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

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

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Texas Medical Association and Dr. Adam Corley bring this action for declaratory and injunctive relief against defendants the United States Department of Health and Human Services, Department of Labor, Department of the Treasury, Office of Personnel Management, and the current heads of those agencies in their official capacities, and allege as follows:

INTRODUCTION

1. This action under the Administrative Procedure Act ("APA") challenges certain provisions of an interim final rule issued by defendants in clear violation of their statutory authority and the APA's notice-and-comment requirement. The rule, entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("September IFR"), implements provisions of the federal surprise medical billing law, the No Surprises Act, Pub. L. 116-260 ("NSA"). The NSA was enacted on December 27, 2020, as part of the Consolidated Appropriations Act, 2021, and its requirements generally go into effect on January 1, 2022.

2. The NSA limits patient cost-sharing when patients receive certain medical services from out-of-network healthcare providers, *i.e.*, physicians and facilities (collectively, "providers") who are not within a health insurance plan's contracted network. It also restricts out-of-network healthcare providers' ability to bill patients for amounts in excess of their in-network cost-sharing obligation. Instead, out-of-network healthcare providers must negotiate with the patient's insurer to obtain adequate reimbursement. When the parties cannot agree on an appropriate reimbursement amount, the NSA provides for binding arbitration before a certified independent dispute resolution ("IDR") entity. The IDR entity must then select one of the parties' offers as the appropriate payment amount. To guide the IDR entity's decision, Congress specified a detailed list of factors that each IDR entity must consider. This action challenges provisions of the September IFR that were improperly issued without the requisite notice and comment and that unlawfully restrict IDR

entities' ability to consider and exercise their discretion in weighing *all* of the required factors identified by Congress when selecting the appropriate payment amount.

3. 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, along with the Office of Personnel Management ("OPM") (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the September IFR and are referred to collectively as "the Departments." Many of the regulations adopted in the September IFR 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, "payors").[1]

4. 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 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

[1] The relevant statutory and regulatory provisions at issue in this case generally appear in triplicate. For ease of reference, this complaint cites the PHS Act provisions and implementing regulations.

to state lawmakers for the problem of surprise billing, advocating for, among other things, increased network adequacy oversight, expansion of the current mediation process, 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, and clear and conspicuous warnings outlining the results of receiving an out-of-network service. In response to incidents of price gouging and surprise medical bills during the COVID-19 pandemic, TMA submitted comments to the Texas House Committee on Insurance, urging lawmakers to avoid cost-shifting from health plans to patients or physicians, both of whom are facing strained resources as they battle the virus.

5. The NSA and its implementing regulations share these same goals. But one aspect of the September IFR undermines Congress's design. The NSA authorizes use of an IDR process to resolve disagreements between out-of-network healthcare providers and payors over the reimbursement those providers receive for their services. As part of that process, each party submits an offer to an IDR entity, which must select one of the parties' offers as the final, binding out-of-network reimbursement rate. The NSA enumerates in detail the factors IDR entities "shall" and "shall not" consider in determining which party's offer to select. Congress directed IDR entities to consider all of the enumerated factors and did not assign priority to any one of them, leaving it to each IDR entity to determine how best to weigh the various factors in light of all the facts and circumstances presented in a particular case.

6. In the September IFR, however, the Departments read into the statute a "rebuttable presumption" that requires IDR entities to give outsized weight to a single statutory factor—the "qualifying payment amount" ("QPA"). The QPA is generally the median of the payor's contracted rates for the relevant item or service, *as calculated by the payor*. The statute says

nothing about any such "rebuttable presumption" and nowhere authorizes the Departments to instruct IDR entities how to decide cases. The Departments nonetheless asserted that the statute is "best interpret[ed]" to require IDR entities always to select the offer closest to the payor's QPA unless "credible information" concerning the additional statutory factors "clearly demonstrates" that the QPA is "materially different from the appropriate out-of-network rate."

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

8. The Departments, moreover, denied plaintiffs an opportunity to raise this issue because they elected to issue the regulation without the notice and comment required by the APA. The IDR process is critical to ensuring that healthcare providers can continue to provide medically necessary care and treatment to patients and be fairly and reasonably reimbursed for those services. The Departments understood the value of stakeholder engagement on this issue. During now-HHS Secretary Xavier Becerra's confirmation hearing, he acknowledged "we have to get this arbitration right."[2] And during an April 2021 congressional hearing on HHS's budget request, when asked whether HHS would give stakeholders advance notice and an opportunity to comment on regulations implementing the NSA, Secretary Becerra responded: "coming from a background as the [California] attorney general where it was always important to take input whenever we would do rule making or take any action, in court or otherwise, I can guarantee you at HHS, before we take an action, we'll take the comments necessary, hear from all the stakeholders to make sure

[2] Confirmation hearing of Xavier Becerra before the Senate Health Committee (Feb. 23, 2021), https://www.c-span.org/video/?c4980098/user-clip-becerra-confirmation-comment-surprise-billing (at minute 1:41:06).

what we're doing is based on the facts, the science, and the law. I can guarantee you, sir, you will find we will have gone through a robust process to get there."[3]

9. This commitment was not honored. Instead, the Departments purported to find "good cause" for circumventing notice and comment. That decision, too, was unlawful. The good cause exception allows agencies to bypass their fundamental obligation to provide notice and comment only in narrowly defined circumstances where delay would cause serious harm. Those exceptional circumstances plainly do not exist here. When Congress enacted the NSA on December 27, 2020, it directed the Departments to issue regulations implementing the IDR process by December 27, 2021. The Departments thus had an entire year to issue final regulations on this issue—more than enough time to provide notice and comment. Yet the Departments waited until late September to act. The Departments cannot rely on their own nine-month delay to create an exigency justifying dispensing with notice and comment.

10. In any event, there was no exigency. The first arbitrations under the statute will not take place until approximately sometime in March 2022—over *five months* after the September IFR was issued—affording ample time to allow for notice and comment. Indeed, by setting a December 27, 2021 deadline for IDR regulations, Congress itself determined that there would be sufficient lead time if final regulations were issued by that date. Yet the Departments issued the September IFR a full three months in advance of the statutory deadline, when that time could have been used to provide notice and comment as required by the APA.

11. The absence of any exigency is especially clear with regard to the critical issue here, the standard to be applied by IDR entities in determining the appropriate reimbursement

[3] Health and Human Services Department Fiscal Year 2022 Budget Request before the House Appropriations Sub-Committee (Apr. 15, 2021), https://www.c-span.org/video/?c4980111/user-clip-becerra-statements-health-human-services-budget-request (at minute 49:06).

amount for out-of-network services. Even if IDR entities needed the Departments' guidance on that issue—which they do not, as the statute itself provides all the guidance needed—they would not need that guidance any sooner than the first arbitrations in March 2022. The Departments could easily have provided notice and comment on the standard to be applied by IDR entities and issued a final rule well in advance of that date. And even if a final rule were not in place by then, the IDR process could function—indeed, it would function precisely as Congress designed it—without the "rebuttable presumption" the Departments engrafted onto the statute. There is no justification whatsoever for imposing that requirement without providing notice and comment.

12. Accordingly, the Court should vacate, as contrary to law and in excess of statutory authority, the provisions of the September IFR requiring IDR entities to employ a rebuttable presumption that the offer closest to the QPA is the appropriate reimbursement amount. At a minimum, the Court should vacate those provisions of the September IFR as having been unlawfully issued without notice and comment and require the Departments to provide notice and comment before issuing any replacement rule.[4]

PARTIES

13. Plaintiff TMA is a trade association that represents more than 55,000 physician providers 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 provider members whose reimbursement for out-of-network services will be determined through the IDR process and who will be harmed by the unlawful rebuttable presumption the Departments imposed in the September IFR. The lawsuit is consistent with TMA's purpose to

[4] As discussed below, the September IFR also contains other provisions, including those relating to providers' obligation to send uninsured and self-pay patients good faith estimates of expected charges, as well as provisions governing a patient-provider billing dispute resolution process. *See infra* ¶ 56. This lawsuit does not challenge any of these other provisions of the September IFR.

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.

14. Plaintiff Adam Corley is a physician who resides and practices in Tyler, Texas. Dr. Corley works through Precision Emergency Physicians, PLLC ("PEP"), of which he owns a percentage. The September IFR injures Dr. Corley by creating an unlawfully structured IDR process that will decrease out-of-network reimbursement rates paid to PEP.

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

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

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

19. Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra 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.

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

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

JURISDICTION AND VENUE

23. The Court has jurisdiction over this action under 28 U.S.C. § 1331 and the APA, 5 U.S.C. §§ 701–06. Plaintiffs are entitled to the requested declaratory and injunctive relief under the APA and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

24. 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.

BACKGROUND

A. The No Surprises Act

25. The NSA creates a comprehensive framework designed to address surprise medical billing, as well as supplemental requirements imposed on providers and plans and issuers to enhance beneficiary transparency regarding the costs they can expect to incur for healthcare items and services.[5]

26. The NSA provides that for emergency services furnished by an out-of-network provider and non-emergency services furnished by an out-of-network provider at an in-network facility, plans and issuers may not impose a cost-sharing requirement that is 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).

27. 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

[5] The NSA also addresses surprise medical billing requirements for air ambulance providers. Those provisions are not at issue in this lawsuit.

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;[6] 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).[7]

28. 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 for the same or similar item or service furnished by a provider in the same or similar specialty and in the same geographic region. *Id.* § 300gg-111(a)(3)(E).

29. 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 payors 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).

30. 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). But unlike with patient-cost sharing, if there is no applicable All-Payer Model Agreement or specified state law, Congress did not set

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

[7] In the July interim final rule, discussed *infra* ¶¶ 45–49, 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).

provider reimbursement at the QPA or otherwise provide a benchmark or mathematical formula. Instead, Congress authorized payors to make an initial payment in an amount of their choosing and then channeled reimbursement disputes between healthcare providers and payors through a carefully balanced process of open negotiation followed, if necessary, by binding arbitration before a certified IDR entity. *Id.*

B. The IDR Process

31. The NSA sets forth a detailed IDR process for resolving disputes between providers and payors 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).

32. As relevant here, the statute also sets out a timeline for the IDR process, *id.* § 300gg-111(c)(1)(B), (c)(4)(F), (c)(5)(A)–(B); and the factors the IDR entity "shall" and "shall not" consider in determining the appropriate payment amount, *id.* § 300gg-111(c)(5)(C)–(D).

1. The Timeline for the IDR Process

33. Congress specified a precise timeline applicable to all parties entering the IDR process. Within 30 days of the healthcare provider's receipt of an initial payment or notice of denial of payment from the payor—which can take a month or more from the date of service to receive—the parties may engage in a 30-day open negotiation process to determine an appropriate payment amount. *Id.* § 300gg-111(c)(1)(A). If the negotiations do not result in an agreed payment amount during those 30 days, either party may, within four days following the conclusion of the open negotiation period, initiate the IDR process. *Id.* § 300gg-111(c)(1)(B).

34. Once the IDR process is initiated, the parties have three business days jointly to select a certified IDR entity to oversee the proceedings. *Id.* § 300gg-111(c)(4)(F)(i). If the parties fail to do so, the relevant agency, not later than six business days after the initiation of the IDR process, must select a certified IDR entity. *Id.* § 300gg-111(c)(4)(F)(ii).

35. Within 10 days of the selection of the certified IDR entity, the provider and payor must submit (1) an offer for a payment amount, (2) any information requested by the IDR entity, and (3) any additional information the party wishes the IDR entity to consider, including information relating to the factors enumerated in the statute. *Id.* § 300gg-111(c)(5)(B).

36. Within 30 days of the selection of the certified IDR entity, the IDR entity must determine the payment amount offer to accept, and then notify the parties of that determination. *Id.* § 300gg-111(c)(5)(A). If the parties agree to a payment amount before the IDR entity makes its determination, then that payment amount controls. *Id.* § 300gg-111(c)(2)(B). If not, then the IDR entity's decision is binding upon the parties absent a fraudulent claim or evidence of factual misrepresentation, and the decision is not subject to judicial review except in certain narrowly defined circumstances set forth in the Federal Arbitration Act. *Id.* § 300gg-111(c)(5)(E)(i).

37. In light of this statutorily prescribed timeline, for a claim for an item or service furnished on or after January 1, 2022, the soonest a provider or payor could reasonably expect to submit an offer as part of the IDR process is approximately March 1, 2022.

2. The Factors Governing the Payment Determination

38. Congress further directed the Departments, "[n]ot later than one year after" the NSA's enactment, *i.e.*, by December 27, 2021, 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).

39. Those "succeeding provisions" describe 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 in detail 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).

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

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

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 payor 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 payor to enter into network agreements, and, if applicable, contracted rates between the healthcare provider and payor 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.*

41. 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. *Id.* § 300gg-111(c)(5)(D).

42. 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[8]—Congress did not assign the Departments any role in dictating how IDR entities should determine which party's offer is the appropriate reimbursement amount.

C. The Timeline for Implementing Regulations

43. The NSA required the Departments to issue implementing regulations on certain issues by specified deadlines, showing that Congress carefully considered how much lead time regulated entities would need to come into compliance with implementing regulations:

- Not later than July 1, 2021: The Secretaries of HHS, Labor, and the Treasury shall establish the methodology that payors shall use to determine the QPA (including the geographic regions to be applied as part of those calculations), the information payors shall share with

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

healthcare providers about how QPAs were calculated, and a process to receive complaints about violations by payors of the rules for calculating QPAs. *Id.* § 300gg-111(a)(2)(B).[9]

- Not later than October 1, 2021: The Secretaries of HHS and the Treasury shall establish a process through which payors are audited by HHS and Treasury to ensure that payors are appropriately calculating and applying QPAs. *Id.* § 300gg-111(a)(2)(A).[10] As part of this audit process, the NSA requires both agencies to audit a sample of payors—up to 25 per year—and also permitted them to audit an unlimited number of additional payors based on a complaint or other information about the payor's noncompliance with the QPA rules. *Id.* § 300gg-111(a)(2)(A)(ii).
- Not later than December 27, 2021:
    - The Secretary of HHS shall specify the form and manner of submission for the reports that plans are required to prepare relating to air ambulance services. NSA § 106d; 42 U.S.C. § 300gg-118.
    - The Secretaries of HHS, Labor, and the Treasury shall establish the IDR process to resolve disputes between healthcare and air ambulance providers and payors regarding out-of-network reimbursement. 42 U.S.C. § 300gg-111(c)(2)(A).

[9] The NSA also directed the Secretary of HHS to release a guidance document, not later than July 1, 2021, that includes a template written notice form, for purposes of healthcare providers seeking to give notice and obtain consent from patients to be balance billed for NSA Covered Services. 42 U.S.C. § 300gg-132(d)(1)(A). On July 1, 2021, the Centers for Medicare and Medicaid Services issued that guidance document. CENTERS FOR MEDICARE & MEDICAID SERVS., *CMS Form Number 10780* (July 1, 2021).

[10] Under Section 504 of ERISA (29 U.S.C. § 1134), the Secretary of Labor has broad preexisting discretion to engage in audits regarding compliance with ERISA, which now includes portions of the NSA.

- The Secretary of Labor shall establish a standardized reporting format for the voluntary reporting by group health plans to State All Payer Claims Databases. 29 U.S.C. § 1191(d)(1).

- Not later than January 1, 2022:
  - The Secretary of Labor shall establish a process under which the Secretary may receive complaints about violations of the NSA committed by payors and transmit those complaints to the States or the Secretary of HHS, as appropriate, for potential enforcement action. *Id.* § 1152(b).
  - The Secretaries of HHS, Labor, and the Treasury shall issue a proposed rule implementing protections against provider discrimination. NSA § 108; 42 U.S.C. § 300gg-5.
  - The Secretaries of HHS, Labor, and the Treasury shall require that the external review process established by the Affordable Care Act shall apply to grandfathered health plans. NSA § 110; 42 U.S.C. § 300gg-19.
  - The Secretary of HHS shall establish a patient-provider dispute resolution process for uninsured or self-pay patients. 42 U.S.C. § 300gg-137(a).

44. The NSA also directed the Secretary of HHS to issue implementing regulations establishing a process to receive consumer complaints about violations of the NSA by healthcare providers, but the statute did not impose a deadline. *See id.* § 300gg-134(b)(3). On other issues, the NSA was silent about the need for implementing regulations.

D. Implementing Rulemaking and Guidance

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

45. On July 1, 2021, the Departments made publicly available an interim final rule with comment to implement certain of the NSA's surprise medical billing requirements. This regulation was published in the Federal Register on July 13 and became effective on September 13, 2021. 86 Fed. Reg. 36,872 (July 13, 2021).

46. Among other provisions, the July IFR set forth a methodology for how payors were to calculate QPAs, 45 C.F.R. § 149.140(c), and the information payors must share with out-of-network providers relating to how they calculated QPAs, *id.* § 149.140(d).[11] These provisions were subject to a rulemaking deadline in the NSA of July 1, 2021. 42 U.S.C. § 300gg-111(a)(2)(B); 86 Fed. Reg. at 36,918.

47. The information payors use to calculate QPAs lies solely within their control, and the mandatory disclosures relating to QPAs are wholly insufficient to allow the Departments, the IDR entities, and, critically, healthcare providers to ascertain whether a payor has correctly calculated the QPA. When payors 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:

- 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;

[11] The interim final rules also addressed, among other things, (1) coverage for emergency services; (2) patient cost-sharing amounts; (3) out-of-network reimbursement rates; (4) the notice and consent exception to the balance billing prohibition; (5) healthcare providers' public disclosure obligations; and (6) a complaint process for alleged violations of the NSA by healthcare providers, plans, and issuers.

- 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 payor. 45 C.F.R. § 149.140(d)(1)(iv).

Upon request of a healthcare provider, payors 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 payor 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 payor'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).

48. This information is insufficient to allow healthcare providers to verify the accuracy of the certification they receive from plans and issuers representing that all relevant QPAs were correctly calculated.

49. 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 government 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, and HHS plans to conduct no more than nine audits annually. *Id.* at 36,935.

2. August 20, 2021 FAQs

50. On August 20, 2021, the Departments of HHS, Labor, and the Treasury issued a guidance document, in the form of a series of FAQs, addressing a number of topics relating to the obligations imposed by the NSA. *See* DEP'TS, *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021).[12]

51. In these FAQs, the Departments announced that they would, as a matter of discretion, delay enforcement of several provisions of the NSA until they could finalize implementing regulations. The Departments announced that they would defer enforcement of the requirement that payors make available a price comparison tool (by internet website, in paper form, or telephone) by an additional year, until January 1, 2023, following the completion of notice-and-comment rulemaking. *Id.* at 3–4. The Departments recognized that it is "likely not possible" for regulated entities to come into compliance by January 1, 2022, with the NSA's requirement that healthcare providers send a good faith estimate of the expected charges for scheduled items and services to insured patients planning to submit a claim for those items and services to their plan or issuer. *Id.* at 5–6. Accordingly, the Departments deferred enforcement of this requirement indefinitely, until the completion of future rulemaking. *Id.* Similarly, the Departments determined that it was "likely not possible" for plans and issuers to incorporate, by January 1, 2022, good faith

[12] *Available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

estimates of expected charges in the advanced explanations of benefits they provide to patients. *Id.* at 6–7. Accordingly, the Departments deferred enforcement of this requirement until after "notice and comment rulemaking." *Id.*

52. For other provisions, the Departments explained that they would not issue implementing regulations before those provisions' effective date of January 1, 2022, but clarified that regulated entities would still need to comply by that date, using a "good faith, reasonable interpretation of the statute." *Id.* at 8 (healthcare provider directory requirements); *id.* at 8–9 (balance billing disclosure requirements for payors); *id.* at 9 (continuity of care requirements).

3. September 10, 2021 Proposed Rulemaking

53. On September 10, 2021, the Departments issued a joint notice of proposed rulemaking implementing provisions of the NSA and other provisions of the Consolidated Appropriations Act, 2021. This proposed rule was published in the Federal Register on September 16, 2021, 86 Fed. Reg. 51,730 (Sept. 16, 2021), and concerned, among other provisions, the process by which HHS would investigate complaints and potential violations of NSA requirements and take enforcement actions.

54. The NSA requires the Secretaries of HHS and the Treasury to establish this audit process through rulemaking "[n]ot later than October 1, 2021." 42 U.S.C. § 300gg-111(a)(2)(A). The comment period for this proposed rule closes on October 18, 2021. 86 Fed. Reg. at 51,730.

4. September IFR

55. On September 30, 2021, the Departments publicly released a second IFR—at issue here—implementing additional provisions of the NSA.[13] This IFR was published in the Federal Register on October 7, 2021, and became effective on that date. 86 Fed. Reg. 55,980.

56. The September IFR implements provisions of the NSA relating to the IDR process governing out-of-network reimbursement rates for healthcare providers, the requirement that healthcare providers send to uninsured or self-pay patients an advance good faith estimate of expected charges, the IDR process governing billing disputes between uninsured/self-pay patients and healthcare providers, and the extension of the Affordable Care Act requirements related to external reviews to grandfathered plans. *Id.* at 55,982, 56,048.

57. As relevant here, the September IFR requires IDR entities to employ a "rebuttable presumption" that the offer closest to the QPA represents the appropriate reimbursement amount. Specifically, the IDR entity "must select the offer closest to the [QPA] unless the certified IDR entity determines that credible information submitted by either party … clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate." *Id.* at 56,104. "[I]f the offers are equally distant from the [QPA] but in opposing directions," then "the certified IDR entity must 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.*

[13] Also on September 30, 2021, HHS issued guidance providing that for the 2022 calendar year, "IDR entities must charge a fixed certified IDR entity fee for single determinations within the range of $200–$500, unless otherwise approved by" HHS, DOL, or the Treasury. HHS, *Technical Guidance No. 2021-01* at 4 (Sept. 30, 2021). If the "IDR entity chooses to charge a different fixed certified IDR entity fee for batched determinations, that fee must be within the range of $268–$670, unless otherwise approved by" HHS, DOL, or the Treasury. *Id.*

58. Thus, under the September IFR, the IDR entity must select the offer closest to the QPA unless "credible information" regarding the additional statutory factors "rebuts that presumption" and "clearly demonstrates" that the QPA is "materially different" from the appropriate out-of-network rate. *Id.* A "material difference" exists "where 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." *Id.* at 55,995.

59. As a result of this new presumption, even if an IDR entity concludes, 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 reflects the value of the services provided and is the appropriate payment amount, the IDR entity may not select that offer unless its proponent satisfies the heightened burden set forth in the September IFR.

60. If the IDR entity does select the offer farther from the QPA, it must provide in its written decision "a detailed explanation" justifying its decision to reject the offer closer to the QPA. *Id.* at 56,000. That detailed explanation must 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 is materially different from the appropriate out-of-network rate." *Id.*

61. The Departments identified no statutory text creating these requirements. Instead, they asserted that the statute is "best interpret[ed]" to require IDR entities 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.*

62. With regard to the decision to issue the IDR regulations as an interim final rule, the Departments acknowledged that the APA requires notice and comment for legislative rules such as this one. *See* 5 U.S.C. § 553(b)(B); 86 Fed. Reg. at 56,043. They concluded, however, that "good cause" existed for bypassing that requirement. 86 Fed. Reg. at 56,043.

63. The Departments conceded that the full year between the NSA's enactment on December 27, 2020, and its effective date of January 1, 2022, "may have allowed for the regulations" to be finalized through notice-and-comment rulemaking before the NSA took effect. *Id.* Nonetheless, the Departments asserted that it was "impracticable and contrary to the public interest to engage in full notice and comment rulemaking" before finalizing the September IFR because "this timeframe would not provide sufficient time for the regulated entities to implement the requirements" relating to the IDR process. *Id.* at 56,044.

64. Specifically, the Departments asserted that payors would need to take into account the IDR regulations as they finalize benefit designs, rates, and plan offerings, and that IDR entities would need time to apply for certification and be prepared to conduct payment determinations after January 1, 2022. *Id.* The Departments further asserted that without the rules established by the September IFR for initiating the IDR process and providing information to the IDR entity, providers "will not be able to resort to the Federal IDR process …, leaving the possibility that they will be undercompensated for their services." *Id.*

65. However, the Departments did not state that it would have been impossible to provide notice and comment and finalize the IDR regulations by the NSA's effective date. They did not explain why—contrary to Congress's judgment as reflected in the December 27, 2021 statutory deadline—final IDR regulations issued by that date would give parties and IDR entities insufficient time to be ready to begin conducting arbitrations on schedule in March 2022. And they did not explain why the rebuttable presumption they created in favor of the QPA was necessary for the IDR process to function or why it would have been impracticable or contrary to the public interest to provide notice and comment before imposing that requirement.

E. Anticipated Impact of the September IFR

66. Texas is one of several states that has implemented a state surprise medical billing law. For some claims, this law will serve as the "specified state law" that will govern healthcare provider out-of-network reimbursement. However, this law is not as comprehensive as the NSA, and, for many out-of-network services, the NSA's IDR process will be used to determine provider reimbursement. For example, the Texas law does not cover self-insured health plans, under which the majority of private sector plan enrollees receive their benefits.[14]

67. For claims subject to the NSA, the unlawful presumption adopted in the September IFR will, by design, result in party offers and IDR decisions that cluster closer to the QPA than they otherwise would. *See* 86 Fed. Reg. at 56,061 (stating that the presumption in favor of the QPA "will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA"). Constraining IDR entities' ability to weigh all factors as they deem appropriate, and instead

[14] *See* Paul Fronstin, *Self-Insured Health Plans: Recent Trends by Firm Size, 1996–2018*, at 7 fig.6, (Emp. Ben. Rsch. Inst., EBRI Issue Brief No. 488, Aug. 1, 2019), https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_488_selfinsur-1aug19.pdf?sfvrsn=bd7e3c2f_6.

mandating that they hew to the QPA, will skew IDR results in favor of payors and undermine providers' ability to obtain adequate compensation for their services.

68. For a variety of reasons, the QPA will often be lower than the fair market value of providers' services as reflected by reimbursement amounts paid in the marketplace. To begin with, in the July IFR, the Departments interpreted the phrase "median of contracted rates" to mean that each *contract* is a data point, rather than each *payment* made pursuant to a contract. *See* 86 Fed. Reg. at 36,889. The Departments could have calculated the median contracted rate as the median of payments made for each item or service, which would have more accurately approximated prevailing market rates. The Departments instead selected the median of contracts, concluding that the median of payments would "put upward pressure on the QPA." *Id.* at 36,930.

69. In addition, the Departments' methodology for calculating the QPA includes certain contracted rates that will often cause the QPA to understate the true market value of providers' services. The Departments do not require that payors actually make a payment pursuant to a contract in order for that contracted rate to be incorporated into the QPA. For example, insurers may require primary care doctors to include rates for emergency room services in their contracts, even though they do not provide those services and thus lack the incentive to negotiate a true market rate. Yet the Departments not only count those rates in calculating the QPA, but give them equal weight with rates that are used frequently.

70. The Departments' QPA methodology also excludes important factors. The Departments excluded risk-sharing, bonus, and incentive payments from the QPA, even though they can amount to 10–15% of the total payment amount to physicians. In addition, the Departments' QPA methodology excludes the significant number of payments not made pursuant to a contract. Because there are limited rules regarding network adequacy for most hospital-based

specialties, those services often are not covered by in-network contractual arrangements. In 2020, for example, only 39% of emergency medicine bills were in-network or contracted and 61% were billed without a contract.[15] The exclusion of these payments from the QPA will further deflate it compared to the true fair market value of providers' services.

71. These flaws in the methodology for calculating the QPA are compounded by a lack of oversight. Payors are solely responsible for calculating and reporting QPAs. Providers have no visibility into how QPAs are calculated, and the government has announced little anticipated auditing of QPAs, despite statutory encouragement to do so. Providers will thus lack pertinent information to assess whether the insurer has calculated the QPA accurately, including whether the claim was downcoded (*i.e.*, the payor selected the QPA for a procedure with lower acuity and thus a lower reimbursement rate), the amount of any bonuses or supplemental payments not included in the QPA, the number of contracts and the number of providers included in the QPA, and the types of specialties that have contracted rates in the dataset used to determine the QPA.

72. Other state surprise medical billing laws have set benchmarks that are similar to the QPA, in that they are based on median contract rates as calculated solely by payors with little government oversight and no visibility by healthcare providers. Experience in these states has shown that tying arbitrations to a benchmark like the QPA drives down provider reimbursement.

73. In 2017, for example, California passed AB72, 2016 Leg., Reg. Sess. (Cal. 2016), which sets reimbursement amounts based on the insurers' average contracted rates and creates an independent dispute resolution process for resolving disputes. Following passage of AB72, payors became more challenging to contract with. According to one survey, 31% of clinicians experienced

[15] *See* Tex. Dep't of Ins., *Balance Billing Protections: Senate Bill 1264 Biennial Report* 18 (2020), https://www.tdi.texas.gov/reports/documents/SB1264-report-december-2020.pdf.

insurers refusing to renew contracts, 23% had an existing contract terminated, and 71% were asked to accept rates below the cost to provide care.[16] At the same time payors forced providers out of network, they also decreased their out-of-network reimbursement rates, recognizing that a below-market median rate would serve as the benchmark in arbitration. Survey results showed that 80% of physicians received reimbursement cuts of up to 30%, with 71% of emergency room physicians experiencing up to 30% rate cuts and 22% of emergency room physicians experiencing 31–50% rate cuts.[17] Another study showed that the per-unit rates for anesthesiology services declined 13.64% for out-of-network services and 10.75% for in-network services following the implementation of California's law.[18]

74. The Departments' new "rebuttable presumption" in favor of the offer closest to the QPA during the IDR process will have similar results. Providers will often receive lower reimbursement that does not reflect the fair market value of their services, and some patients will lose access to their in-network physicians.

COUNT I

THE PRESUMPTION IN FAVOR OF THE QPA EXCEEDS THE DEFENDANTS' STATUTORY AUTHORITY AND IS 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))

75. The foregoing paragraphs are incorporated by reference.

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[16] Cal. Med. Ass'n, *Surprise Billing Survey Results* 4 (rev. Nov. 1, 2019), https://www.cmadocs.org/Portals/CMA/files/public/CMA%20Suprise%20Billing%20Survey%20Results%202019.pdf.

[17] *Id.*

[18] Ambar La Forgia et al., *Association of Surprise-Billing Legislation with Prices Paid to In-Network and Out-of-Network Anesthesiologists in California, Florida, and New York: An Economic Analysis*, 181 JAMA Internal Med. 1324, 1328 tbl.2 (2021).

76. The September IFR's requirement that IDR entities employ a rebuttable presumption that the offer closest to the QPA is the appropriate reimbursement amount is contrary to law and exceeds the Departments' statutory authority.

77. The NSA specifies in exhaustive detail the factors the IDR entity "shall" and "shall not" consider in determining which party's offer to select as the appropriate reimbursement amount. The statute requires the IDR entity to consider each of the enumerated factors, and it does not assign primacy to any of them or dictate how the IDR entity must weigh the various factors. Instead, Congress left to each IDR entity's discretion how to balance the statutory factors in light of all the relevant facts and circumstances in a particular case.

78. By requiring IDR entities to select the offer closest to the QPA unless "credible information" regarding the additional factors enumerated in the statute "clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate," the September IFR unlawfully circumscribes the discretion Congress granted to the IDR entities.

79. The Departments' claim that the statute is "best interpret[ed]" to require IDR entities to employ a rebuttable presumption in favor of the offer closest to the QPA is untenable. No language in the statute can even arguably be "interpreted" to require IDR entities to select the offer closest to the QPA unless the opposing party carries the heightened burden the Departments imposed to "clearly demonstrate that the QPA is materially different" from the appropriate rate.

80. Nor can such a requirement be found in between the statutory lines, particularly in a statute as prescriptive as this one. If Congress had intended IDR entities to begin with the presumption that the QPA is an appropriate reimbursement amount, and to treat the additional factors as relevant only insofar as they clearly rebut that presumption, Congress would have said so. Congress knows how to create rebuttable presumptions when it wants to—indeed, it did so

elsewhere in the Consolidated Appropriations Act, 2021 itself[19]—and did not do so here. The statute cannot reasonably be read to impose the presumption the Departments invented.

81. In reality, the Departments' rebuttable presumption in favor of the QPA is not an "interpretation" of the statute at all, but an attempt to rewrite it by imposing requirements on IDR entities' decisional processes that Congress did not include in the statute. Even if the Departments had the authority to impose additional requirements, the provisions creating the rebuttable presumption must be vacated because the Departments erroneously claimed that *Congress* created the presumption. Congress manifestly did not, and the Departments cannot now claim they were exercising authority delegated by Congress to supplement the statute.

82. Regardless, the Departments lack authority to impose additional requirements as to how IDR entities must balance the statutory factors in deciding cases. Congress itself exhaustively addressed that issue and left no room for supplementation by the Departments. Congress directed the Departments to promulgate rules under which IDR entities would determine the appropriate reimbursement amount "in accordance with the succeeding provisions of this subsection"—*not* in accordance with rules specified by the Departments. And, in stark contrast to many other provisions in which Congress directed the Departments to supplement the statute's IDR provisions, *see supra* ¶ 42 n.8, the "Payment determination" provision assigns no implementation role to the Departments. Rather, Congress spoke directly to the IDR entities and itself specified the considerations they must and must not take into account, without creating any presumption in favor of the QPA or otherwise constraining IDR entities' decision-making.

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

83. Accordingly, the provisions of the September IFR creating a presumption in favor of the offer closest to the QPA must be set aside as "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 DEFENDANTS UNLAWFULLY ISSUED THE SEPTEMBER IFR WITHOUT THE NOTICE AND COMMENT REQUIRED BY THE APA (5 U.S.C. §§ 553, 706)

84. The foregoing paragraphs are incorporated by reference.

85. The APA requires federal agencies to provide public notice of proposed rules and an opportunity for comment unless the agencies "for good cause" find that notice and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).

86. This bedrock procedural protection of the APA is designed to ensure that members of the public have notice of proposed regulations that might affect their interests and an opportunity to present their views to the agency, both to inform and improve the agency's decision-making and to promote public confidence in the administrative process.

87. Accordingly, notice and comment are required for legislative rules in all but exceptional circumstances. While the APA permits agencies to bypass notice and comment for "good cause," this is a narrow exception reserved for emergency situations in which delay would cause serious harm and interfere with the agency's ability to carry out its statutory mandate.

88. The Departments cannot satisfy the high bar necessary to establish good cause. Congress gave the Departments an entire year to promulgate IDR regulations. That is more than sufficient time to formulate proposed rules and provide notice and opportunity for comment. The Departments cannot rely on their own delay to create an exigency establishing good cause.

89. In any event, there was no exigency that could justify dispensing with notice and comment. The first arbitrations will not occur until at least March 2022. Had the Departments

promulgated the September IFR as a proposed rule and sought comment, they could easily have finalized a rule with sufficient time for the IDR process to begin functioning on schedule in March 2022. Indeed, by setting a December 27, 2021 deadline for the final IDR rules, Congress determined that there would be sufficient time to stand up the IDR process if final rules issued by that date. If more time was necessary, Congress would have set an earlier deadline, as it did elsewhere in the NSA. Yet the Departments issued the September IFR three months before the statutory deadline, when they could have used that time to provide notice and comment.

90. At a minimum, there was no justification for failing to provide notice and comment before issuing the rules establishing the rebuttable presumption in favor of the QPA. Even if IDR entities needed guidance from the Departments as to the standard to be applied in determining which party's offer to select—which they do not, as the statute is self-executing in that regard—they would not need that guidance any sooner than March 2022 when they will first begin hearing cases. Notice and comment could easily have been provided.

91. Accordingly, there was no good cause for circumventing notice and comment, and the provisions of the September IFR creating the presumption in favor of the offer closest to the QPA were issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

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

A. A declaration that the Departments acted unlawfully in (i) promulgating the provisions of the September IFR requiring IDR entities to employ a rebuttable presumption that the offer closest to the QPA is the appropriate reimbursement amount and (ii) doing so without providing public notice and comment;

B. An order vacating the provisions of the September IFR requiring IDR entities to employ a rebuttable presumption that the offer closest to the QPA is the appropriate reimbursement amount:

a. 45 C.F.R. § 149.510(a)(2)(viii); the second 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)(viii); the second 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)(viii); the second 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).

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

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

E. Any other just and proper relief.

Dated: October 28, 2021

Respectfully submitted,

/s/ *Penny P. Reid*

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JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

TEXAS MEDICAL ASSOCIATION and DR. ADAM CORLEY

(b) County of Residence of First Listed Plaintiff Travis County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Penny P. Reid SIDLEY AUSTIN LLP
2021 McKinney Ave., Ste. 2000 Dallas, TX 75201 Tel:

DEFENDANTS

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DEPARTMENT OF LABOR

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
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- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
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- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
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- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
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- ☐ 423 Withdrawal 28 USC 157

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- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
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- ☐ 871 IRS—Third Party 26 USC 7609

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- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
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- ☐ 850 Securities/Commodities/ Exchange
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- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
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- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. §§ 553 & 706

Brief description of cause:
Certain provisions of interim final rules violate the Administrative Procedure Act (APA) because they exceed the issuing agencies' statutory author

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
October 28, 2021

SIGNATURE OF ATTORNEY OF RECORD
/s/ Penny P. Reid

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____