IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, DR. ADAM CORLEY, and TYLER REGIONAL HOSPITAL, LLC, *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, *Defendants*.	)	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Texas Medical Association, Dr. Adam Corley, and Tyler Regional Hospital LLC 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, and the current heads of those agencies in their official capacities, and allege as follows:

INTRODUCTION

1. This action under the Administrative Procedure Act ("APA") challenges certain provisions of a final rule issued by defendants in clear violation of their statutory authority and the APA's reasoned decisionmaking requirement. The rule, entitled "Requirements Related to Surprise Billing," 87 Fed. Reg. 52,618 (Aug. 26, 2022) ("Final Rule"), implements provisions of the federal surprise medical billing law, the No Surprises Act, Pub. L. 116-260, div. BB, tit. I, 1182, 2758–890 (2020) ("NSA").

2. The NSA limits patient cost-sharing when patients receive certain medical services from out-of-network healthcare providers, *i.e.*, physicians and facilities who are not within a health insurance plan's contracted network. It also restricts out-of-network providers' ability to bill patients for amounts in excess of their in-network cost-sharing obligation for those services. Instead, out-of-network healthcare providers must negotiate with the patient's insurer to obtain adequate reimbursement for their services.

3. When the parties cannot agree on an appropriate reimbursement amount, either party may initiate arbitration before a certified independent dispute resolution ("IDR") entity. The arbitration proceeds "baseball-style": after each party submits an offer, the arbitrator must select one of their offers as the appropriate payment amount. To guide arbitrators' decisions, Congress specified a detailed list of factors that arbitrators must consider, without "instruct[ing] arbitrators

to weigh any one factor or circumstance more heavily than the others." *Tex. Med. Ass'n v. Dep't of Health & Hum. Servs.* ("*TMA I*"), No. 6:21-CV-425-JDK, 2022 WL 542879, at *8 (E.D. Tex. Feb. 23, 2022). This action challenges provisions of the Final Rule that unlawfully restrict arbitrators' ability to consider and exercise their discretion in weighing *all* of the required factors identified by Congress when selecting the appropriate payment amount.

4. The NSA 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 issued the Final Rule and are referred to collectively as "the Departments." Many of the regulations adopted in the Final Rule are parallel provisions that apply, as relevant, to group health plans ("plans") and health insurance issuers offering group or individual health insurance coverage ("issuers") (collectively, "insurers").[1]

5. Plaintiffs are committed to being part of a healthcare system that furnishes affordable, transparent, and accessible services. The Texas Medical Association ("TMA") and its physician members recognize that surprise medical billing is a significant problem in Texas and throughout the country. Its physician members have frequently drawn attention to the fact that a confusing health insurance system can leave patients with unexpected out-of-pocket costs and inadequate coverage and physicians frustrated by limited access to patients and their health plan networks. TMA has supported state legislation that would strengthen insurance plan networks and

[1] The relevant statutory and regulatory provisions at issue in this case generally appear in triplicate. The NSA's IDR provisions are codified at 42 U.S.C. § 300gg-111(c) (PHS Act), 29 U.S.C. § 1185e(c) (ERISA), and 26 U.S.C. § 9816(c) (IRC). For ease of reference, this complaint cites the PHS Act provisions and implementing regulations.

arm patients with more information to lessen the likelihood of receiving a surprise bill, while preserving physicians' rights to bill for care they provide. And it has proposed legislative solutions to state lawmakers for the problem of surprise billing, advocating for, among other things, increased network adequacy oversight, a requirement that insurers inform their customers about the network status of physicians and others who may bill for services as part of any procedure subject to prior authorization, clear and conspicuous warnings outlining the results of receiving an out-of-network service, and passage of the current state independent dispute resolution process.

6. The NSA shares these same goals. The Act as a whole, and in particular the process for resolving disputes between healthcare providers and insurers over out-of-network reimbursement rates, was the product of extensive congressional deliberation and compromise. Of particular concern was the role to be played by the so-called "qualifying payment amount" ("QPA"). The QPA is generally the median of the insurer's contracted rates for the relevant item or service, *as calculated by the insurer*, and it serves as a benchmark rate for patient cost-sharing under the Act.

7. During the legislative process, insurers lobbied Congress to use the QPA as a benchmark for healthcare provider reimbursement as well. Multiple proposed bills would have set out-of-network reimbursement at the QPA or made the QPA the default payment amount subject to potential adjustment through an arbitration process only in exceptional circumstances. *See*, *e.g.*, H.R. 3630, 116th Cong. (2019); S. 1895, 116th Cong. (2019). But after extensive negotiation and debate, Congress rejected those proposals and instead created a process in which an independent arbitrator would consider *all* factors bearing on the appropriate out-of-network rate—without imposing any presumptions or otherwise prioritizing one factor over the others.

8. Since the statute's enactment, however, the Departments have been working to unravel this congressional compromise by rewriting the NSA to give outsized weight to the QPA.

Last year, the Departments promulgated an interim final rule that unlawfully required arbitrators to presume that the QPA was the appropriate out-of-network reimbursement rate and to select the offer closest to the QPA unless the opposing party met the heightened burden to "clearly demonstrate" that the QPA was "materially different" from the appropriate out-of-network rate. *See* "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("September IFR"). In *TMA I*, this Court invalidated the Departments' "rebuttable presumption" in favor of the QPA as incompatible with the NSA and its clear instruction to arbitrators to consider all of the statute's enumerated factors. 2022 WL 542879, at *7–9.

9. Now, despite the Court's ruling in *TMA I*, the Departments have issued a final rule that replaces the earlier presumption with a new set of requirements that, although not described by the Departments as a "presumption," have the same effect. Under these new requirements, arbitrators must consider the QPA first and may *not* give any weight to the other circumstances Congress required them to consider *unless* they determine that a variety of extrastatutory criteria are met. Like the invalidated QPA presumption, these new requirements unlawfully elevate the QPA over the other statutory factors, making the QPA the *de facto* benchmark rate.

10. These provisions of the Final Rule are manifestly unlawful and will unfairly skew IDR results in insurers' favor, granting them a windfall they were unable to obtain in the legislative process. At the same time, they will undermine healthcare providers' ability to obtain adequate reimbursement for their services, to the detriment of both providers and the patients they serve.

11. Accordingly, the Court should vacate, as contrary to law, in excess of statutory authority, and arbitrary and capricious, the challenged provisions of the Final Rule that work together to place a thumb on the scale for the QPA in the IDR process.

PARTIES

12. Plaintiff TMA is a trade association that represents more than 56,000 physicians and medical students. The nation's largest state medical society, TMA has its headquarters and principal place of business in Austin, Texas. TMA brings this suit on behalf of its healthcare provider members whose reimbursement amounts for out-of-network services are determined through the IDR process. This lawsuit is consistent with TMA's purpose to resolve challenges its members encounter in caring for their patients, and neither the claim asserted nor the relief requested requires participation of TMA's individual members.

13. Plaintiff Adam Corley is a physician who resides and practices in Tyler, Texas. Dr. Corley works through Precision Emergency Physicians, PLLC ("PEP"), for which he receives hourly reimbursement for providing emergency medical services. Dr. Corley also owns a percentage of a freestanding emergency department in Tyler, Texas, and receives dividends based on profits from the facility.

14. Plaintiff Tyler Regional Hospital, LLC d/b/a UT Health East Texas ("Tyler Regional Hospital") is a hospital in Tyler, Texas, that provides emergency services as defined in the NSA.

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

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

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

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

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

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

JURISDICTION AND VENUE

21. The Court has jurisdiction over this action under 28 U.S.C. § 1331 and the APA, 5 U.S.C. §§ 701–706. Plaintiffs are entitled to the requested declaratory and injunctive relief under the APA and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

22. 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, at least one plaintiff resides in this district, and no real property is involved in this action.

STANDING

23. TMA's members, Dr. Corley, and Tyler Regional Hospital face imminent, concrete, and particularized injury due to the challenged provisions of the Final Rule. TMA's members and Dr. Corley furnish out-of-network services that are subject to the balance-billing provisions of the NSA and currently participate in the IDR process to resolve disputes with insurers over appropriate reimbursement rates. Tyler Regional Hospital also furnishes out-of-network emergency services that are subject to the balance-billing provisions of the NSA and anticipates participating in the IDR process to resolve disputes with insurers over appropriate reimbursement rates.

24. The provisions of the Final Rule elevating the QPA in the IDR process injure TMA's members, Dr. Corley, and Tyler Regional Hospital by "depriv[ing] them of the arbitration process established" by the NSA. *TMA I*, 2022 WL 542879, at *4. In the NSA, Congress crafted an IDR procedure in which arbitrators would resolve reimbursement disputes after considering all

of the statutory factors. This process was designed in part to protect the concrete economic interests of healthcare providers in receiving fair and adequate compensation for their services. The Rule dismantles that protection by "put[ting] a substantial thumb on the scale in favor of the QPA." *Id.*

25. TMA's members, Dr. Corley, and Tyler Regional Hospital are also likely to suffer financial harm as a result of the Final Rule. They have submitted offers, or expect to submit offers, in the IDR process that are higher than the QPA, and they anticipate that their offers will almost always be higher than and farther from the QPA than insurers' offers because the QPA—an insurer-calculated figure—often does not accurately reflect their cost of providing services. By placing a thumb on the scale for the QPA, the challenged provisions of the Final Rule will make it more challenging for their bids to be chosen in the IDR process. As a result, the amounts they are reimbursed for their out-of-network services will decrease, along with their income.

BACKGROUND

A. The No Surprises Act

26. The NSA creates a comprehensive framework designed to address surprise medical billing, as well as supplemental requirements imposed on healthcare providers and insurers to enhance beneficiary transparency regarding the costs they can expect to incur for healthcare items and services.[2]

27. The NSA provides that for emergency services furnished by an out-of-network provider and non-emergency services furnished by an out-of-network physician (or other healthcare personnel) at an in-network facility, insurers may not impose a cost-sharing requirement that is

[2] The NSA and the Final Rule also address surprise medical billing requirements for air ambulance providers. Those provisions are not at issue in this lawsuit.

greater than the cost-sharing requirement that would apply had the items or services been furnished by an in-network provider. 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A).

28. The cost-sharing requirement is calculated using a "recognized amount." *Id.* § 300gg-111(a)(1)(C)(iii), (b)(1)(B). The "recognized amount" is (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, the amount determined by a "specified state law," which is a state law that provides a method for determining the total amount payable by the patient;[3] or (3) if there is no applicable All-Payer Model Agreement and no specified state law, the QPA for that item or service. *Id.* § 300gg-111(a)(3)(H).[4]

29. For each item or service, the QPA is statutorily defined as generally being the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service furnished by a provider in the same or similar specialty and in the same geographic region, with annual inflation adjustments. *Id.* § 300gg-111(a)(3)(E).

30. For covered services, the NSA prohibits out-of-network healthcare providers from billing a patient for any amount that exceeds the statutorily calculated patient cost-sharing amount, unless an exception applies. Instead, the statute obligates insurers to reimburse out-of-network healthcare providers by paying them the "out-of-network rate" as defined in statute, less any cost-sharing from the patient. *Id.* § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D).

[3] "Specified state law" is defined at 42 U.S.C. § 300gg-111(a)(3)(I).

[4] In the July interim final rule, discussed *infra* ¶¶ 41–45, the government took the position that if there is no applicable All-Payer Model Agreement and no specified state law, then the recognized amount is the lesser of the provider's billed charges or the QPA. 45 C.F.R. § 149.130(b)(2).

31. The "out-of-network rate" is determined through a process similar to that for determining patient cost-sharing, but with one significant difference. As with patient cost-sharing, provider reimbursement is governed by any applicable All-Payer Model Agreement under section 1115A of the Social Security Act or, if there is no such agreement, then by any applicable specified state law providing a method for determining the total amount of reimbursement for the out-of-network healthcare provider. *Id.* § 300gg-111(a)(3)(K).

32. But unlike with patient-cost sharing, if there is no applicable All-Payer Model Agreement or specified state law, Congress did not set provider reimbursement at the QPA or otherwise provide a benchmark or mathematical formula. Instead, Congress authorized insurers to make an initial payment in an amount of their choosing and then channeled reimbursement disputes between healthcare providers and insurers through a carefully balanced process of open negotiation followed, if necessary, by binding arbitration before a certified IDR entity. *Id.*

B. The IDR Process

33. The NSA sets forth a detailed IDR process for resolving disputes between providers and insurers over out-of-network reimbursement for covered services. *See id*. § 300gg-111(c). Among other things, the statute sets forth rules governing how IDR entities can become certified and selected to preside over disputes, *id.* § 300gg-111(c)(4); rules for when multiple disputed items and services can be considered jointly, *id.* § 300gg-111(c)(3); and rules allocating responsibility for paying the IDR entity's fees, *id.* § 300gg-111(c)(5)(F). Relevant here, the statute also sets out the factors the IDR entity "shall" and "shall not" consider in determining the appropriate payment amount, *id.* § 300gg-111(c)(5)(C)–(D).

34. Congress directed the Departments to issue regulations establishing a process under which IDR entities would determine the appropriate payment amount "in accordance with the succeeding provisions of this subsection." *Id.* § 300gg-111(c)(2)(A).

35. Those "succeeding provisions" describe in detail how the IDR entity should determine the appropriate payment amount. Within 30 days after selection of the IDR entity, the IDR entity must choose one of the parties' offers after "taking into account the considerations in subparagraph (C)." *Id*. § 300gg-111(c)(5)(A)(i). Subparagraph (C), entitled "Considerations in determination," spells out the precise factors the IDR entity "shall consider" in "determining which offer is the payment to be applied." *Id.* § 300gg-111(c)(5)(C)(i).

36. In particular, Congress provided that IDR entities "shall consider":

37. 1) The QPA for comparable items or services furnished in the same geographic area. *Id*. § 300gg-111(c)(5)(C)(i)(I).

38. 2) Information on five "additional circumstances":

i) The level of training, experience, and quality and outcomes measurements of the healthcare provider that furnished the item or service. *Id.* § 300gg-111(c)(5)(C)(ii)(I).

ii) The market share of the healthcare provider or insurer in the geographic region where the item or service was provided. *Id.* § 300gg-111(c)(5)(C)(ii)(II).

iii) The acuity of the individual receiving the item or service or the complexity of furnishing such item or service to such individual. *Id.* § 300gg-111(c)(5)(C)(ii)(III).

iv) The teaching status, case mix, and scope of services of the facility that furnished the item or service. *Id.* § 300gg-111(c)(5)(C)(ii)(IV).

v) Demonstrations of good faith efforts (or lack of good faith efforts) made by the healthcare provider or insurer to enter into network

agreements, and, if applicable, contracted rates between the healthcare provider and insurer during the previous 4 plan years. *Id.* § 300gg-111(c)(5)(C)(ii)(V).

3) Any information the IDR entity requests from the parties to the IDR proceeding. *Id.* § 300gg-111(c)(5)(C)(i)(II).

4) Any additional information submitted by either party relating to its offer. *Id.*

39. In subparagraph (D), Congress further specified factors that IDR entities "shall not consider": (1) the usual and customary charges, (2) the amount the provider would have billed had the NSA's provisions regarding balance billing not applied, and (3) the amount that would have been paid by a public payor, including under Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, or 38 U.S.C. § 1701. 42 U.S.C. § 300gg-111(c)(5)(D).

40. Congress thus defined with precision and care the factors that IDR entities must and must not consider in determining the appropriate reimbursement amount. Nowhere did Congress specify that the QPA, or any other factor for that matter, should be given primacy over the other enumerated factors. Nor did Congress otherwise constrain the IDR entity's discretion to weigh and balance the various factors as it deems appropriate in light of all the facts and circumstances presented in a particular case. And—in marked contrast to numerous other provisions of the statute addressing the IDR process, where Congress left gaps for the Departments to fill[5]—

[5] *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

Congress did not assign the Departments any role in dictating how IDR entities should weigh the statutory factors in determining which party's offer is the appropriate reimbursement amount.

C. 2021 Interim Final Rulemakings

1. July 2021 Interim Final Rule ("July IFR")

41. On July 1, 2021, the Departments made publicly available an interim final rule to implement certain of the NSA's surprise medical billing requirements. 86 Fed. Reg. 36,872 (July 13, 2021). Among other provisions, the July IFR set forth a methodology for how insurers were to calculate QPAs. 45 C.F.R. § 149.140(c).

42. The July IFR also specified information insurers must share with out-of-network providers relating to how they calculated QPAs. *Id.* § 149.140(d).

43. The information insurers use to calculate QPAs lies solely within their control, and the mandatory disclosures relating to QPAs are wholly insufficient to allow the Departments, arbitrators, and, critically, healthcare providers to ascertain whether an insurer has correctly calculated the QPA. When insurers are not bound by an applicable All-Payer Model Agreement or specified state law, the Departments require them to share only the following information about the QPA when issuing an initial payment or notice of denial of payment to a healthcare provider:

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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").

- the actual QPA amount for each item or service involved;
- a statement certifying that the QPA applies and was accurately calculated in compliance with the Departments' methodology;
- a statement indicating that the healthcare provider can initiate a 30-day open negotiation period, and if those negotiations fail, the healthcare provider can initiate the IDR process; and
- contact information for a person who can begin open negotiations on behalf of the insurer. 45 C.F.R. § 149.140(d)(1)(iv).[6]

Upon request of a healthcare provider, insurers must also provide:

- information about whether the QPA was calculated using contracted rates that were not fee-for-service and, if so, whether the QPA was determined using underlying fee schedule rates or a derived amount;
- if the insurer used an independent database to determine the QPA, which database was used;
- if a related service code was used to determine the QPA, which service code was used; and
- if applicable, a statement that the insurer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA. *Id*. § 149.140(d)(2).

[6] As noted *infra* ¶ 58 n.9, in the Final Rule, the Departments also required insurers to disclose certain additional information when the insurer has "downcoded" the billed claim, including what the QPA would have been had the insurer not downcoded the claim. 87 Fed. Reg. at 52,652.

44. Even when provided (which insurers have not consistently been doing), this information is insufficient to allow healthcare providers to verify the accuracy of the certification they receive from insurers that all relevant QPAs were correctly calculated.

45. The July IFR noted that HHS would amend its enforcement regulations through future notice-and-comment rulemaking to reflect the amendments made to the PHS Act by the NSA, but that HHS and the other agencies would generally use their existing enforcement processes to police compliance with the NSA provisions. 86 Fed. Reg. at 36,899. HHS has primary enforcement authority over issuers only if the Secretary of HHS makes a determination that a state is failing to substantially enforce a provision of the NSA. The Departments also each have independent authority to audit the QPA calculations of insurers, to ensure compliance with the federal QPA methodology. *Id.*; *see also* 42 U.S.C. § 300gg-111(a)(2); 26 U.S.C. § 9816(a)(2). However, HHS has stated that it plans to conduct no more than nine audits annually. 86 Fed. Reg. at 36,935.

46. In August 2022, the Departments answered a number of Frequently Asked Questions about implementation of the July IFR. DEP'TS, *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* (Aug. 19, 2022).[7] The Departments acknowledged that they "have been informed" that insurers were not consistently complying with how the Departments intended them to calculate separate QPAs for providers in the "same or similar specialty." *Id.* at 16–17. The Departments also stated that they "have been informed" that some insurers "enter $0 in their fee schedule" for certain items and services and instructed insurers that "$0 does not represent a contracted rate" and thus "plans and issuers should not include $0 amounts in calculating median contracted rates." *Id.* at 17 n.29.

[7]https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-55.pdf.

2. September 2021 Interim Final Rule ("September IFR")

47. On September 30, 2021, the Departments released a second IFR—at issue in *TMA I*—implementing additional provisions of the NSA. 86 Fed. Reg. 55,980. The September IFR required arbitrators to employ a "rebuttable presumption" that the offer closest to the QPA represented the appropriate reimbursement amount. This presumption and related provisions adopted in the September IFR were vacated as unlawful in *TMA I*. *See infra* ¶¶ 52–56.

48. Specifically, the September IFR directed arbitrators to "select the offer closest to the [QPA]" unless they "determine[d] that credible information submitted by either party … clearly demonstrate[d] that the [QPA] [was] materially different from the appropriate out-of-network rate." *Id.* at 56,104. "[I]f the offers [were] equally distant from the [QPA] but in opposing directions," then arbitrator was directed to select the offer that it "determine[d] best represents the value of the qualified IDR item or services, which could be either offer." *Id.* A "material difference" was defined as a "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." *Id.* at 55,995.

49. As a result of this presumption, even if an arbitrator concluded, after considering all the factors Congress directed it to consider in light of the particular facts and circumstances of the case, that the offer farther from the QPA better reflected the value of the services provided and was the appropriate payment amount, the arbitrator was forbidden from selecting that offer unless its proponent satisfied the heightened burden set forth in the September IFR.

50. If the arbitrator did select the offer farther from the QPA, it was required to provide in its written decision "a detailed explanation" justifying its decision to reject the offer closer to the QPA. *Id*. at 56,000. The arbitrator had to describe "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 [was] materially different from the appropriate out-of-network rate." *Id.*

51. The Departments identified no statutory text creating these requirements. Instead, they asserted that the statute was "best interpret[ed]" to require arbitrators to employ a rebuttable presumption in favor of the QPA because "[t]he statutory text lists the QPA as the first factor," the other factors "are described in a separate paragraph" and are "subject to a prohibition on considering certain factors," and the statute "sets out detailed rules for calculating the QPA" and requires the QPA to be used in determining patient cost-sharing. *Id*. at 55,996. The Departments also cited various "policy considerations" for "[a]nchoring" the payment amount to the QPA, which they believed would "increase the predictability of IDR outcomes" and "encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs." *Id.*

D. This Court's Decision in *TMA I*

52. In *TMA I,* this Court vacated the September IFR's provisions requiring IDR entities to employ a rebuttable presumption in favor of the offer closest to the QPA. 2022 WL 542879, at *1, *15. This presumption, the Court held, unlawfully added decisionmaking requirements not found in the NSA and imposed extrastatutory limits on arbitrators' discretion.

53. The Court decided first that the "Departments' interpretation of the statute" was "owed no" deference because the NSA already "sp[eaks] clearly on the issue relevant here" by "unambiguously establish[ing] the framework for deciding payment disputes." *Id.* at *7–8. In mandating that arbitrators "shall consider" statutory factors, 42 U.S.C. § 300gg-111(c)(5)(C)(i), the Court explained, the NSA "plainly requires arbitrators to consider all the specified information in determining which offer to select." *TMA I,* 2022 WL 542879,. at *7. And the NSA does not, the Court emphasized, "instruc[t] arbitrators to weigh any one factor or circumstance more heavily

than the others" or "suggest anywhere that the other factors or information is less important than the QPA." *Id.* at *8.

54. The Court held that the Departments had "impermissibly altered" these clear statutory requirements by "treating the QPA as the default payment amount and imposing on any party attempting to show otherwise a heightened burden of proof that appears nowhere in the statute." *Id.* at *8–9 (cleaned up). The Court rejected as "unpersuasive" the Departments' defense that the "overall statutory scheme supports" elevating the QPA over the other factors. *Id.* at *8. Rather than "restrict[ing] arbitrators' discretion and limit[ing] how they could consider the other factors," the Court reasoned, the NSA "'clearly sets forth a list of considerations and does not dictate a procedure' or a 'procedural order for [those] considerations.'" *Id.* (quoting *Mo.-Kan.-Tex. R.R. Co. v. United States*, 632 F.2d 392, 412 (5th Cir. 1980)). For these reasons, the Court concluded that the Departments' "thumb on the scale" for the QPA "'rewr[ote] clear statutory terms'" and was unlawful. *Id.* at *8–9 (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014)).

55. The Court further held that the Departments had violated the APA's notice-and-comment requirement in issuing the September IFR and that this failure "provide[d] a second and independent basis" to invalidate the challenged provisions of the rule. *Id.* at *14.

56. In light of these infirmities, and after rejecting the Departments' requests for remand without vacatur and vacatur as applied only to plaintiffs, the Court vacated the provisions of the September IFR creating the presumption in favor of the QPA. *Id*. at *14–15.[8]

[8] *TMA I* also rejected challenges to plaintiffs' standing. 2022 WL 542879, at *4–6.

E. The Final Rule

57. On August 19, 2022, the Departments released the Final Rule at issue here. The Rule was published in the Federal Register on August 26, 2022, and becomes effective on October 25, 2022. 87 Fed. Reg. at 52,618.

58. The Final Rule "remove[s] from the regulations the language vacated" in *TMA I*, *id.* at 52,625, but replaces those provisions with new requirements arbitrators must follow in considering the statutory factors, selecting an offer, and issuing their decisions.[9]

59. *First*, the Final Rule requires arbitrators to start by "consider[ing] the [QPA] for the applicable year for the same or similar item or service." *Id.* at 52,652 (45 C.F.R. § 149.510(c)(4)(iii)(A)). Only after the arbitrator has looked to the QPA, may the arbitrator "*then* consider information submitted by a party" concerning the other statutory circumstances. *Id*. (45 C.F.R. § 149.510(c)(4)(iii)(B)) (emphasis added). Although the statute does not prescribe a procedural order for considering the factors, the Departments determined that requiring arbitrators to begin with the QPA was "reasonable" because it is listed first and "must be a quantitative figure," whereas "the information received related to the additional circumstances … will often be qualitative and open to subjective evaluation." *Id.* at 52,627; *see also id.* at 52,628. The Departments failed to mention that the other information submitted by the parties may also include quantitative figures, for example, the "contracted rates between the provider or facility … and the plan or issuer … during the previous 4 plan years." 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(V).

[9] The Final Rule also imposes an additional QPA-disclosure requirement on insurers. Under the Rule, when a QPA is calculated "based on a downcoded service code or modifier"—that is, one "alter[ed]" by an insurer to a new code "associated with a lower [QPA] than the service code or modifier billed by the provider"—the insurer must disclose the following information: (1) a statement that the code was downcoded; (2) an explanation of why the claim was downcoded, including a description of which codes were altered; and (3) the amount that the QPA would have been if the insurer had not downcoded. 87 Fed. Reg. at 52,652.

60. *Second*, the Final Rule requires arbitrators to evaluate the credibility of any information presented to them—except the QPA—and forbids them to "give weight to information to the extent it is not credible." 87 Fed. Reg. at 52,652. The Departments exempted the QPA from this credibility requirement on the ground that the July IFR's requirements provided sufficient assurance of credibility, *see* 45 C.F.R. § 149.510(c)(4)(iii)(E), even though the Departments recognized that the QPA would be credible only "to the extent [it] is calculated consistent with the detailed rules issued under the [July IFR], and is communicated in a way that satisfies the applicable disclosure requirements." 87 Fed. Reg. at 52,627. Although the Departments required IDR to verify the credibility of information other than the QPA, the Departments emphasized that it is not the IDR entity's "responsibility" to "monitor the accuracy of the plan or issuer's QPA calculation methodology." *Id.* at 52,627 n.31. The Departments did not grapple with the reality that, in most cases, the QPA will be an unaudited number calculated by the insurer and that neither the Departments, healthcare providers, nor arbitrators will have visibility into whether the QPA was calculated consistent with the July IFR's "detailed rules." Nowhere, for example, did the Departments acknowledge, as they had in the August FAQs, that insurers were failing to comply with certain of the Departments' requirements for calculating QPAs. *See supra* ¶ 46.

61. *Third*, arbitrators must evaluate all information—again, except the QPA—to determine whether it "relates to the offer[s] submitted." *Id.* at 52,652 (45 C.F.R. § 149.510(c)(4)(iii)(E)). Arbitrators may not "give weight to" any other information—including information on the "additional circumstances" that Congress mandated arbitrators "shall consider," 42 U.S.C. § 300gg-111(c)(5)(C)(ii)— if it "does not relate to either party's offer." 87 Fed. Reg. at 52,652. Thus, although the statute expressly requires arbitrators to consider the provider's level of training and experience, 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(III), and although the statute

makes clear that such information *always* relates to the party's offer, *id.* § 300gg-111(c)(5)(B)(ii), the Final Rule prohibits arbitrators from giving weight to this factor if the information does not meet the Departments' "related to" test because, *e.g.*, it "does not show that the provider's level of training and experience was necessary for providing" the service at issue "or that the training or experience made an impact on the care that was provided." 87 Fed. Reg. at 52,653.

62. *Fourth*, arbitrators may not "give weight to" any information, including information relating to the "additional circumstances," to the extent the information is "already accounted for by the [QPA]." *Id.* at 52,652. Thus, although the statute expressly requires arbitrators to consider patient acuity and the complexity of furnishing the item or service at issue, 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(III), the Final Rule prohibits arbitrators from giving any weight to these factors if "the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the [QPA]." 87 Fed. Reg. at 52,653. The Departments did not explain how IDR entities or providers would determine whether the QPA had already accounted for a piece of information, given that the QPA is a figure calculated in secret by the insurer and is transparent to the insurer alone.

63. Relatedly, if the arbitrator does give weight to any information other than the QPA, it has an additional explanatory burden: its "written decision must include an explanation of why" it "concluded that this information was not already reflected" in the QPA. *Id.* at 52,654. In the Departments' view, these requirements are warranted because "in many cases, the additional factors for the certified IDR entity to consider other than the QPA will already be reflected in the QPA," and "giving additional weight to information that is already incorporated into the calculation of the QPA would be redundant, possibly resulting in the selection of an offer that does not

best represent the value of the qualified IDR item or service and potentially over time contributing to higher health care costs." *Id.* at 52,629.

64. Thus, under the Final Rule, the QPA "will be relevant to a payment determination" and must be considered first "in all cases." *Id.* at 52,627. But information on the other factors Congress required arbitrators to consider must be disregarded unless it satisfies extrastatutory criteria imposed by the Departments. And not only must the QPA be considered first, it is the lens through which all other information must be viewed. According to the Departments, the QPA "will aid certified IDR entities in their consideration of each of the other statutory factors, as these entities will then be in a position to evaluate whether the 'additional' factors present information that may not have already been captured in the calculation of the QPA." *Id.* at 52,628.

COUNT I

THE CHALLENGED PROVISIONS ARE IN EXCESS OF STATUTORY AUTHORITY AND NOT IN ACCORDANCE WITH LAW (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 foregoing paragraphs are incorporated by reference.

66. The NSA "unambiguously establishes the framework for deciding payment disputes." *TMA I*, 2022 WL 542879, at *7. Congress specified in exhaustive detail the factors arbitrators "shall" and "shall not" consider in determining which party's offer to select as the appropriate reimbursement amount. The statute requires arbitrators to consider each of the enumerated factors, and it does not assign primacy to any of them or dictate how arbitrators must weigh them.

67. Nor—in stark contrast to many other provisions directing the Departments to supplement the statute's IDR provisions, *see supra* ¶ 40 n.5—did Congress assign the Departments any implementation role with regard to the weighing of the statutory factors. Instead, Congress left to the arbitrators' sound discretion how to balance the factors in light of all the relevant facts and

circumstances in a particular case. "If Congress had wanted to restrict arbitrators' discretion and limit how they could consider the other factors, it would have said so—especially here, where Congress described the arbitration process in meticulous detail." *TMA I*, 2022 WL 542879, at *8.

68. The challenged provisions of the Final Rule are unlawful because, like the provisions invalidated in *TMA I*, they add material terms not found in the statute, undermine the NSA's balanced design by privileging the QPA, and impermissibly circumscribe the discretion Congress granted to the IDR entities to weigh all relevant information without extrastatutory constraints.

69. The Departments may not require arbitrators to consider the QPA first or otherwise command them to make the QPA the starting point of the analysis. As the *TMA I* Court already held, the NSA "does not dictate a procedure or a procedural order" for evaluating the statutory factors. *TMA I*, 2022 WL 542879, at *7–8 (internal quotation marks omitted).

70. The Departments similarly lack authority to adopt their lopsided credibility test. Nothing in the statute obligates arbitrators to presume that the QPA is credible while viewing information about the other statutory factors with skepticism. In requiring arbitrators to do so anyway, the Departments have unlawfully restricted arbitrators' ability to consider all the statutory information in light of the facts and circumstances of each case.

71. Nor may the Departments require arbitrators to disregard information about the "additional circumstances" on the ground that the information does not "relate to" a party's offer. The NSA mandates, without qualification, that arbitrators "shall consider" "information on any circumstance described in clause (ii)" (*i.e.*, the "additional circumstances"). 42 U.S.C. § 300gg-111(c)(5)(C)(i)(II). And Congress authorized parties to submit "any information relating to" their offers, "including information relating to any circumstance described in subparagraph (C)(ii)" (*i.e.*,

the "additional circumstances"). *Id.* § 300gg-111(c)(5)(B)(ii). The statute thus makes unambiguously clear that information on the "additional circumstances" *always* relates to a party's offer and must be considered. The Departments may not require arbitrators to ignore it. *See TMA I*, 2022 WL 542879, at *6 ("Because 'the word 'shall' usually connotes a requirement,' the Act plainly requires arbitrators to consider all the specified information in determining which offer to select." (quoting *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016)).

72. For the same reason, the Departments cannot forbid arbitrators to give weight to information on the ground that it is already accounted for in the QPA. Nothing in the NSA prohibits arbitrators from attaching greater or repeated significance to a piece of information if it is relevant to more than one statutory factor. Nor does the statute permit an arbitrator to disregard information submitted by the parties simply because the arbitrator believes that information was an input in the QPA calculation. To the contrary, Congress clearly commanded arbitrators to consider the "additional circumstances" and other information submitted by the parties relating to their offers *in addition* to the QPA, 42 U.S.C. § 300gg-111(c)(5)(C)(i)(II), knowing full well that those circumstances and the QPA may encompass similar information. Demanding a showing that information was not accounted for in the QPA before that information may be given any weight thus "imposes a heightened burden of proof that appears nowhere in the statute." *TMA I*, 2022 WL 542879, at *9.

73. Each of these requirements unlawfully limits arbitrators' discretion to weigh the statutory factors and "impermissibly alter[s] the Act's requirements." *Id.* at *8. And they work in concert to place an unmistakable "thumb on the scale for the QPA," even though "the Act nowhere states that the QPA is the 'primary' or 'most important' factor," or "suggest[s] that the other factors or information is less important than the QPA." *Id.*

74. Accordingly, the challenged provisions are "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706(2)(C), and "not in accordance with law," *id*. § 706(2)(A).

COUNT II

THE CHALLENGED PROVISIONS ARE ARBITRARY AND CAPRICIOUS (5 U.S.C. § 706; 42 U.S.C. § 300gg-111(c); 29 U.S.C. § 1185e(c); 26 U.S.C. § 9816(c))

75. The foregoing paragraphs are incorporated by reference.

76. Even if the Departments had some authority to issue rules supplementing the statute's directions regarding the weighing of the statutory factors, and even if the challenged provisions were not foreclosed by the statute, they are nonetheless unlawful because they are unreasonable and are not the product of the reasoned decisionmaking the APA requires.

77. The combined effect of the challenged provisions is to arbitrarily and unreasonably privilege the QPA above the other statutory factors, discouraging arbitrators from giving weight to any other information and placing a thumb on the scale in favor of the offer closest to the QPA.

78. The Departments' reasoning for imposing these requirements is also arbitrary and capricious. The mere fact that the QPA is listed first and is a quantitative figure does not imply that it must always be the starting point of the analysis. The Departments still "cite no authority holding that a statutory factor is entitled to more weight … because it is the first in a list." *TMA I*, 2022 WL 542879, at *8. Moreover, the QPA will not necessarily be the only quantitative figure submitted to the arbitrator. Information on the "additional circumstances" may also include quantitative figures, such as the "contracted rates between the provider or facility … and the plan or issuer … during the previous 4 plan years." 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(V). The Departments nowhere explained why quantitative information is better than qualitative information or why other quantitative information apart from the QPA is less important.

79. Nor did the Departments rationally explain why arbitrators should be required to presume that the QPA is credible while viewing all other information skeptically. In most cases, the QPA will be an unaudited figure unilaterally calculated by the insurer. There has been little auditing or monitoring of the accuracy of QPA calculations, and as a result, the Departments have little to support their assertion that QPAs are generally credible. The Departments themselves recognized that the QPA may not be credible if it was not "calculated … consistent with the detailed rules issued under the [July IFR]" or "communicated in a way that satisfies the applicable disclosure requirements." 87 Fed. Reg. at 52,627. And the Departments have already acknowledged that insurers have failed to comply with certain aspects of the Departments' rules for calculating QPAs. *See supra* ¶ 46. There is no sound reason arbitrators should not be able to take these issues into account in deciding how much weight to give to the QPA compared to the other factors. And the Departments did not grapple adequately with concerns about the credibility of QPA calculations.

80. The Departments' explanation for their "related to" requirement is similarly deficient. Nowhere did the Departments explain how information that Congress expressly mandated be considered could fail to be "related to" a party's offer or the arbitrators' task. Nor did they explain why a healthcare provider's level of training and experience should be irrelevant to the appropriate reimbursement rate absent a showing that the provider's level of training and experience was "necessary" for providing the service and "made an impact on the care that was provided." 87 Fed. Reg. at 52,653. The Departments' *ipse dixit* is not reasoned decisionmaking.

81. The Departments also failed to explain how their no-double-counting rule is supposed to work. In fact, the rule is wholly *un*workable because the QPA remains a black box into which healthcare providers and arbitrators have no meaningful insight or input. The QPA is a figure that is unilaterally calculated by the insurer and about which the insurer must disclose only

limited information. Without a complete picture of how the QPA was calculated, providers offering additional information that they believe demonstrates why their offer represents the appropriate payment amount cannot reasonably be expected to show that this information was not already accounted for in the QPA. Nor can arbitrators be expected to determine on their own whether the QPA accounts for a particular piece of information. The Departments nowhere addressed this significant aspect of the problem.

82. Accordingly, the challenged provisions are "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court enter judgment in their favor and grant the following relief:

A. A declaration that the Departments acted unlawfully in promulgating the challenged provisions of the Final Rule that unlawfully elevate the QPA above the other information Congress required IDR entities to consider;

B. An order vacating the following provisions of the Final Rule:

   a. The word "then" in 45 C.F.R. § 149.510(c)(4)(iii)(B); the entirety of 45 C.F.R. §§ 149.510(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 45 C.F.R. § 149.510(c)(4)(vi)(B).

   b. The word "then" in § 26 C.F.R. § 54.9816-8(c)(4)(iii)(B); the entirety of 26 C.F.R. § 54.9816-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 26 C.F.R. § 54.9816-8(c)(4)(vi)(B).

   c. The word "then" in 29 C.F.R. § 2590-716-8(c)(4)(iii)(B); the entirety of 29 C.F.R. § 2590-716-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 29 C.F.R. § 2590-716-8(c)(4)(vi)(B).

C. An injunction barring the Departments from enforcing the foregoing provisions;

D. A judgment remanding with instructions to the Departments that any additional regulations or guidance to IDR entities on the weighing of the factors may not privilege the QPA;

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

F. Any other just and proper relief.

September 22, 2022

Respectfully submitted,

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