UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

AMERICAN SOCIETY OF ANESTHESIOLOGISTS
1061 American Lane,
Schaumburg, IL 60173,

and

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
4950 W. Royal Lane
Irving, TX 75063,

and

AMERICAN COLLEGE OF RADIOLOGY
1891 Preston White Dr.
Reston, VA 20191,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

and

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF LABOR
200 Constitution Avenue, N.W.
Washington, DC 20210,

and

Case No. 1:21-cv-06823

MARTIN J. WALSH, in his official capacity as Secretary of the United States Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210,

and

UNITED STATES DEPARTMENT OF THE TREASURY
1500 Pennsylvania Avenue, N.W.
Washington, DC 20220,

and

JANET YELLEN, in her official capacity as Secretary of the United States Department of the Treasury
1500 Pennsylvania Avenue., N.W.
Washington, DC 20220,

and

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
1900 E Street, N.W.
Washington, DC 20415,

and

KIRAN AHUJA, in her official capacity as Director of the United States Office of Personnel Management
1900 E Street, N.W.
Washington, DC 20415,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, the American Society of Anesthesiologists ("ASA"), the American College of Emergency Physicians ("ACEP"), and the American College of Radiology ("ACR"), bring this action against Defendants, the United States Department of Health and Human Services

("HHS"), the United States Department of Labor ("DOL"), the United States Department of the Treasury ("DOT"), the United States Office of Personnel Management ("OPM"), and the current heads of those agencies in their official capacities (collectively, the "Departments"), and state as follows:

INTRODUCTION

1. This is a civil action brought to obtain declaratory and injunctive relief to halt the implementation of specific provisions of an interim final rule ("IFR") jointly published by the Departments to implement the No Surprises Act, Pub. L. No. 116-260, 134 Stat. 1182 (2020).[1] Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021) [hereinafter "October IFR"]. The No Surprises Act addresses two interrelated problems with the private health insurance market: 1) insurers demand unreasonably low reimbursement rates as a condition of physicians participating in their networks, thus forcing many physicians to stay out of network to remain economically viable; and 2) patients who unknowingly receive certain care from out-of-network providers are responsible for amounts not paid by their insurance companies, which is known as "surprise billing." Plaintiffs support Congress's reforms, which, if properly implemented, will ensure fair reimbursement for physicians and reasonable cost sharing by patients. Unfortunately, the Departments have turned these reforms upside down and transformed an act intended to protect patients and their doctors into a giveaway to private insurers that will harm patients and providers. Certain provisions of the Departments' October IFR must be reversed because they are contrary to the No Surprises Act and violate rulemaking

[1] The No Surprises Act amended provisions of the Public Health Service Act, the Employee Retirement Income Security Act, the Internal Revenue Code, and the Federal Employees Health Benefits Act. The Federal Employees Health Benefits Act, as amended by the No Surprises Act, cross references the requirements described in 42 U.S.C. § 300gg-111, 29 U.S.C. § 1185e, and 26 U.S.C. § 9816 (as applicable). 5 U.S.C. § 8902(p).

requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b)-(d).

2. These provisions of the October IFR are unlawful because they tie the hands of a statutorily mandated independent arbitrator—referred to as an independent dispute resolution ("IDR") entity—that determines the appropriate reimbursement amount for certain health care items and services furnished by a provider or facility that is not within the network of the insurer. October IFR, 86 Fed. Reg. at 56,104, 56,116, 56,128. The October IFR's provisions dictating the IDR entity's determination of the appropriate out-of-network rate for such items and services are invalid because they eliminate the IDR entity's statutory authority to weigh multiple factors impacting the rate of payment and instead require the IDR entity to give "presumptive weight" to only one factor, the qualifying payment amount ("QPA"), which is skewed in favor of insurers.

3. The No Surprises Act establishes protections for participants, beneficiaries, and enrollees (collectively, "patients") in group health plans and group and individual health insurance coverage (collectively, "insurers") from surprise billing when patients receive (1) emergency services provided by an out-of-network provider or out-of-network emergency facility, or (2) non-emergency services from an out-of-network provider with respect to a visit at an in-network health care facility. The No Surprises Act addresses surprise billing that occurs when a patient unknowingly receives items or services from an out-of-network provider at an in-network healthcare facility or emergency care provided out-of-network, and the patient is billed for amounts not covered by the patient's insurance.

4. The No Surprises Act creates a framework for determining fair payment for the provision of certain out-of-network items and services. 42 U.S.C. § 300gg-111(c); 29 U.S.C. § 1185e(c); 26 U.S.C. § 9816(c). Congress established an IDR process requiring the IDR entity to take a balanced approach to setting the amount of payment for the applicable out-of-network

items or services. 42 U.S.C. § 300gg-111(c)(5); 29 U.S.C. § 1185e(c)(5); 26 U.S.C. § 9816(c)(5). Congress unambiguously delineated a list of factors that the IDR entity "shall consider" when identifying the appropriate reimbursement amount. 42 U.S.C. § 300gg-111(c)(5)(C); 29 U.S.C. § 1185e(c)(5)(C); 26 U.S.C. § 9816(c)(5)(C). To ensure a balanced and independent process, Congress did not give any one specific factor presumptive weight. Nor did Congress authorize the Departments to determine how the IDR entity should weigh each factor.

5. Despite this clear directive, the Departments promulgated the October IFR, which unlawfully abrogates the discretion granted by Congress to IDR entities by dictating how the IDR entity should balance the statutory factors. Instead of requiring the consideration of all information that Congress deemed relevant to payment, the Departments improperly gave presumptive weight to one factor—the QPA—over all other factors unless the party can satisfy additional requirements that are not stated in the No Surprises Act. October IFR, 86 Fed. Reg. at 56,104, 56,116, 56,128.

6. The October IFR requires IDR entities to "presume that the QPA is an appropriate payment amount" unless a party provides "credible information" concerning the factors enumerated in the statute "clearly demonstrating" that the QPA is "materially different from the appropriate out-of-network rate," or unless the payment offers submitted by the provider/facility and the insurer are equally distant from the QPA but in opposing directions. *Id*. at 55,995. Under the No Surprises Act, the QPA is the insurer's median in-network rate within a particular geographic area. 42 U.S.C. § 300gg-111(a)(3)(E)(i); 29 U.S.C. § 1185e(a)(3)(E)(i); 26 U.S.C. § 9816(a)(3)(E)(i). Thus, the October IFR effectively imposes the insurer's in-network rate—the QPA—on out-of-network providers/facilities.

7. Except in the rare circumstance that the offers are equally distant from the QPA

but in opposing directions, the IDR entity is *not* required to consider any of the other statutory factors unless "credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate." *Id*. at 55,995. Therefore, the October IFR's "rebuttable presumption" in favor of the QPA significantly deviates from the statute's text, upending the careful balance Congress created in establishing the IDR process.

8. Moreover, this flawed policy was promulgated in excess of the authority granted to the Departments pursuant to the No Surprises Act. Congress did not specifically delegate authority to the Departments to promulgate rules imposing additional requirements on how IDR entities must weigh the statutory factors when determining the appropriate payment amount.

9. The October IFR's rebuttable presumption in favor of the QPA will harm providers/facilities and patients. The QPA is not reflective of the fair market value of items and services furnished by out-of-network providers/facilities in the marketplace. By significantly restricting the IDR entity's consideration of all statutory factors, the October IFR will result in a disproportionately high number of IDR decisions that are closer to the QPA. As a result, the October IFR's rebuttable presumption will undermine providers' and facilities' ability to be fairly reimbursed for their out-of-network services, which will, in turn, threaten their ability to operate in the marketplace. Accordingly, the October IFR's rebuttable presumption will hinder patients' access to care.

10. Because the QPA is tied to the insurer's median in-network rates and the October IFR's rebuttable presumption will skew IDR decisions in favor of the QPA, the Departments have created a perverse incentive for insurers to significantly reduce their in-network rates or to refuse to enter into network agreements with providers/facilities.. Consequently, this rebuttable presumption has adversely impacted providers/facilities' negotiating position with insurers. If

more providers/facilities are forced out-of-network due to this rebuttable presumption, patients will lose access to in-network care.

11. Moreover, the Departments' flawed rebuttable presumption in favor of the QPA is procedurally invalid under the APA. Prior to the publication of the October IFR, the Departments failed to provide notice of proposed rulemaking or an opportunity for the public to engage in the rulemaking process by submitting written comments. Because the Departments did not demonstrate good cause for circumventing the APA's rulemaking procedures, the October IFR's rebuttable presumption must be vacated.

12. Therefore, this Court must set aside the October IFR's rebuttable presumption in favor of the QPA as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (2)(B).

JURISDICTION AND VENUE

13. Plaintiffs bring this action under the APA, 5 U.S.C. § 551 *et seq.,* and the Declaratory Judgment Act, 28 U.S.C. § 2201.

14. This Court has jurisdiction under 28 U.S.C. § 1331 because all causes of action arise under the laws of the United States.

15. Venue in this Court is proper under 28 U.S.C. § 1391(c)(2) because Plaintiff ASA maintains its headquarters and principal place of business in the Northern District of Illinois.

PARTIES

16. Plaintiff ASA is a voluntary professional association comprised of approximately 54,000 physician anesthesiologists and others involved in the medical specialty of anesthesiology, critical care, and pain medicine. ASA is headquartered in Schaumburg, Illinois. One of ASA's purposes is to advocate for the interests of its members and their patients,

including on matters concerning adequate and fair reimbursement for anesthesia services. ASA brings this action on behalf of its members who will be adversely impacted by the October IFR's rebuttable presumption that the QPA is the appropriate payment amount for out-of-network services.

17. Plaintiff ACEP is a voluntary professional association comprised of more than 40,000 emergency physicians, residents, and medical students. ACEP is headquartered in Irving, Texas. One of ACEP's core purposes is to advocate for the interests of emergency physicians and their patients. Among its many purposes, ACEP seeks to ensure that insurers provide patients and their emergency physicians with adequate and fair reimbursement for emergency services. ACEP brings this action on behalf of its members who will be adversely impacted by the October IFR's rebuttable presumption that the QPA is the appropriate payment amount for out-of-network services.

18. Plaintiff ACR is a voluntary professional association comprised of approximately 40,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. ACR is headquartered in Reston, Virginia. ACR's core functional areas—advocacy, economics, education, quality and safety, research, and membership value—seek to improve, promote, and protect the practice of radiology. One of ACR's purposes is to advocate for the interests of its members and their patients. This includes advocating for adequate and fair reimbursement for radiology services provided to patients. ACR brings this action on behalf of its members who will be adversely impacted by the October IFR's rebuttable presumption that the QPA is the appropriate payment amount for out-of-network services.

19. Members of ASA, ACEP, and ACR have standing to challenge the Departments'

October IFR because they are the objects of the October IFR. *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 656 F.3d 580, 585 (7th Cir. 2011) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562-63 (1992)). This action does not require the participation of individual members of ASA, ACEP, or ACR because this action "raises a pure question of law." *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 287 (1986). Additionally, in this action, "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Retired Chicago Police Ass'n v. City of Chicago*, 7 F.3d 588, 603-04 (7th Cir. 1993) (quoting *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)).

20. In support for this action, Plaintiffs hereby offer the declarations of Christopher Young, MD, a current member of ASA; Jennifer Raley, MD, a current member of ACEP; and Lauren Golding, MD, a current member of ACR.

21. Defendant HHS is a department of the federal executive branch and is headquartered in Washington, DC.

22. Defendant Xavier Becerra is the Secretary of HHS and is the federal officer responsible for administering the Public Health Service Act, as amended by the No Surprises Act. Defendant Xavier Becerra is sued in his official capacity.

23. Defendant DOL is a department of the federal executive branch and is headquartered in Washington, DC.

24. Defendant Martin J. Walsh is the Secretary of DOL and is the federal officer responsible for administering the Employee Retirement Income Security Act, as amended by the No Surprises Act. Defendant Martin J. Walsh is sued in his official capacity.

25. Defendant DOT is a department of the federal executive branch and is

headquartered in Washington, DC.

26. Defendant Janet Yellen is the Secretary of DOT and is the federal officer responsible for administering the Internal Revenue Code, as amended by the No Surprises Act. Defendant Janet Yellen is sued in her official capacity.

27. Defendant OPM is an independent federal agency of the United States and is headquartered in Washington, DC.

28. Defendant Kiran Ahuja is the Director of OPM and is the federal officer responsible for administering the Federal Employees Health Benefits Act, as amended by the No Surprises Act. Defendant Kiran Ahuja is sued in her official capacity.

BACKGROUND

I. REIMBURSEMENT FOR CERTAIN OUT-OF-NETWORK SERVICES

29. Many insurers create networks of health care providers in which the insurer negotiates rates with providers for particular services as a condition of including the providers in the insurer's network. If a patient receives health care items or services from a provider in the network, the insurer will reimburse the provider the contracted, in-network rate for the covered items and services. The patient will be responsible for a cost-sharing amount, which may include a deductible and/or a copayment. The patient's out-of-pocket obligation will be less for in-network services than if the patient received care from a provider outside the insurer's network. *See, e.g.*, Blue Cross Blue Shield Blue Care Network of Mich., *What's the Difference Between In-Network and Out-of-Network Benefits?* (last visited Dec. 22, 2021).[2] If the provider has signed a network agreement with the insurer, the provider will not charge the patient the difference between the provider's charges and the negotiated, in-network rate.

[2] http://www.bcbsm.com/index/health-insurance-help/faqs/topics/how-health-insurance-works/difference-between-in-network-out-of-network-benefits.html.

30. If the patient receives care from a provider that is not in the patient's insurance network, the provider will be reimbursed by the patient's insurer at the insurer's out-of-network rate. The out-of-network rate, as the name implies, is not negotiated in advance by the provider and the insurer. Unless prohibited under state law, any difference between the provider's charge and the insurer's out-of-network payment may be billed by the provider to the patient. The practice of billing the patient for the part of the bill not paid by insurance is known as "balance billing." Generally, in states that prohibit balance billing, the provider accepts the insurer's payment for out-of-network services as payment in full, even if the payment falls well below the provider's charge.

31. "Surprise billing" occurs when the patient unknowingly receives items or services from an out-of-network provider at an in-network healthcare facility or emergency care provided out-of-network, and the patient is billed for cost sharing amounts that are not paid by the insurer and are higher than if the patient received care at an in-network provider.

32. Over the years, "surprise billing" has become more common due to insurers offering inadequate in-network rates to emergency and other ancillary service providers, including anesthesiologists and radiologists, forcing these providers to stay out-of-network.

II. THE NO SURPRISES ACT

33. On December 27, 2020, the President signed into law the No Surprises Act as part of the Consolidated Appropriations Act, 2021, which established, among other things, a framework to protect patients from balance and surprise billing under certain circumstances and to determine fair payment to providers for applicable out-of-network items and services. No Surprises Act, Pub. L. No. 116-260, 134 Stat. 2757 (2020).

A. Reforms to Patient Cost Sharing

34. The No Surprises Act applies to non-emergency items or services provided by an

out-of-network provider at an in-network health care facility, or emergency services provided by an out-of-network provider or an out-of-network emergency facility.[3] 42 U.S.C. § 300gg-111; 29 U.S.C. § 1185e; 26 U.S.C. § 9816. An out-of-network emergency facility is statutorily defined as "an emergency department of a hospital, or an independent freestanding emergency department, that does not have a contractual relationship" with the insurer for providing such item or service under the plan or coverage. 42 U.S.C. § 300gg-111(a)(3)(F)(i); 29 U.S.C. § 1185e(a)(3)(F)(i); 26 U.S.C. § 9816(a)(3)(F)(i). The No Surprises Act defines a "health care facility" as (1) a hospital, (2) a hospital outpatient department, (3) a critical access hospital, (4) an ambulatory surgical center, and (5) any other facility specified by the Departments. 42 U.S.C. § 300gg-111(b)(2)(A)(ii); 29 U.S.C. § 1185e(b)(2)(A)(ii); 26 U.S.C. § 9816(b)(2)(A)(ii).

35. Under the No Surprises Act, insurers are prohibited from imposing a cost-sharing requirement for such items or services that is greater than the amount that would apply if these items or services were provided in-network.[4] 42 U.S.C. § 300gg-111(a)(1)(C)(iii), (b)(1)(A); 29 U.S.C. § 1185e(a)(1)(C)(iii), (b)(1)(A); 26 U.S.C. § 9816(a)(1)(C)(iii), (b)(1)(A).

36. The No Surprises Act requires insurers to calculate the cost-sharing requirement using the "recognized amount." 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(B); 29 U.S.C. § 1185e(a)(1)(C)(ii), (b)(1)(B); 26 U.S.C. § 9816(a)(1)(C)(ii), (b)(1)(B). The "recognized amount" is statutorily defined as follows: (1) the amount that the state approves under the applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) the amount determined in accordance with the "specified state law" (as defined in 42 U.S.C. § 300gg-

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[3] Additionally, the No Surprises Act contains special provisions concerning providers of air ambulance services. These statutory provisions are not at issue in this action.

[4] The No Surprises Act provides an exception to this prohibition for non-emergency items and services if certain notice and consent criteria are satisfied. 42 U.S.C. § 300gg-111(b)(1)(A); 42 U.S.C. § 300gg-132(d); 29 U.S.C. § 1185e(b)(1)(A); 26 U.S.C. § 9816(b)(1)(A).

111(a)(3)(I), 29 U.S.C. § 1185e(a)(3)(I), and 26 U.S.C. § 9816(a)(3)(I)) if there is no applicable All-Payer Model Agreement under section 1115A of the Social Security Act; or (3) the amount that is the QPA for the item or service if there is no "specified state law" or applicable All-Payer Model Agreement under section 1115A of the Social Security Act. 42 U.S.C. § 300gg-111(a)(3)(H); 29 U.S.C. § 1185e(a)(3)(H); 26 U.S.C. § 9816(a)(3)(H).

37. The QPA is generally defined in statute as the "median of the contracted rates recognized by the [insurer] … for the same or a similar item or service that is provided by a provider in the same or similar specialty and … geographic region … increased by the percentage increase in the consumer price index for all urban consumers." 42 U.S.C. § 300gg-111(a)(3)(E)(i); 29 U.S.C. § 1185e(a)(3)(E)(i); 26 U.S.C. § 9816(a)(3)(E)(i).

B. Reforms to Out-of-Network Reimbursement

38. The No Surprises Act requires insurers to reimburse the out-of-network provider/facility an "out-of-network rate," less the cost-sharing requirement of the patient. 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D); 29 U.S.C. § 1185e(a)(1)(C)(iv)(II), (b)(1)(D); 26 U.S.C. § 9816(a)(1)(C)(iv)(II), (b)(1)(D). Similar to the provisions governing the cost-sharing requirement, the "out-of-network rate" is determined by the applicable All-Payer Model Agreement under section 1115A of the Social Security Act, or if no such agreement exists, the "specified state law." 42 U.S.C. § 300gg-111(a)(3)(K)(iii); 29 U.S.C. § 1185e(a)(3)(K)(iii); 26 U.S.C. § 9816(a)(3)(K)(iii).

39. However, unlike the No Surprises Act's provisions governing cost-sharing requirements, Congress did not establish the QPA as the "out-of-network rate" when there is no "specified state law" or applicable All-Payer Model Agreement under section 1115A of the Social Security Act.

40. Instead, Congress authorized insurers to determine the initial out-of-network reimbursement amount and to send the provider/facility the initial payment, or a notice of denial of payment, not later than 30 calendar days after the bill is transmitted by the provider/facility to the insurer. 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(I), (b)(1)(C); 29 U.S.C. § 1185e(a)(1)(C)(iv)(I), (b)(1)(C); 26 U.S.C. § 9816(a)(1)(C)(iv)(I), (b)(1)(C). If the provider/facility disagrees with the payment determination, the provider/facility may initiate open negotiations with the insurer to determine the amount of payment for the out-of-network item or service. 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K)(ii), (c)(1)(A); 29 U.S.C. § 1185e(a)(1)(C)(iv)(I), (a)(3)(K)(ii), (c)(1)(A); 26 U.S.C. § 9816(a)(1)(C)(iv)(I), (a)(3)(K)(ii), (c)(1)(A). The open negotiation period is a 30-day period beginning on the date of initiation of the negotiations. 42 U.S.C. § 300gg-111(c)(1)(A); 29 U.S.C. § 1185e(c)(1)(A); 26 U.S.C. § 9816(c)(1)(A). If open negotiations do not result in a determination of an amount of payment for the out-of-network item or service, either the provider/facility or the insurer may, within four days after the open negotiation period, initiate the IDR process. 42 U.S.C. § 300gg-111(c)(1)(B); 29 U.S.C. § 1185e(c)(1)(B); 26 U.S.C. § 9816(c)(1)(B).

41. The provider/facility and the insurer may, within three business days following the date of the initiation of the IDR process, jointly select an independent IDR entity. 42 U.S.C. § 300gg-111(c)(4)(F)(i); 29 U.S.C. § 1185e(c)(4)(F)(i); 26 U.S.C. § 9816(c)(4)(F)(i). The applicable agency will select an independent IDR entity if the parties fail to make a selection. 42 U.S.C. § 300gg-111(c)(4)(F)(i); 29 U.S.C. § 1185e(c)(4)(F)(i); 26 U.S.C. § 9816(c)(4)(F)(i).

42. Within ten days of the selection of the IDR entity, the provider/facility and insurer must each submit to the IDR entity an offer for a payment amount and information requested by the IDR entity relating to the offer. 42 U.S.C.§ 300gg-111(c)(5)(B)(i); 29 U.S.C. §

1185e(c)(5)(B)(i); 26 U.S.C. § 9816(c)(5)(B)(i). Within the same timeframe, the provider/facility and insurer may each submit to the IDR entity any additional information relating to such offer submitted by either party. 42 U.S.C. § 300gg-111(c)(5)(B)(ii); 29 U.S.C. § 1185e(c)(5)(B)(ii); 26 U.S.C. § 9816(c)(5)(B)(ii).

43. The IDR entity, within thirty days of its selection, "shall … tak[e] into account the considerations specified in subparagraph (C)" (the "Subparagraph C Factors") and "select one of the offers submitted" by the parties to be the amount of payment for such item or service furnished out-of-network. 42 U.S.C. § 300gg-111(c)(5)(A)(i); 29 U.S.C. § 1185e(c)(5)(A)(i); 26 U.S.C. § 9816(c)(5)(A)(i).

44. Subparagraph C sets forth the factors that the IDR entity "shall consider" when determining which offer to select:

> (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) … information on any circumstance described in clause (ii), such information as requested [by the IDR entity relating to the party's offer], and any additional information [submitted by a party relating to such offer of either party].

42 U.S.C. § 300gg-111(c)(5)(C)(i)(I)-(II), (c)(5)(B)(i)(II), (c)(5)(B)(ii); 29 U.S.C. § 1185e(c)(5)(C)(i)(I)-(II), (c)(5)(B)(i)(II), (c)(5)(B)(ii); 26 U.S.C. § 9816(c)(5)(C)(i)(I)-(II), (c)(5)(B)(i)(II), (c)(5)(B)(ii). "Clause (ii)," referenced above, enumerates five additional factors that the IDR 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 ….
>
> (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.
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> (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.

42 U.S.C. § 300gg-111(c)(5)(C)(ii); 29 U.S.C. § 1185e(c)(5)(C)(ii); 26 U.S.C. § 9816(c)(5)(C)(ii).

45. Congress did not give any of the Subparagraph C factors presumptive weight. Nor did Congress authorize the Departments to determine how the IDR entity should weigh the factors.

46. The No Surprises Act further provides that the IDR entity "shall not consider" usual and customary charges; the reimbursement rate for such items and services payable by a public payer (e.g., Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, United States Department of Veterans Affairs); or the amount that the out-of-network provider/facility would have billed for the item or service had the No Surprises Act not applied. 42 U.S.C. § 300gg-111(c)(5)(D); 29 U.S.C. § 1185e(c)(5)(D); 26 U.S.C. § 9816(c)(5)(D).

47. The No Surprises Act directs the Departments to establish a process to certify IDR entities to ensure that the entities have "sufficient medical, legal, and other expertise and sufficient staffing" to select an offer taking into account the factors that the IDR entity "shall" and "shall not" consider. 42 U.S.C. § 300gg-111(c)(4)(A); 29 U.S.C. § 1185e(c)(4)(A); 26 U.S.C. § 9816(c)(4)(A).

48. If the parties agree on a payment amount during the IDR process but before the

date on which the IDR entity makes a payment determination, that amount will constitute the out-of-network rate. 42 U.S.C. § 300gg-111(a)(3)(K)(ii), (c)(2)(B); 29 U.S.C. § 1185e(a)(3)(K)(ii), (c)(2)(B); 26 U.S.C. § 9816(a)(3)(K)(ii), (c)(2)(B).

49. The No Surprises Act directs the Departments to promulgate regulations implementing its statutory provisions by specified deadlines. Among other deadlines, Congress required the Departments to establish through rulemaking, by December 27, 2021, the IDR process "in accordance with the succeeding provisions of this subsection" (i.e., the statutory provisions governing how the IDR entity determines the appropriate payment amount). 42 U.S.C. § 300gg-111(c)(2)(A); 29 U.S.C. § 1185e(c)(2)(A); 26 U.S.C. § 9816(c)(2)(A).

III. INTERIM FINAL RULE PUBLISHED ON OCTOBER 7, 2021

A. Promulgation Without Notice-and-Comment Rulemaking

50. On October 7, 2021, approximately nine months after the enactment of the No Surprises Act, the Departments published in the Federal Register an interim final rule with comment period to implement the No Surprises Act's provisions governing the IDR process, among other things. October IFR, 86 Fed. Reg. 55,980 (Oct. 7, 2021). This interim final rule with comment period went into effect on the same day of publication—October 7, 2021.

51. Prior to this publication, the Departments did not provide general notice of proposed rulemaking and did not afford interested parties an opportunity to participate in the rulemaking through the submission of written comments.

52. The Departments asserted that "good cause" existed for circumventing the APA's notice-and-comment rulemaking requirements. *Id*. at 56,043-44. Specifically, the Departments concluded that it was "impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until a full public notice and comment process has been completed." *Id*. at 56,043. The Departments also claimed that "there is good cause to

waive the delay in effective date for certain provisions of these interim final rules." *Id*.

B. Provisions Governing the Selection of an Offer Under the IDR Process

53. Despite Congress's enumeration of factors that the IDR entity "shall consider" in selecting an offer, the Departments' October IFR creates a rebuttable presumption that the offer closest to the QPA is the appropriate out-of-network rate. *Id*. at 56,104, 56,116, 56,128. Under the October IFR, the IDR entity "*must* select the offer closest to the [QPA]" unless it "determines that *credible information* submitted by either party … *clearly demonstrates* that the [QPA] is *materially different* from the appropriate out-of-network rate, or if the offers are equally distant from the QPA but in opposing directions." *Id*. (emphasis added). Under these circumstances, the Departments require the IDR entity to "select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer." *Id*.

54. In other words, the October IFR establishes "the QPA as the presumptive factor" in selecting an offer. *Id*. at 55,997.

55. Indeed, except in the rare circumstance that the offers are equally distant from the QPA but in opposing directions, the IDR entity is not required to consider the other Subparagraph (C) Factors unless a party submits information about additional circumstances that the IDR entity deems "credible." *See id*. at 55,996-97, 56,104, 56,116, 56,128. In determining whether information is "credible," the October IFR directs the IDR entity to conduct a "*critical analysis*" of whether information is worthy of belief and is trustworthy. *Id*. at 55,995, 56,100, 56,113, 56,125 (emphasis added).

56. In contrast to this critical analysis of the information relating to the Subparagraph (C) Factors, the October IFR makes clear that "it is not the role of the certified IDR entity to

determine whether the QPA has been calculated by the [issuer] correctly." *Id*. at 55,996.

57. When offers are not equally distant from the QPA but in opposite directions, the October IFR constructs barriers to the consideration of all Subparagraph (C) Factors. The October IFR requires the presentation of credible information concerning the Subparagraph (C) Factors that "*clearly demonstrate[s]* that the QPA is *materially different* from the appropriate out-of-network rate." *Id.* at 55,995, 55,997-98 (emphasis added). The October IFR specifies that a "material difference" exists:

> [W]here there is substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out of network rate and view the information as showing that the QPA is not the appropriate out-of-network rate under such additional circumstances.

Id. at 55,995.

58. If the IDR entity does not select the offer closest to the QPA, the IDR entity must provide a written decision including "a detailed explanation 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." *Id*. at 56,000.

59. Notwithstanding the plain language of the No Surprises Act, the Departments claim that the October IFR's provisions governing the IDR entity's selection of an offer is the "best interpretation" of the No Surprises Act because the QPA "represents a reasonable market-based payment for relevant items and services." *Id.* at 55,996. The Departments "justify" their rebuttable presumption in favor of the offer closest to the QPA with a convoluted statutory analysis divorced from established canons of construction:

> The statutory text lists the QPA as the first factor that the certified IDR entity must consider in determining which offer to select. The "additional circumstances" that the certified IDR entity must consider if relevant, credible information is provided are described in a separate paragraph, and the certified IDR entity's consideration of additional circumstances is subject to a prohibition on considering certain factors. Additionally, whereas the statute provides relatively limited guidance on how to consider or define these additional circumstances, the statute sets out detailed rules for calculating the QPA, suggesting that an accurate and clear calculation of the QPA is integral to the application of consumer cost sharing and to the certified IDR entity's determination of the out-of-network rate. . . . Cost sharing for participants, beneficiaries, and enrollees for items and services will be based on the recognized amount, which will generally be the QPA for services eligible for the Federal IDR process, indicating that the QPA is a reasonable out-of-network rate. The Departments are also required to report how payment determinations compare to the corresponding QPA, reflecting that the QPA is a benchmark for determining the appropriate out-of-network rate. Taken together, these statutory elements reflect the importance the No Surprises Act assigns to the QPA in the Federal IDR process, and show that the statute contemplates that typically the QPA will be a reasonable out-of-network rate.

Id. (internal citation omitted).

60. Additionally, in support for their decision to "[anchor] the determination of the out-of-network rate to the QPA," the Departments point to several "policy considerations," including that the rebuttable presumption "will increase the predictability of IDR outcomes, which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs, and will aid in reducing prices that *may* have been inflated due to the practice of surprise billing prior to the No Surprises Act." *Id*. (emphasis added).

61. However, the Departments fail to explain how any of these justifications overcome the clear and unambiguous text of the No Surprises Act listing the Subparagraph (C) Factors that the IDR "shall" consider. 42 U.S.C. § 300gg-111(c)(5)(C); 29 U.S.C. § 1185e(c)(5)(C); 26 U.S.C. § 9816(c)(5)(C).

IV. THE ADMINISTRATIVE PROCEDURE ACT

62. The APA states that an agency may adopt a substantive rule only after the agency

publishes notice of proposed rulemaking in the Federal Register, provides an opportunity to the public to participate in the rulemaking through the submission of comments, considers the comments from the public, and then finalizes the rule. 5 U.S.C. § 553(b)-(d). After considering the comments it receives from the public, the agency may then publish its final rule not less than 30 days before its effective date. *Id*. § 553(c)-(d). These procedures are commonly referred to as "notice-and-comment rulemaking."

63. The APA creates an exception to the notice-and-comment rulemaking requirement if the agency for good cause finds that such procedures are "impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(B), (d)(3). If an agency believes that good cause exists, it must publish "the finding and a brief statement of reasons" in the rule. *Id.* § 553(b)(B), (d)(3).

64. The "good cause" exception under 5 U.S.C. § 553 is "narrowly construed and only reluctantly countenanced." *See New Jersey, Dep't Env't Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980); *United States. v. Cain*, 583 F.3d 408, 420 (6th Cir. 2009); *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981). In determining whether good cause exists, courts do not accord deference to the agency's findings. *Mack Trucks*, *Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012).

65. Under the APA, courts must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." *Id.* § 706(2)(D). Accordingly, a substantive rule that does not fall within the "good cause" exceptions and is promulgated without notice-and-comment rulemaking is invalid. *Id.* § 706(2)(D).

COUNT I

THE OCTOBER IFR'S REBUTTABLE PRESUMPTION IN FAVOR OF THE OFFER CLOSEST TO THE QPA EXCEEDS THE DEFENDANTS' STATUTORY AUTHORITY AND IS NOT IN ACCORDANCE WITH LAW (42 U.S.C. § 300GG-111(C); 29 U.S.C. § 1185E(C); 26 U.S.C. § 9816(C); 5 U.S.C. § 706)

66. Plaintiffs reallege and incorporates by reference paragraphs 1-65 as if fully set forth below.

67. The No Surprises Act enumerates specific factors—Subparagraph C Factors—that IDR entities "shall" consider when selecting one of the offers for payment for the item or service furnished out-of-network. 42 U.S.C. § 300gg-111(c)(5)(C); 29 U.S.C. § 1185e(c)(5)(C); 26 U.S.C. § 9816(c)(5)(C). In establishing the list of Subparagraph C Factors, Congress did not assign presumptive weight to any one factor—such as the QPA—and did not prescribe how the IDR entity should balance such factors. Instead, Congress granted discretion to the IDR entity to determine, in light of the facts and circumstances of each case, how to balance the Subparagraph C Factors.

68. The Departments flouted the plain language of the No Surprises Act when they promulgated the October IFR requiring the IDR entity to "select the offer closest to the [QPA]" unless it "determines that credible information submitted by either party … clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the [QPA] but in opposing directions." October IFR, 86 Fed. Reg. at 56,104, 56,116, 56,128.

69. The October IFR's rebuttable presumption in favor of the QPA unlawfully abrogates the discretion granted by Congress to IDR entities by dictating how the IDR entity should balance the Subparagraph C Factors. By requiring IDR entities to "presume that the QPA is an appropriate payment amount" unless a party provides "credible information" concerning the

Subparagraph (C) Factors "clearly demonstrating" that the QPA is "materially different from the appropriate out-of-network rate," the October IFR improperly gives presumptive weight to one factor—the QPA—over all other factors unless the party can meet additional requirements that are not supported by the text of the No Surprise Act. *Id*. at 55,996.

70. In other words, except in the rare circumstance that the offers are equally distant from the QPA but in opposing directions, the IDR entity is *not* required to consider any of the other Subparagraph (C) Factors unless "credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate." *Id*. at 55,995. Therefore, the October IFR's rebuttable presumption violates the No Surprises Act's clear mandate requiring the IDR entity to consider *all* Subparagraph C factors when selecting the offer for payment. 42 U.S.C. § 300gg-111(c)(5)(C); 29 U.S.C. § 1185e(c)(5)(C); 26 U.S.C. § 9816(c)(5)(C).

71. The October IFR contradicts Congress's unambiguous directive that the IDR entity "shall consider" *all* Subparagraph C Factors in determining which offer is the payment to be applied. 42 U.S.C. § 300gg-111(c)(5)(C); 29 U.S.C. § 1185e(c)(5)(C); 26 U.S.C. § 9816(c)(5)(C). It is well established that "no deference is due to agency interpretations at odds with the plain language of the statute itself." *Smith v. City of Jackson, Miss*., 544 U.S. 228, 266 (2005).

72. Had Congress wanted to establish a presumption in favor of the QPA in the event of a payment dispute between providers/facilities and insurers, it would have done so. "Where 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). Notably,

Congress established rebuttable presumptions elsewhere in the Consolidated Appropriations Act, 2021. For instance, in a section entitled "Rebuttable Presumption of Irreparable Harm," Congress provided that 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 …." Consolidated Appropriations Act of 2021, Pub. L. No. 116-260, 134 Stat. 1182, 2208 (codified at 15 U.S.C. § 1116(a)) (emphasis added). Contrary to such provisions of the Consolidated Appropriations Act, 2021, Congress chose not to establish a rebuttable presumption in favor of the QPA in the No Surprises Act. Instead, Congress outlined a list of considerations that the IDR entity must take into account when selecting an offer for payment. 42 U.S.C. § 300gg-111(c)(5)(C); 29 U.S.C. § 1185e(c)(5)(C); 26 U.S.C. § 9816(c)(5)(C). This can only be construed to mean that Congress did not intend to establish a rebuttable presumption in favor of the QPA.

73. Indeed, by letter dated October 4, 2021, the Chairman and Ranking Member of the House Ways and Means Committee expressed concerns to the Departments that the October IFR "do[es] not reflect the law that Congress passed." Letter from Richard E. Neal, Chairman, Comm. on Ways & Means, and Kevin Brady, Ranking Member of Comm. on Ways & Means, to Xavier Becerra, Janet Yellen, and Martin Walsh, Dep't Sec'ys (Oct. 4, 2021).[5] This letter confirmed that the No Surprises Act "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 payer's offer." *Id*. at 2 (emphasis added). "Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process." *Id*.

74. "The jurisdiction and authority of [administrative agencies] is confined solely to

[5] https://www.gnyha.org/wp-content/uploads/2021/10/2021.10.04-REN-KB-Surprise-Billing-Letter80.pdf.

that which Congress bestows." *Marquette Cement Mfg Co. v. FTC*, 147 F.2d 589, 592-93 (7th Cir. 1945). Congress did not specifically delegate authority to the Departments to promulgate rules imposing additional requirements on how IDR entities must weigh the Subparagraph C factors. The No Surprises Act only directs the Departments to establish by regulation an IDR process under which an IDR entity will determine the appropriate amount of payment "in accordance with the succeeding provisions of this subsection." 42 U.S.C. § 300gg-111(c)(2)(A); 29 U.S.C. § 1185e(c)(2)(A); 26 U.S.C. § 9816(c)(2)(A). The "succeeding provisions" unambiguously specified which factors the IDR entity must consider when selecting an offer. These provisions do not authorize, and cannot be reasonably interpreted to authorize, the October IFR's rebuttable presumption in favor of the QPA.

75. The October IFR's rebuttable presumption in favor of the QPA also contravenes the purpose of the No Surprises Act. In establishing the IDR process, Congress avoided the creation of a rebuttable presumption in favor of the QPA and for good reasons. Health care costs are highly complex and vary by patient characteristics, condition, severity, geography, and market dynamics, among other things. Congress acknowledged this reality when it designed an IDR process that directs the IDR entity to evaluate *all* Subparagraph (C) Factors. By establishing a rebuttable presumption standard, the Departments have rewritten the No Surprises Act, effectively creating *de facto* rate setting. *See* Letter from Members of Congress to Xavier Becerra, Janet Yellen, and Martin Walsh, Dep't Sec'ys, 1-2 (Nov. 5, 2021).[6]

76. Therefore, the October IFR's rebuttable presumption in favor of the offer closest to the QPA violates the APA because the October IFR is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and is "in excess of statutory jurisdiction,

[6] https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf.

authority, or limitations." 5 U.S.C. § 706(2)(A), (2)(C). Therefore, the October IFR's rebuttable presumption is invalid.

COUNT II

VIOLATION OF THE APA'S NOTICE-AND-COMMENT RULEMAKING REQUIREMENTS (5 U.S.C. §§ 553, 706)

77. Plaintiffs reallege and incorporate by reference paragraphs 1-76 as if fully set forth below.

78. Under the APA, an agency may adopt a substantive rule only after providing general notice of proposed rulemaking to the public, considering comments received from the public, and publishing the final rule not less than 30 days before the rule's effective date. 5 U.S.C. § 553(b)-(d).

79. Agencies may forego these notice-and-comment rulemaking requirements only if "the agency for good cause finds … that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(B); *see id.* § 553(d)(3). However, this "exemption of situations of emergency or necessity is not an 'escape clause' in the sense that any agency has discretion to disregard [the APA's] terms." S. Doc. No. 79-248, at 200 (1946).

80. In promulgating the October IFR's provisions unlawfully establishing a rebuttable presumption in favor of the QPA, the Departments failed to provide notice of proposed rulemaking and an opportunity for interested stakeholders to participate in the rulemaking process though the submission of comments. Further, these provisions of the October IFR went into effect on the same day of its publication in the Federal Register. October IFR, 86 Fed. Reg. at 55,980.

81. The Departments justified this violation of the APA's notice-and-comment rulemaking requirements by invoking the "good cause" exception. However, the Departments

fail to meet the high bar necessary for exercising this exception. *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (good cause exists in "emergency situations, or where delay could result in serious harm") (internal citation omitted); *United States v. Vasquez*, 576 F. Supp. 2d 928, 941 (N.D. Ill. 2008) (finding good cause to forgo notice and comment regarding a sex offender registration act due to the "concern for public safety and the risks" of delay).

82. Congress gave the Departments more than sufficient time—an entire year—to promulgate regulations on the IDR process. 42 U.S.C. § 300gg-111(c)(2)(A); 29 U.S.C. § 1185e(c)(2)(A); 26 U.S.C. § 9816(c)(2)(A). The Departments cannot show good cause to forego notice-and-comment procedures when the Departments waited almost nine months to engage in the notice-and-comment rulemaking process.

83. Moreover, the Departments published the October IFR on October 7, 2021—approximately three months before the statutory deadline for promulgating regulations governing the IDR process. The Departments could have engaged in notice-and-comment rulemaking during this time before the IDR process commenced in 2022.

84. Accordingly, good cause did not exist for circumventing the APA's notice-and-comment rulemaking procedures when issuing the October IFR's provisions establishing the rebuttable presumption in favor of the offer closest to the QPA. Hence, the Departments promulgated the October IFR's rebuttable presumption in favor of the QPA in violation of the APA's notice-and-comment rulemaking procedures. Such provisions of the October IFR were issued "without observance of procedure required by law," and are, therefore, invalid. 5 U.S.C. § 706(2)(D).

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request relief as follows:

1. A declaration by the Court that the following provisions of the Departments' October IFR's are arbitrary, capricious, an abuse of discretion, and contrary to statutory law, and are, therefore, invalid:

   a. 45 C.F.R. § 149.510(a)(2)(v); 45 C.F.R. § 149.510(a)(2)(viii); the second and third sentence of 45 C.F.R. § 149.510(c)(4)(ii)(A); the final sentence of 45 C.F.R. § 159.510(c)(4)(iii)(C); 45 C.F.R. § 510(c)(4)(iv); and 45 C.F.R. § 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 sentence 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 sentence 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).

2. A declaration by the Court that the aforementioned provisions of the October IFR are invalid because the Departments promulgated them without observance of procedure required by law.

3. An order from this Court vacating the aforementioned provisions of the Departments' October IFR and enjoining the Departments from implementing or enforcing them.

4. An order from this Court awarding Plaintiffs the costs and fees incurred in this

litigation and granting such other relief in law and/or equity as this Court may deem just and proper.

Respectfully submitted,

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Dated: December 22, 2021