.pdf.

[3] Press Release, House Ways & Means Comm., Neal and Brady Release Legislative Text of Surprise Medical Billing Proposal (Feb. 7, 2020), https://waysandmeans.house.gov/media-center/press-releases/neal-and-brady-release-legislative-text-surprise-medical-billing ("Our bipartisan approach differs from other proposals in that . . . we create a *more balanced negotiation process* to encourage all parties to resolve their reimbursement differences before using the streamlined and fair dispute resolution process." (emphasis added)).

payment amounts requested or offered, and the arbitrator must select one as the appropriate payment rate. This system was designed to ensure that the parties submit their most-reasonable and best-supported offers.

4. Congress expressly listed the factors that an arbitrator "shall" consider in determining which offer to select. Consistent with its goal of creating a balanced, independent process that protects patients by keeping them out of negotiations between providers and insurers, the Act did not assign any one statutory factor presumptive weight. Indeed, as key House and Senate Committee Leaders stated when announcing the final Act:

> "We have reached a bipartisan, bicameral deal in principle to protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers[.]"
>
> . . . .
>
> If the parties choose to utilize the IDR process, both parties would each submit an offer to the independent arbiter. When choosing between the two offers the arbiter is required to consider the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, and any other information submitted by the parties.

Press Release, House Ways & Means Comm., Congressional Committee Leaders Announce Surprise Billing Agreement (Dec. 11, 2020), https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement.

5. In contravention of the Act, the September Rule imposes a presumption in favor of just one of Congress's enumerated factors. Under the Rule, the "qualifying payment amount" ("QPA")—which is calculated exclusively by insurers—presumptively determines the appropriate payment rate, and hence the appropriate offer.

6. To effectuate this presumption, the September Rule erects two separate barriers to an arbitrator's consideration of the other statutorily mandated factors.

a. *First*, the September Rule provides that the arbitrator may not consider any of the non-QPA statutory factors unless a party submits "credible information" about them, 45 C.F.R. § 149.510(c)(4)(iii)(B), and the Rule defines "credible information" to require the arbitrator to skeptically analyze that information, *id.* § 149.510(a)(2)(v) (defining "credible information" as "information that upon *critical analysis* is worthy of belief and is trustworthy" (emphasis added)). In vivid contrast, the September Rule contains no such credibility requirement for the QPA factor. In fact, the Departments affirmatively forbid the arbitrator from scrutinizing the QPA, commanding her to take the insurer's proffered QPA as given. *See* 86 Fed. Reg. at 55,996 ("[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly[.]"). To be clear: plaintiffs always assumed that parties would submit credible evidence and that arbitrators would take credibility into account in analyzing *each* of the statutorily mandated factors. Plaintiffs' objection is that the September Rule sets up a skeptical, one-sided evidentiary burden that is found nowhere in the statute and makes it more difficult for the arbitrator to fairly consider all six statutory factors as Congress intended.

b. *Second*, and more importantly, the September Rule provides that the arbitrator "*must* select the offer closest to the QPA" unless a party meets a heightened burden of proof found nowhere in the Act. 45 C.F.R. § 149.510(c)(4)(ii)(A) (emphasis added). Specifically, to overcome the presumption in favor of the QPA, a party must "clearly demonstrate[]" that the QPA is "materially different from the appropriate out-of-network rate." *Id.*

7. In inventing these extra-statutory barriers, the Departments acted contrary to Congress's deliberate compromise, which mandated that the arbitrator "shall" consider *all* enumerated factors, without giving categorical priority to any single one. Congress left it to the discretion of the arbitrator—not the Departments—to determine which factors were most important in light of the facts and circumstances of a particular case. And, as the principal architects of the final Act have explained, "the law provides for an IDR process overseen by an independent and neutral arbiter who must consider a number of factors equally in deciding whether to select the provider or [insurer]'s offer." Letter from Chairman Neal and Ranking Member Brady of the House Ways and Means Committee to Department Secretaries (Oct. 4, 2021) ("Neal and Brady Letter"), https://www.gnyha.org/wp-content/uploads/2021/10/2021.10.04-REN-KB-Surprise-Billing-Letter80.pdf. The September Rule undermines the independence of the IDR process and the fairness of the No Surprises Act by severely tilting the scales towards the QPA.

8. The Departments claim that theirs is the "best interpretation" of the Act. 86 Fed. Reg. at 55,996. But as the Act's principal architects recently explained, the September Rule "strays from the No Surprises Act in favor of an approach that Congress *did not* enact in the final law," given that "Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process." Neal and Brady Letter. Strikingly, Chairman Neal and Ranking Member Brady also wrote that the September Rule "affronts the provisions enacted into law." *Id*. Amplifying these same concerns, a recent letter from 150 other Members of Congress explained that the September Rule's presumption-based approach for determining payment rates "do[es] not reflect the way the law was written, do[es] not reflect a policy that could have passed Congress, and do[es] not create a balanced process to settle payment disputes." Letter from Members of Congress to

Departments Secretaries (Nov. 5, 2021), https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf.

9. The September Rule will harm patients. *First*, the rule will encourage insurers to narrow the network of providers available to patients and potentially eschew providers with higher costs, including teaching and other hospitals that provide trauma care, burn units, and neonatal intensive care services that are critical for their communities. Because insurers can now rely on the IDR process for an unfairly low rate, they will have little incentive to include providers with higher costs (and frequently higher quality and specialized services) in their network, all to the detriment of patients. In fact, one insurer, Blue Cross Blue Shield North Carolina, has already threatened to "terminate agreements" with providers who do not agree to lower rates in light of the new rule, on the ground that "the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." Letter from Mark Werner, Blue Cross Blue Shield of North Carolina, to Provider (Nov. 5, 2021), https://tinyurl.com/y3dfvtts. *Second*, undercompensating providers could, as the Departments themselves recognized, "threaten the viability of these providers [and] facilities," which "in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care[.]" 86 Fed. Reg. at 56,044. Put simply, this lawsuit seeks to preserve access to care; the September Rule would reduce it. Congress did not intend that result.

10. The Court should accordingly set aside, as contrary to law and in excess of the Departments' statutory authority, the provisions of the September Rule requiring arbitrators to

employ a presumption in favor of the QPA when determining a payment amount in the IDR process.[4]

JURISDICTION AND VENUE

11. The Court has jurisdiction over this action under 28 U.S.C. § 1331.

12. The Court has the authority to grant the requested declaratory and injunctive relief under the Administrative Procedure Act and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

13. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States and at least one defendant resides in this district.

PARTIES

14. The American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state and in every medical specialty.

15. The American Hospital Association (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. Founded in 1898, the AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are heard

[4] The September Rule contains a number of provisions, including those relating to providers' obligation to send uninsured and self-pay patients good faith estimates of expected charges, as well as provisions governing a patient-provider billing dispute resolution process. This lawsuit challenges only the aspects of the Rule that relate to its requirement that the arbitrator presumptively select the offer closest to the QPA. It does not challenge or seek to set aside any other provision in the September Rule.

and addressed in national health policy development, legislative and regulatory debates, and judicial matters.

16. The AMA and AHA bring this suit on behalf of their provider members (physicians and hospitals, respectively) who will be harmed by the unlawful presumption the Departments imposed in the September Rule.[5]

17. Plaintiff Renown Health is an integrated healthcare system based in Reno, Nevada. It is northern Nevada's largest locally governed, nonprofit healthcare network. It includes four hospitals, 100 sites for primary, urgent, and specialty care; telehealth; and an integrated, provider-sponsored health insurance plan and accountable care organization that serves more than 150,000 members across northern Nevada. It provides the region's only Level II Trauma Center, serving over one million people and 100,000 square miles, from Sacramento to Salt Lake City. Renown also provides the region's first and only children's emergency room, which was opened in 2009.

18. Plaintiff UMass Memorial Health is the largest healthcare system in Central and Western Massachusetts. In 1997, the creation of UMass Memorial Health was authorized by state legislation that approved combining the nonprofit Memorial Hospital with the public University of Massachusetts Medical Center. While allowing the combination of these entities into a new private, nonprofit system, the legislation also mandated that UMass Memorial Health permanently fulfill a unique, three-part public mission: (1) to provide highly specialized clinical services unavailable elsewhere in Central Massachusetts, (2) to provide free care to indigent patients, and

[5] Because the AMA's and AHA's members are the object of the September Rule (and the No Surprises Act, which the Rule purports to interpret), their standing to bring this lawsuit is "self-evident." *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002); *see American Ins. Ass'n v. U.S. Dep't of Hous. and Urban Dev.*, 74 F. Supp. 3d 30, 37-37 (D.D.C. 2014), *vacated on other grounds*, No. 14-5321 (D.C. Cir. Sept. 23, 2015) (per curiam order).

(3) to support the Commonwealth's only public medical school. Consistent with that mission, UMass Memorial Health serves some of the most vulnerable patients and communities in Massachusetts. UMass Memorial Health includes four hospitals: UMass Memorial Medical Center (Worcester), UMass Memorial Health – HealthAlliance-Clinton Hospital (Fitchburg, Clinton, and Leominster), UMass Memorial Health – Marlborough Hospital (Marlborough), and UMass Memorial Health - Harrington Hospital (Southbridge). UMass Memorial Health also includes the only designated Level I Trauma Center for adults in Central Massachusetts and the region's only Level III Neonatal Intensive Care Unit, which provides expert care for ill or premature newborns.

19. Plaintiff Stuart M. Squires, M.D., is a licensed physician and practicing anesthesiologist. He is the president of Cumberland Anesthesia Associates in Fayetteville, NC, where he has practiced medicine for 21 years. Dr. Squires is a member of the American Medical Association.

20. Plaintiff Victor F. Kubit, M.D., is a licensed physician and practicing anesthesiologist. He has practiced medicine at Cumberland Anesthesia Associates in Fayetteville, NC, for 20 years. Dr. Kubit is a member of the American Medical Association.

21. Defendant Department of Health and Human Services is an executive department of the United States headquartered in Washington, D.C.

22. Defendant Department of the Treasury is an executive department of the United States headquartered in Washington, D.C.

23. Defendant Department of Labor is an executive department of the United States headquartered in Washington, D.C.

24. Defendant Office of Personnel Management is an executive agency of the United States headquartered in Washington, D.C.

25. Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra is sued in his official capacity only.

26. Defendant Janet Yellen is the Secretary of the Treasury. Secretary Yellen is sued in her official capacity only.

27. Defendant Martin J. Walsh is the Secretary of Labor. Secretary Walsh is sued in his official capacity only.

28. Defendant Kiran Ahuja is the Director of OPM. Director Ahuja is sued in his official capacity only.

FACTS

I. The No Surprises Act

A. Payments Framework Prior to Enactment of the No Surprises Act

29. When a patient with private insurance coverage receives medical care from an in-network provider, the insurer pays the provider a negotiated, contracted rate for covered items or services. The patient is responsible for only the cost-sharing, such as a co-pay, that is required by her insurance plan. If there is a difference between a provider's billed charges and the contracted rate a provider receives from the insurer, the provider does not bill the patient for the difference. For this reason, the provider will negotiate her contract with the insurer to ensure that the contracted rate is a reasonable one.

30. If, however, the insurer and provider have not signed a network agreement, the provider is out-of-network. When a patient receives care from an out-of-network provider, the provider submits a bill to the patient's insurer, and the insurer determines how much to pay the

provider. The outstanding balance—the difference between what the provider billed and how much the insurer paid—is the patient's responsibility. To collect that balance, the provider has traditionally sent the patient a "balance bill."

31. "Balance bills" are sometimes called "surprise bills" because they often result from situations in which the patient had no choice about her care, such as in the case of emergency care or care provided by an ancillary healthcare provider, like an out-of-network clinical lab.

B. Payments Framework Under the No Surprises Act

32. The Act addresses scenarios in which surprise out-of-network billing occurs, such as emergency medical situations.

33. In emergency situations, providers are required to treat patients regardless of ability to pay. *See, e.g.*, 42 U.S.C. § 1395dd(a) ("[I]f any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department[.]"); *Roberts v. Galen of Virginia Inc.*, 525 U.S. 249, 249 (1999) (per curiam) ("The Emergency Medical Treatment and Active Labor Act . . . places obligations of screening and stabilization upon hospitals and emergency rooms that receive patients suffering from an 'emergency medical condition.'").

34. The Act mandates that, in situations where a patient has not consented to out-of-network care, a patient's cost-sharing requirement for emergency services furnished by an out-of-network provider, or non-emergency services furnished by an out-of-network provider at an in-network facility, will not exceed the cost-sharing requirement that would apply if the services had

been provided by an in-network provider or facility. 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A).

35. The actual cost-sharing amount is calculated using the "recognized amount." 42 U.S.C. § 300gg-111(a)(1)(C)(iii), (b)(1)(B). If there is no applicable All-Payer Model Agreement under section 1115A of the Social Security Act and no state law mandating a method to determine the total amount payable by a patient, the "recognized amount" is the qualifying payment amount ("QPA") for the item or service. *Id.* § 300gg-111(a)(3)(H).[6]

36. The QPA is generally the "median of the contracted rates recognized by the" insurer as of January 31, 2019 in the same insurance market for "the same or similar item or service" provided by a provider "in the same or similar specialty and . . . geographic region," increased by inflation over 2019. 42 U.S.C. § 300gg-111(a)(3)(E)(i).

37. Because the Act ensures that patients will not be billed in excess of their expected cost-sharing amounts, providers must look to insurers to ensure fair payment for their out-of-network services.

38. The Act requires insurers to pay providers an "out-of-network rate," less the patient's cost-sharing requirement. 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D). Unlike the cost-sharing requirement based upon the "recognized amount" paid by patients, Congress did not simply select the QPA as the appropriate "out-of-network" rate to be paid by insurers. Instead, the Act establishes a process for insurers and providers to carefully negotiate an appropriate "out-of-network" rate.

[6] Under the Departments' July 2021 interim final rule, if there is no applicable All-Payer Model Agreement and no relevant state law, the recognized amount is the lesser of the provider's billed charges or the QPA. "Requirements to Surprise Billing; Part I," 86 Fed. Reg. 36,872, 36,888 (July 13, 2021).

39. If there is no applicable All-Payer Model Agreement and no relevant state law mandating a method to determine the total amount payable to an out-of-network provider, the Act authorizes insurers first to send the provider an initial payment or notice of denial of payment. 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K). It can take a month or more from the date of service for the provider to receive the insurer's initial payment or notice of denial of payment. If the provider disagrees with the insurer's payment determination, the provider has 30 days to enter into a 30-day period of open negotiation with the insurer. *Id.* § 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K), (c)(1)(A). If the provider and insurer are unable to reach agreement during the 30-day negotiation period, either party may, within four days following the conclusion of the open negotiation period, initiate binding arbitration through the IDR process. *Id.* § 300gg-111(a)(3)(K), (c)(1)(B).[7]

40. Given this timeline, for a service furnished on or after January 1, 2022, providers and insurers should reasonably expect to initiate the IDR process by approximately March 1, 2022.

C. The IDR Process

41. Once the IDR process is initiated, the parties have three business days to jointly select an arbitrator, or "certified IDR entity." 42 U.S.C. § 300gg-111(c)(4)(F)(i). If the parties fail to do so, the relevant agency will select the arbitrator. *Id.* § 300gg-111(c)(4)(F)(ii).

42. The statute prescribes a "baseball-style" arbitration process whereby the provider and insurer submit their best and final offers for the amount each considers to be reasonable payment. Specifically, once an arbitrator is selected, the provider and insurer have 10 days to submit (1) an offer for a payment amount, (2) any information requested by the arbitrator, and

[7] The parties may continue their negotiations during the arbitration process. If they reach an agreement on the out-of-network rate before the arbitrator determines an out-of-network rate, the agreed-upon rate controls. 42 U.S.C. § 300gg-111(c)(2)(B).

(3) any additional information the party wishes the arbitrator to consider, including information relating to statutory factors the arbitrator must consider. 42 U.S.C. § 300gg-111(c)(5)(B), (C)(ii).

43. The arbitrator then reviews the offers and "shall . . . select one of the offers" after "taking into account the considerations in subparagraph (C)" (the "Subparagraph C Factors"). 42 U.S.C. § 300gg-111(c)(5)(A). The arbitrator must have "sufficient medical, legal, and other expertise and sufficient staffing to" select an appropriate out-of-network rate based on the Subparagraph C Factors. *Id.* § 300gg-111(c)(4)(A).

44. In subparagraph C, titled "Considerations in determination," Congress mandates that, "[i]n determining which offer" to select, the arbitrator "shall consider":

> (I) the qualifying payment amounts . . . for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and
>
> (II) subject to subparagraph D, information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

42 U.S.C. § 300gg-111(c)(5)(C)(i). As incorporated in subsection II above, "clause (ii)" lists the following five factors that the arbitrator entity "shall" consider:

> (I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).
>
> (II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.
>
> (III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.
>
> (IV) The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.

> (V) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

Id. § 300gg-111(c)(5)(C)(ii). Also as incorporated in subsection II above, the arbitrator must consider any information it requests from the parties, *id.* § 300gg-111(c)(5)(C)(i)(II), as well as any additional information submitted by either party relating to its offer, *id.*

45. Congress further specified three factors that the arbitrator "shall not consider": (1) usual and customary charges; (2) the amount the provider would have billed for the item or service if the Act's billing provisions did not apply; and (3) the amount a public payer (like Medicare) would have paid. *Id.* § 300gg-111(c)(5)(D).

46. The Act lists the above factors the arbitrator "shall consider" without giving presumptive weight to any single one. Although elsewhere Congress specifically delegated authority to the Secretaries to fill in gaps in the statute,[8] Congress did not specifically assign the

[8] *See* 42 U.S.C. § 300gg-111(c)(1)(B) (the notification initiating the IDR process must contain "such information as specified by the Secretary" and the process begins upon submission of the notification or "such other date specified by the Secretary"); *id.* § 300gg-111(c)(3)(A) ("the Secretary shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination . . . ."); *id.* § 300gg-111(c)(3)(A)(iv) (batched items and services must be furnished during a 30-day period "or an alternative period as determined by the Secretary"); *id.* § 300gg-111(c)(3)(B) ("the Secretary shall provide" for the treatment of bundled payments); *id.* § 300gg-111(c)(4)(A) ("The Secretary . . . shall establish a process to certify" IDR entities); *id.* § 300gg-111(c)(4)(A)(vii) (the IDR entity must meet specified requirements and "such other requirements as determined appropriate by the Secretary"); *id.* § 300gg-111(c)(4)(F) ("The Secretary shall . . . provide for a method" for selecting a certified IDR entity); *id.* § 300gg-111(c)(7)(C) (to be certified, IDR entities must "submit to the Secretary such information as the Secretary determines necessary to carry out the provisions of this subsection"); *id.* § 300gg-111(c)(7)(D) ("The Secretary shall ensure the public reporting" does not disclose privileged or confidential information); *id.* § 300gg-111(c)(8)(A) (fees for participating in the IDR process shall be paid "at such time and in such manner as specified by the Secretary"); *id.* § 300gg-111(c)(8)(B) (the amount of the fee is to be "an amount established by the Secretary"); *id.* § 300gg-111(c)(9) ("[t]he Secretary may modify" deadlines or timing requirements "in cases of extenuating circumstances, as specified by the Secretary").

Departments any role in determining how the Subparagraph C Factors should be considered. Congress mandated that the arbitrator must consider each of these factors in determining which offer to select, but Congress left it to the discretion and expertise of the arbitrator to decide how much weight to give each factor in light of the facts and circumstances of a particular case.

47. That was intentional. "Multiple proposals that ultimately did not become law relied on the median in-network rate [effectively, the QPA] as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate." Neal and Brady Letter; *see, e.g.*, Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020); Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019); No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019). Congress considered and rejected these proposals. Instead, in a bipartisan, bicameral compromise, Congress set forth a detailed scheme of factors the arbitrator must (and must not) consider.

48. The Act provides that an arbitrator's decision is not subject to judicial review. 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II).

D. Timeline for Implementing Relevant Regulations

49. The Act required the Departments to issue implementing regulations on certain issues by specified deadlines.

50. By July 1, 2021, the Departments were required to establish the methodology insurers should use to determine the QPA, including the geographic regions for such calculations; the information insurers should share with providers about how they calculated QPAs; and a process for receiving complaints about insurers' alleged violations of the rules for calculating QPAs. 42 U.S.C. § 300gg-111(a)(2)(B).

51. By December 27, 2021, the Departments are required to establish the IDR process for resolving disputes between insurers and providers regarding out-of-network payment. 42 U.S.C. § 300gg-111(c)(2)(A).

II. September 30, 2021 Interim Final Rule ("September Rule")

52. On September 30, 2021, the Departments published the IFR at issue here. Among other things, this Rule establishes regulations governing the IDR process, as well as the arbitrator's determination of the appropriate out-of-network payment rate. It became effective on October 7, 2021. 86 Fed. Reg. 55,980.

53. The September Rule mandates that the arbitrator "must presume that the QPA is [the] appropriate" out-of-network rate. 86 Fed. Reg. at 55,995.

54. Consistent with this atextual presumption, the September Rule establishes multiple barriers to the consideration of any Subparagraph C Factor other than the QPA. As an initial matter, under the September Rule, the arbitrator need not consider any factor beyond the QPA unless "a party submits information . . . that the certified IDR entity determines is credible." 86 Fed. Reg. at 55,997; *see id.* (entity "must consider" Congress's other five mandated factors only "to the extent credible information is submitted by a party"). And the September Rule explicitly instructs the arbitrator to consider evidence related to the non-QPA factors with skepticism. *See* 45 C.F.R. § 149.510(a)(2)(v) (defining "credible information" as "information that upon *critical analysis* is worthy of belief and is trustworthy" (emphasis added)). By contrast, the Rule affirmatively forbids the arbitrator from scrutinizing the QPA, commanding her to take the insurer's proffered QPA as given. *See* 86 Fed. Reg. at 55,996 ("[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly[.]").

55. This first barrier is contrary to the Act. Congress could have directed the arbitrator to consider with skepticism information about each of the Subparagraph C Factors, except the QPA. But it did not. *See* 42 U.S.C. § 300gg-111(c)(5)(C)(i) (requiring the arbitrator to simply consider "information on any circumstance described in [subparagraph C]"). Under the text and design of the Act, arbitrators should be able to evaluate the credibility of all evidence submitted to them. The Departments' skeptical, one-sided evidentiary burden is found nowhere in the statute and impermissibly makes it much more difficult for an arbitrator to fairly consider the non-QPA statutory factors.

56. Even if a party surmounts this first hurdle, the September Rule erects an even higher one. Specifically, the Rule requires that, presumptively, the arbitrator "must select the offer closest to the [QPA]." 45 C.F.R. § 149.510(c)(4)(ii)(A). It further provides that the arbitrator may consider the non-QPA factors only in determining whether there is a clear demonstration that the QPA is "materially different" from the appropriate rate. *Id.* § 149.510(b)(4)(ii)(A). The Departments define "material difference" to mean "a substantial likelihood that [an arbitrator] . . . would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate." *Id.* § 149.510(a)(2)(viii).

57. The September Rule gives an example of how this unbalanced consideration of the other Subparagraph C Factors will work in practice. It describes a situation in which a provider submits "credible information" relating to the acuity of the patient and complexity of the furnished service—a factor expressly specified in the statute. 45 C.F.R. § 149.510(b)(4)(iv)(C). In this hypothetical, the provider submits that the QPA is not commensurate with the acuity of the patient and the complexity of the service. The arbitrator, however, is prohibited from even considering

the patient's acuity and the service's complexity with respect to the parties' offers unless the provider "clearly demonstrates" that the QPA does not properly account for these factors. *Id*.

58. Additional aspects of the September Rule further demonstrate how far the Departments strayed from the balanced approach set forth in the Act's text:

a. Despite the Act's mandate that the arbitrator "shall consider" all Subparagraph C Factors, the September Rule does not require the parties to submit, or the arbitrator to obtain, information related to any of the non-QPA Subparagraph C Factors. *See* 45 C.F.R. § 149.510(b)(4)(i)(A).

b. If the arbitrator does not choose the offer closest to the QPA, it must provide a "detailed explanation" as to why it found the QPA to be materially different from the appropriate rate, including a description of "the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate." 86 Fed. Reg. at 56,000. The September Rule includes no similar requirement in cases where the arbitrator selects the offer closest to the QPA.

c. The only time under the September Rule that the arbitrator is allowed to "select the offer that the [arbitrator] determines best represents the value of the items or services" without first determining that the QPA is "materially different from the appropriate out-of-network rate" is where

> the parties' "offers are equally distant from the QPA but in opposing directions." 86 Fed. Reg. at 55,995. Yet under the No Surprises Act, the arbitrator is supposed to select the offer that the arbitrator determines best represents the value of items or services in every case, not just in the (exceedingly rare) situation described by the Rule.

59. Thus, contrary to the Act, the September Rule does not require the arbitrator to consider *all* Subparagraph C Factors "[i]n determining which offer" is the best. 42 U.S.C. § 300gg-111(c)(5)(C)(i).

60. Notably, the Departments identify no gap or ambiguity in the Act's description of how an arbitrator should select an appropriate out-of-network rate. Instead, the Departments claim only that theirs is the "best interpretation" of the relevant Act provisions. 86 Fed. Reg. at 55,996.

61. In support of their "interpretation," the Departments rely on several heretofore unknown canons of construction, including that (i) "[t]he statutory text lists the QPA as the first factor," (ii) the other factors "are described in a separate paragraph" and are "subject to a prohibition on considering certain factors," and (iii) the statute "sets out detailed rules for calculating the QPA" and requires the QPA to be used in determining patient cost-sharing. 86 Fed. Reg. at 55,996. None of those features can overcome Congress's clear and straightforward text listing the "considerations" that the arbitrator "shall" and "shall not" consider.

62. The Departments also cite various "policy considerations," such as "increas[ing] the predictability of IDR outcomes," "encourag[ing] parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs," and "aid[ing] in reducing prices that *may* have been inflated due to the practice of surprise billing prior to the No Surprises Act." 86 Fed. Reg. at 56,061 (emphasis added). But "[d]isagreeing with Congress's expressly codified policy

choices isn't a luxury administrative agencies enjoy." *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016).

63. Although the Departments were provided a full year to implement provisions of the No Surprises Act—from December 2020 to December 2021—they waited nine months to promulgate the September Rule. Even then, when Congress issued the September Rule, Congress's December 27, 2021 deadline for final IDR rules was still three months away, with the first arbitrations not set to take place until approximately two months thereafter, in March 2022. Accordingly, had the Departments promulgated the payment determination portions of the September Rule as a proposed rule and sought comment in September, they would have had ample time to finalize that rule by December 27, 2021, leaving sufficient time for the IDR process to begin in March 2022.

64. Nevertheless, in promulgating the September Rule, the Departments deemed it "impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until a full notice and comment process has been completed." 86 Fed. Reg. at 56,043.

STATEMENT OF CLAIMS FOR RELIEF

COUNT I

THE SEPTEMBER RULE'S PRESUMPTION IN FAVOR OF THE QPA IS NOT IN ACCORDANCE WITH LAW AND EXCEEDS THE DEFENDANTS' STATUTORY AUTHORITY (5 U.S.C. § 706; 42 U.S.C. § 300gg-111(c); 29 U.S.C. § 1185e(c); 26 U.S.C. § 9816(c))

65. The preceding paragraphs are incorporated by reference.

66. The APA provides that courts will "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

67. The Act exhaustively details the Subparagraph C Factors an arbitrator "shall consider" "[i]n determining which offer" to select. 42 U.S.C. § 300gg-111(c)(5)(C). The Act does not give any one of those factors priority or otherwise dictate how the arbitrator should weigh the factors. Instead, the Act requires the arbitrator to have "sufficient medical, legal, and other expertise" to determine an appropriate out-of-network rate, and it gives the expert arbitrator discretion to determine how best to weigh the Subparagraph C Factors in light of the facts and circumstances of a particular case. *Id.* § 300gg-111(c)(4)(A). The September Rule unlawfully alters Congress's balanced approach by requiring arbitrators to select the offer closest to the QPA, unless a party "clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate." 86 Fed. Reg. at 55,995. Contravening the discretion Congress gave the arbitrator, the Departments have unlawfully arrogated that discretion to themselves.

68. The Departments' "interpretation" of the Act is contrary to the statute's plain meaning. The Act instructs the arbitrator to consider every Subparagraph C Factor "[i]n determining which offer" to select, not just in determining whether the QPA is materially different from the appropriate out-of-network rate. 42 U.S.C. § 300gg-111(c)(5)(C). "Congress carefully avoided attaching any particular weights to the various concerns that must be taken into account," *Public Service Co. of Indiana, Inc. v. I.C.C.*, 749 F.2d 753, 763 (D.C. Cir. 1984), and it certainly did not assign any one factor presumptive weight. The Departments' decision "[t]o treat one of the . . . statutory factors in such a dramatically different fashion distorts the judgment Congress" made to give the expert arbitrator discretion to determine how best to assess the Subparagraph C Factors in light of the facts and circumstances of a particular case. *American Corn Growers Ass'n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002).

69. Congress knows how to establish a presumption when it wants to, as it did elsewhere in the Consolidated Appropriations Act, 2021.[9] Congress chose not to do so with respect to the Subparagraph C Factors. That is especially telling here because "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (citation omitted).

70. Congress also knew how to establish the QPA as a "benchmark" for payment if it wanted to, as reflected in other bills related to surprise billing. *See, e.g.,* Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019) ("ESTABLISHMENT OF BENCHMARK.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall pay facilities or practitioners furnishing services for which such facilities and practitioners are prohibited from billing enrollees under section 2719A(g), the median in-network rate[.]"); *see also, e.g.*, Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020); No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019). But it ultimately decided against doing so in the Act.

71. The Departments' "interpretation" of the "Payments determination" provision of the Act is an impermissible attempt to rewrite statutory language. The Departments cannot defend their atextual reading on the ground that Congress was silent or ambiguous with respect to the weighting of the Subparagraph C Factors. Congress's detailed listing of the factors IDR entities "shall" and "shall not" consider left no room for supplementation by the Departments.

[9] *See, e.g.*, Consolidated Appropriations Act, 2021, Section 226 (15 U.S.C. § 1116), "Rebuttable Presumption of Irreparable Harm" ("A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection[.]").

72. Nor can the Departments take advantage of the fact that the Act was "not written in 'thou shalt not' terms," *i.e.*, terms that expressly bar the agencies from imposing their invented presumption on the independent arbitration process. *American Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995); *Aid Ass'n for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) ("In this case, the Postal Service's position seems to be that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency. We reject this position as entirely untenable under well-established case law."). "Were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony[.]" *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) (emphasis in original).

73. Nor can the Departments claim that Congress specifically delegated authority to the Departments to promulgate rules governing how an arbitrator should select an offer, as Congress did with other aspects of the Act. For example, the Act specifically authorizes the Departments to "establish a process to certify . . . [IDR] entities under this paragraph." 42 U.S.C. § 300gg-111(c)(4)(A). Likewise, the Act specifically provides that, in addition to four statutorily mandated criteria, the Departments "shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity." *Id.* at § 300gg-111(c)(3)(A). Congress thus specifically delegated authority to the Departments to supplement statutorily mandated criteria found elsewhere in the Act. Yet Congress did not do the same in prescribing the Subparagraph C Factors. *See id.* § 300gg-111(c)(5) ("Not later than 30 days after the date of selection of the certified IDR entity . . . , the certified IDR entity shall" "taking into account the [Subparagraph C Factors]" select one of the offers.); *Russello*, 464 U.S. at 23. In any case, the Departments have in fact disclaimed any such delegation by insisting—

erroneously—that all they have provided is the "best interpretation" of the statute. 86 Fed. Reg. at 55,996.

74. Nor can Defendants defend their "interpretation" of the Act under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837, 842-43 (1984). Not only is there no specific delegation in the Act, and not only is the Departments' interpretation foreclosed by the "unambiguously expressed intent" of Congress in the plain text of the statute, *id*. at 843, but the September Rule also is "procedurally defective," *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) (quoting *United States v. Mead Corp*., 533 U.S. 218, 227 (2001)). The APA requires federal agencies to provide public notice of proposed rules and an opportunity for comment, unless the agencies "for good cause" find that notice and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).[10] But the Departments cannot satisfy the high bar necessary to establish "good cause" here. *E.g*., *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754 (D.C. Cir. 2001) ("[T]he 'good cause' exception is to be narrowly construed and only reluctantly countenanced. The exception is not an escape clause; its use should be limited to emergency situations." (internal citations and quotation marks omitted)). Because Defendants failed "to follow the correct procedures in issuing the regulation," "*Chevron* deference is not warranted." *Encino Motorcars, LLC*, 579 U.S. at 220.

[10] HHS Secretary Xavier Becerra in fact "guarantee[d]" that before HHS took any action on the Act, it would "take the comments necessary, hear from all the stakeholders to make sure what we're doing is based on the facts, the science, and the law." Health and Human Services Department Fiscal Year 2022 Budget Request before the House Appropriations Sub-Committee (Apr. 15, 2021), https://www.c-span.org/video/?c4980111/userclip-becerra-statements-health-human-services-budget-request (at minute 49:06). The Departments did not keep this promise.

75. The Departments' attempt to override the language of the statute and upset the balanced approach that Congress required the arbitrator to follow when making payment determinations is *ultra vires* and contrary to the No Surprises Act.

PRAYER FOR RELIEF

For those reasons, Plaintiff respectfully requests that this Court enter judgment in its favor and grant the following relief:

(1) A declaration that the Departments acted unlawfully in promulgating the provisions of the September Rule requiring IDR entities to employ a presumption in favor of the offer closest to the QPA;

(2) An order vacating the provisions of the September Rule requiring IDR entities to employ a presumption in favor of the offer closest to the QPA:

a. 45 C.F.R. § 149.510(a)(2)(v); 45 C.F.R. § 149.510(a)(2)(viii); the second and third sentences of 45 C.F.R. § 149.510(c)(4)(ii)(A); the final sentence of 45 C.F.R. § 149.510(c)(4)(iii)(C); 45 C.F.R. § 149.510(c)(4)(iv); and 45 C.F.R. § 149. 510(c)(4)(vi)(B).

b. 26 C.F.R. § 54.9816-8T(a)(2)(v); 26 C.F.R. § 54.9816-8T(a)(2)(viii); the second and third sentences of 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A); the final sentence of 26 C.F.R. § 54.9816-8T(c)(4)(iii)(C); 26 C.F.R. § 54.9816-8T(c)(4)(iv); and 26 C.F.R. § 54.9816-8T(c)(4)(vi)(B).

c. 29 C.F.R. § 2590.716-8(a)(2)(v); 29 C.F.R. § 2590.716-8(a)(2)(viii); the second and third sentences of 29 C.F.R. § 2590.716-8(c)(4)(ii)(A); the final sentence of 29 C.F.R. § 2590.716-8(c)(4)(iii)(C); 29 C.F.R. § 2590.716-8(c)(4)(iv); and 29 C.F.R. § 2590.716-8(c)(4)(vi)(B).

(3) An injunction barring the Departments from enforcing the foregoing provisions;

(4) An injunction barring the Departments from promulgating replacement provisions without notice and comment;

(5) Attorney's fees and costs pursuant to 28 U.S.C. § 2412; and

(6) Any other just and proper relief.

Respectfully submitted,

/s James E. Tysse

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