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*.	)	Case No.: 6:21-cv-00425-JDK

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF SUMMARY JUDGMENT

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INTRODUCTION

In the NSA, Congress created a fair, balanced, and "independent" process for resolving disputes between healthcare providers and payors over out-of-network reimbursement rates. As plaintiffs' *amici* have ably shown, and as is apparent on the face of the statute's text, the legislation Congress enacted was the result of extensive negotiation, culminating in a bipartisan compromise in which Congress purposely *rejected* proposals that would have made the QPA the benchmark or default reimbursement amount in favor of an IDR process in which an independent arbitrator would consider all relevant factors. Congress directed IDR entities to "consider" and "tak[e] into account"—without imposing any presumptions or otherwise prioritizing one factor over the others—*all* of the enumerated considerations in determining which party's offer best reflects the appropriate out-of-network rate in light of all the relevant facts and circumstances.

In the September IFR, the Departments upended this careful legislative compromise and rewrote the statute to make the QPA the *de facto* benchmark for healthcare provider reimbursement—a decision that will systematically bias IDR results in payors' favor, to the detriment of healthcare providers and, ultimately, the patients they serve. Without providing notice or an opportunity to comment, the Departments purported to discover, lurking in between the statutory lines, an unwritten requirement that IDR entities must always select the offer closest to the QPA unless "credible information" submitted by the parties "clearly demonstrates" that the QPA "is materially different from the appropriate out-of-network rate." As plaintiffs showed, this "rebuttable presumption"—nowhere to be found in the statute's text—violates the fundamental principle of statutory interpretation that neither agencies nor courts may alter statutes by reading into them material new terms not found there. The Departments, moreover, lacked any semblance of "good cause" to issue the presumption without the notice and comment required by the APA.

The Departments' response does nothing to refute plaintiffs' showing. As to the statutory question, the Departments sound the retreat, seeking to disavow their characterization of their rules as creating a "presumption in favor of the QPA," 86 Fed. Reg. 55,980 56,060 (Oct. 7, 2021), and pretending that they merely require IDR entities to consider the statutory factors in a particular sequence. These *post hoc* rationalizations from agency counsel cannot save the Departments' rules. Regardless of how they are labeled, the Departments' rules improperly add material terms to the statute that do not appear there. And those terms do not merely require IDR entities to consider the QPA "first." They explicitly require IDR entities to give controlling *weight* to the QPA by selecting the offer closest to it unless a heightened burden is met. The Departments may not agree with Congress's decision to vest IDR entities with discretion to weigh the statutory factors without presumptions, but they have no authority to rewrite the statute to suit their policy preferences.

Nor can the Departments justify their decision to proceed without notice and comment. As every court to consider the question has held, the Departments' organic statutes do not authorize them to bypass notice and comment. The APA itself provides that its requirements apply unless a subsequent statute "expressly" overrides them, and the organic statutes do not do that. Good cause was thus required, and it was plainly lacking. The Departments cannot justify issuing the QPA presumption by pointing to the asserted good cause for other rules not challenged here. They have no persuasive explanation for why they waited nine months to act or why they could not have used the remaining three months before the statutory deadline to provide notice and comment. And the error was not harmless—it deprived plaintiffs of the opportunity to comment on the QPA presumption and the Departments' asserted justifications for it before the Departments etched it into law.

Because these errors are serious, and because freeing IDR entities from the Departments' QPA presumption would not be disruptive, the Court should vacate the challenged rules.

ARGUMENT

I. Plaintiffs Have Standing.

As a threshold matter, plaintiffs clearly have standing to bring this case. While the Court need only determine that "at least one plaintiff has standing," *McAllen Grace Brethren Church v. Salazar*, 764 F.3d 465, 471 (5th Cir. 2014), plaintiffs' declarations and elementary principles of standing law establish that both TMA and Dr. Corley have standing to bring this suit.[1]

Standing is generally "self-evident" where, as here, the challenge is brought by a regulated party or an association representing regulated parties. *See, e.g.*, *Markle Interests, LLC v. U.S. Fish & Wildlife Serv.*, 40 F. Supp. 3d 744, 756 (E.D. La. 2014); *Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008) ("[S]tanding is usually self-evident when the plaintiff is a regulated party or an organization representing regulated parties."). That is because when a party is an "object of" government action, there is "ordinarily little question that the action" concretely affects the party, causing an injury in fact that supports standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). So the law, in this circuit as elsewhere, is that the "object of a government" rule, or an association suing on behalf of directly regulated members, "ordinarily has standing to challenge" that rule. *Duarte v. City of Lewisville*, 759 F.3d 514, 518 (5th Cir. 2014).

This case is no exception. Plaintiffs have standing to bring this suit as, or on behalf of, parties directly regulated by the September IFR. The challenged rules directly regulate healthcare providers by dictating the terms under which IDR entities will resolve disputes over reimbursement

[1] TMA has associational standing to sue on behalf of its members if (1) any of its members would have standing to sue in his or her own right, (2) the interests TMA seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 342–43 (1977). Here, the Departments challenge only the first element. Attached to this brief as Exhibits A–C are declarations from three TMA members detailing the injuries the Departments' QPA presumption will cause them, as well as a supplemental declaration from Dr. Corley (Ex. D).

rates for providers' covered out-of-network services. Among the providers affected are Dr. Corley and TMA members such as Drs. Cook, Dao, and Ford. *See* Villareal Decl. (Doc. 25-1) ¶ 7; Corley Decl. (Doc 25-2) ¶ 5; Supp. Corley Decl. ¶¶ 5–6; Cook Decl. ¶¶ 7–8; Dao Decl. ¶¶ 7–8; Ford Decl. ¶¶ 7–8. The IFR on its face concretely and adversely affects these providers by subjecting them to an IDR procedure that is unlawfully structured and features a rebuttable presumption that will systematically bias results in payors' favor. *See* Villareal Decl. ¶ 8; Corley Decl. ¶ 9; Supp. Corley Decl. ¶¶ 9–11; Cook Decl. ¶¶ 9–13; Ford Decl. ¶¶ 9–14; Dao Decl. ¶¶ 10–14.

The Departments misunderstand the nature of the asserted injury and, as a result, misrepresent plaintiffs' evidentiary burden. To demonstrate "an injury that is traceable to the rule," plaintiffs need not "pro[ve]" that they (or their members) will obtain lesser awards under the September IFR than they would under a process freed from the Departments' unlawful presumption. *See* Opp. 16–17. "A plaintiff can show a cognizable injury if [he] has been deprived of 'a procedural right to protect [his] concrete interests.'" *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009)); *see also Lujan*, 504 U.S. at 573 n.8. That is the injury here. In the NSA, Congress carefully designed an IDR procedure—one in which an independent arbitrator would resolve reimbursement disputes based on *all* relevant factors—to protect the economic interests of healthcare providers like Dr. Corley and TMA's members. The September IFR strips away that protection by replacing Congress's balanced scheme with the unlawful presumption that IDR entities must select the offer closest to the QPA. Plaintiffs have standing to vindicate this procedural right if at least one member of TMA or Dr. Corley provides services subject to reimbursement through the IDR process and will in at least one case submit the

offer farther from the QPA.[2] This is not just "reasonably certain" to occur. *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1119 (D.C. Cir. 2005). It is inevitable. *See S. Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882, 895–96 (D.C. Cir. 2006) (association of oil refineries had standing to challenge EPA regulation establishing air pollution standards where it was "inconceivable" that the regulation "would fail to affect ... even a single" member of the association).

In any event, plaintiffs unquestionably will suffer financial harm as a result of the September IFR—and the Departments should not be heard to contend otherwise given that their brief repeatedly relies on the premise that the QPA presumption will systematically reduce out-of-network reimbursement compared to an IDR process without such a presumption. *See, e.g.*, Opp. 10–11, 22, 32, 37; *see also* Michael McAuliff, *Doctors Are Mad About Surprise Billing Rules. Becerra Says Stop Gouging Patients*, NPR (Nov. 22, 2021) (HHS Secretary Becerra stating that healthcare providers will "have to tighten their belt[s]" under the Departments' new rules).[3]

Plaintiffs' declarations provide far more than "speculation," Opp. 16, that the rule will cause them (or their members) pocketbook injuries. Dr. Corley and three TMA members explain why the offers they submit generally will be above the QPA—and farther from the QPA than payors' offers. Supp. Corley Decl. ¶¶ 7–8; Cook Decl. ¶¶ 8–10; Dao Decl. ¶¶ 10–11; Ford Decl. ¶¶ 9–10. The QPA presumption thus makes it more likely that their bids will lose out in the IDR process, decreasing reimbursement rates for their services, and therefore their compensation. Supp. Corley Decl. ¶¶ 3, 9–10; Cook Decl. ¶¶ 4, 11–12; Dao Decl. ¶¶ 4, 12–13; Ford Decl. ¶¶ 4, 12–13.

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[2] In fact, the injury will occur at an even earlier stage—when the parties are determining their offers—because the QPA presumption will pressure healthcare providers to lower their offers toward the QPA to increase the likelihood they will be selected. *See* 86 Fed. Reg. at 56,061 (stating that the presumption will "encourage" parties "to make offers that are closer to the QPA").

[3] *See* https://www.npr.org/sections/health-shots/2021/11/22/1057985191/becerra-defends-hhs-rulesaimed-at-reining-in-surprise-medical-bills.

The Departments' last-ditch effort to disqualify Dr. Corley as a "proper plaintiff" also goes nowhere. Opp. 16–17. Dr. Corley is not a third party seeking to challenge the rule "on behalf of" the company through which he practices medicine. Opp. 17. Rather, as already shown, Dr. Corley has Article III standing as a party directly regulated by a rule that is likely to cause him redressable harm. That companies with which he has ties may also have interests at stake here does not eliminate Dr. Corley's standing to sue on his own behalf. *See, e.g.*, *Meland v. Weber*, 2 F.4th 838, 845 (9th Cir. 2021) (shareholder had Article III standing to challenge rule regulating corporations where shareholders were also "one of the objects" of the rule); *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 656 F.3d 580, 585–86 (7th Cir. 2011) (truckers had standing as "objects" of rule also directed at motor carriers).

Indeed, the shareholder rule the Departments cite is at most a prudential standing consideration, not a question of Article III standing, which requires only injury, causation, and redressability. And the shareholder rule presents no obstacle here because Dr. Corley, as a provider of covered out-of-network services under the NSA, is clearly within the "zone of interests" of the NSA's IDR provisions. *See, e.g.*, *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224–25 (2012). The APA thus grants him a "[r]ight of review" as a person "adversely affected or aggrieved by agency action," 5 U.S.C. § 702, notwithstanding any prudential limits that might apply in other contexts. *See Collins v. Mnuchin*, 938 F.3d 553, 575 (5th Cir. 2019) (en banc), *rev'd in part on other grounds sub nom. Collins v. Yellen*, 141 S. Ct. 1761 (2021); *see also Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 (2014) ("[A] court ... cannot limit a cause of action that Congress has created merely because 'prudence' dictates."); *FAIC Sec., Inc. v. United States*, 768 F.2d 352, 357 (D.C. Cir. 1985) (Scalia, J.).

II. The Departments' QPA Presumption Is Inconsistent With The Statute.

A. The Departments' rules conflict with the statute's unambiguous text by adding new terms that materially alter it.

The statutory analysis in this case should begin—and end—with a basic principle of statutory interpretation: neither agencies nor courts may "add provisions to a federal statute," *Alabama v. North Carolina*, 560 U.S. 330, 352 (2010), or "rewrite statutory language by ascribing additional, material terms," *Texaco Inc. v. Duhe*, 274 F.3d 911, 920 (5th. Cir 2001); *accord Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2637, 2381 (2020); *Rotkiske v. Klemm*, 140 S. Ct. 355, 360–61 (2019). This principle, "so obvious that it seems absurd even to recite it," rests on the core separation-of-powers principle that only Congress has the power to make the laws, and thus those charged with interpreting the laws may not "supply words or even whole provisions that have been omitted." Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012). The assertion of such a power—in effect, the power to amend a statute through interpretation—"flatly contradicts democratic self-governance." *Id.* at 96; *accord Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 327 (2014) (allowing agencies to "revise clear statutory terms" would "deal a severe blow to the Constitution's separation of powers").

The Departments have no answer to this dispositive point. They do not, because they cannot, identify any language in the statute that requires IDR entities to presume that the QPA is the appropriate out-of-network rate or to select the offer closest to the QPA unless the opposing party overcomes that presumption. But rather than accept the inescapable conclusion from that fact—that the statute does not impose these requirements—the Departments, under the guise of "interpretation," effectively took a red pencil to the statute as follows, with the Departments' additions to the statutory text shown in bold and deletions in strikethrough:

> Not later than 30 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the certified IDR entity shall—

> (i) taking into account the considerations specified in subparagraph (C), select ~~one of the offers submitted under subparagraph (B)~~ **the offer submitted under subparagraph (B) that is closest to the qualifying payment amount** to be the amount of payment for such item or service determined under this subsection for purposes of subsection (a)(1) or (b)(1), as applicable, **unless the certified IDR entity determines that credible information submitted by either party under subsection (c)(5)(C)(i)(II) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate**, **or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, 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.**

Compare 42 U.S.C. § 300gg-111(c)(5)(A)(i), *with* 45 C.F.R. § 149.510(c)(4)(ii)(A).

> In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider—
>
> > (I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and
> >
> > (II) subject to subparagraph (D), information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii). **This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.**

Compare 42 U.S.C. § 300gg-111(c)(5)(C)(i), *with* 45 C.F.R. § 149.510(c)(4)(iii)(C).[4]

[4] The Departments further baked the bolded requirements into the written decision requirement they imposed on IDR entities. *See* 45 C.F.R. § 149.510(c)(4)(vi)(B) (requiring IDR entities, if and only if they select the offer farther from the QPA, to "include an explanation of the credible information that the certified IDR entity determined demonstrated that the [QPA] was materially different from the appropriate out-of-network rate"). The Departments' assertion that plaintiffs "offer no argument … to challenge the validity of this provision," Opp. 37 n.9, is perplexing. The validity of this provision clearly rises and falls with the validity of the presumption. If the statute does not require IDR entities to employ a rebuttable presumption in favor of the QPA in making their decisions—and it does not—then the Departments cannot require IDR entities to explain why they determined the presumption was rebutted whenever they select the offer farther from the QPA. Nothing in the Departments' reporting obligations is to the contrary, as the Departments are not required to report anything about the IDR entities' reasoning. *See* 42 U.S.C. § 300gg-111(c)(7).

It is difficult to imagine a clearer example of "reading words or elements into a statute that do not appear on its face." *Bates v. United States*, 522 U.S. 23, 29 (1997); *see United States v. Maturino*, 887 F.3d 716, 723 (5th Cir. 2018) ("We cannot revise language … under the guise of interpreting it."); *Anco Insulations, Inc. v. Nat'l Union Fire Ins. Co.*, 787 F.3d 276, 288 n.34 (5th Cir. 2015) ("[W]e shall not read requirements into the statute outside of its plain language.").

Unable to identify any language that could be "interpreted" to impose a presumption in favor of the QPA, the Departments instead play word games in an effort to downplay what their rules require. They assert that their rules require only that IDR entities "begin with the [QPA], and then … move on to take into account the other statutory factors," Opp. 20, and that the Departments' repeated references to a "presumption" in the preamble were merely "shorthand" for this order of operations, Opp. 23. But the bolded requirements above do not just impose a temporal *sequence* on IDR entities' consideration of the factors. They demand that IDR entities give controlling *weight* to the QPA, by selecting the offer closest to it unless a heightened burden is satisfied. The result is exactly as the Departments described it—to "establish the QPA as the presumptive factor," 86 Fed. Reg. at 55,997, by requiring the party whose offer is farther from the QPA to "rebu[t] the presumption that the QPA is the appropriate out-of-network rate," *id.* at 55,998. Indeed, the guidance the Departments recently issued to IDR entities based on the rules has an entire section entitled "Standards for Rebutting the Presumption."[5] Agency counsel's *post hoc* rationalizations do not and cannot change this reality. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947).

[5] U.S. Dep't of Health & Human Servs., *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities*, at 20 (Dec. 2021), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Federal-Independent-Dispute-Resolution-Process-Guidance-for-Certified-IDR-Entities.pdf.

In all events, regardless of how they are labeled, the requirements above do not appear in the statute, and that is ultimately all that matters. The Departments may not insert new terms "to suit [their] own sense of how the statute should operate." *Util. Air Regul. Grp.*, 573 U.S. at 328.

B. Other interpretive tools confirm that Congress did not *sub silentio* make the QPA the *de facto* benchmark for healthcare provider reimbursement.

While the canon against supplying absent provisions suffices, by itself, to reject the Departments' "interpretation," their position is weaker still. Other indicia of statutory meaning powerfully reinforce the conclusion that Congress did not require IDR entities to give the QPA presumptive weight. *See* Mot. 14–17. The Departments' responses are unpersuasive.

Take the "backdrop of existing law" against which Congress legislated. *McQuiggin v. Perkins*, 569 U.S. 383, 398 n.3 (2013). Courts have long held that when Congress charges a decision maker with weighing factors without assigning weights, the weighing of the factors is left to the decision maker's sound discretion. *See* Mot. 16 (citing cases). The Departments point out that, in those cases, the decision maker to whom Congress assigned the task of weighing the factors was an agency, not an arbitrator. Opp. 24. True but irrelevant. Here, the relevant decision makers are the IDR entities—Congress spoke directly to *them* and required *them* to consider the statutory factors. *See* 42 U.S.C. § 300gg-111(c)(5)(A)(i) ("*the certified IDR entity* shall—tak[e] into account the considerations specified in subparagraph (C)" (emphasis added)); *id.* § 300gg-111(c)(5)(C) ("*the certified IDR entity* … shall consider" the factors (emphasis added)). And while there is no doubt that Congress "*can* 'prescribe a structure'" governing the consideration of factors, Opp. 24 (emphasis added), the question here is whether Congress *did*. The teaching of the case law is that an unadorned list of factors to consider—all we have here—is not such a "structure."

This does not mean IDR entities have "unfettered discretion." Opp. 25. Indeed, among the limits courts have identified on a decision maker's consideration of a multifactor statutory list is

that the decision maker may neither "ignore any individual factor entirely," *Tex. Oil & Gas Ass'n v. EPA*, 161 F.3d 923, 934 (5th Cir. 1998), nor "select any *one* factor as controlling," *Pub. Serv. Co. of Ind. v. ICC*, 749 F.2d 753, 763 (D.C. Cir. 1984). Here, the Departments' rules improperly *require* IDR entities to abuse their discretion by treating one factor as controlling and ignoring the other factors Congress required them to consider unless they "clearly demonstrate" that the QPA is inadequate. *See* 86 Fed. Reg. at 55,997 (stating that "[i]n order for a certified IDR entity to consider this additional information," it "must clearly demonstrate" that the QPA is inadequate). Viewed another way, the Departments' rules essentially deem it a *per se* abuse of discretion to select the offer farther from the QPA unless the Departments' QPA presumption is rebutted. Nothing in the statute's text or structure imposes this constraint on IDR entities' discretion, nor is there any support for it in the case law. It is an administrative fabrication, pure and simple. *See, e.g.*, *Am. Corn Growers Ass'n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002) (where Congress charged states with weighing statutory factors without assigning weights, an agency rule that required states to consider one factor "in a dramatically different fashion" from the others was unlawful).

The Departments further err in dismissing the relevance of the intense legislative scrutiny surrounding the role the QPA would play in determining healthcare provider reimbursement. As plaintiffs' *amici* showed, Congress considered a variety of approaches, including bills that would have made the QPA determinative or the default payment amount. *See* Br. of Members of Congress, Doc. 57, at 4–11; Br. of Emergency Dep't Practice Mgmt. Ass'n ("EDPMA") *et al.*, Doc. 41, at 8–13. But Congress rejected these approaches in favor of a "fair and balanced" IDR process in which "both the provider's offer and the plan's offer receive equal weight"; the IDR entity "considers, but isn't bound by the median in-network rate"; and "the provider is not left in a position to disprove the adequacy of such a rate." Br. of EDPMA *et al.*, Ex. 5, at 3 (statement of House

Ways and Means Committee Chairman Richard Neal explaining the bipartisan compromise that Congress "worked together for many months to craft" to create a fair process that would consider information from both sides without "giving too much weight to … a benchmark rate"); *see also id.*, Ex. 6 ("This text includes **NO** benchmarking or rate-setting" and requires arbitrators to "equally consider many factors" in light of "the facts and relevant data of each case").

This legislative history is relevant for at least two reasons. *First*, courts have consistently cautioned against reading into legislation terms that Congress considered and rejected. *See, e.g.*, *Doe v. Chao*, 540 U.S. 614, 622–23 (2004); *Smith v. United States*, 507 U.S. 197, 202 n.4 (1993); *In re Katrina Canal Litig. Breaches*, 524 F.3d 700, 705 (5th Cir. 2008); *Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 459 (D.C. Cir. 2017) (Kavanaugh, J.). Making the QPA the default rate for out-of-network reimbursement and requiring providers to disprove its adequacy would do precisely that. The Departments accuse plaintiffs of reading in rejected terms, Opp. 25, but they miss the mark. The bills they cite included no list of factors IDR entities were required to consider. *See id.* (citing S. 1266, 116th Cong. (2019); H.R. 4223, 116th Cong. (2019)). Plaintiffs do not advocate that approach. Rather, they seek to free IDR entities to apply the statute as written, without extra-statutory constraints on their ability to consider and give effect to the non-QPA factors.

Second, the close attention Congress paid to the IDR process in general and to the role of the QPA in particular—reflected not only in the legislative record, but also in the care and detail evident on the statute's face, *see* Mot. 14–15—belie the notion that Congress intended the QPA to be given presumptive weight but failed to say so expressly and instead left the requirement to be inferred from the sort of "penumbras and emanations" the Departments rely on. Without question, a QPA presumption is an "elephant" in this scheme. Clear language would therefore be needed to impose it. But the problem is not just the "possibility of clearer phrasing." Opp. 23. It is the absence

of any language *at all* that could be read to require IDR entities always to select the offer closest to the QPA unless additional information "clearly demonstrates" that the QPA "is materially different from the appropriate out-of-network rate." Just as statutory elephants do not hide in mouseholes, they cannot be conjured into existence *ex nihilo*. *See Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 753 (5th Cir. 2011) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself." (quoting *Alexander v. Sandoval*, 532 U.S. 275, 292 (2001))).

The Departments implausibly claim the elephant is "standing in an open field," Opp. 26, but they can do so only by distorting both the issue and plaintiffs' position. The question is not whether the QPA is "a central feature" of the NSA. *Id.* The QPA certainly plays a central role in determining patient cost-sharing—showing yet again that Congress knew how to adopt a benchmark approach when it wanted to. The question, rather, is whether Congress made the QPA presumptively controlling for healthcare provider reimbursement—but without saying so. The question all but answers itself. *Cf.* Opp. 22 (urging use of "common sense"). Nor do plaintiffs contend the QPA is "irrelevant to the arbitration process" or that IDR entities have "free rein to ignore" it. Opp. 26. They can no more ignore the QPA than they can ignore the other statutory factors. It is the Departments, not plaintiffs, who are "attacking a straw man of their own devising." Opp. 22.

C. The Departments' QPA presumption is not implicit in the statute.

As plaintiffs previously showed, the Departments' attempts in the preamble to tease their QPA presumption out from in between the statutory lines all fail. *See* Mot. 17–20. The Departments' efforts to rehabilitate those arguments here fare no better.

To begin, the Departments now contend for the first time that their QPA presumption is implicit in Congress's characterization of the other factors as "additional" circumstances. Opp. 20. But the word "additional" does not mean "less important," "subordinate," or "relevant only in limited circumstances." It means that Congress required IDR entities to consider those factors in

addition to the QPA. By contrast, some bills that Congress did *not* enact used the term "extenuating circumstances." *See* H.R. 2328, 116th Cong. (2020); H.R. 5800, 116th Cong. (2020).[6] Congress's choice of the neutral term "additional" shows that Congress did *not* believe the additional factors should be relevant only to the extent they provide an excuse for departing from the QPA. Here again, the Departments are seeking to read into the Act language that Congress rejected.

The Departments highlight that Congress directed them to report award amounts expressed as a percentage of the QPA and how often awards exceed the QPA. Opp. 22. But these reporting requirements do not require IDR entities to give the QPA presumptive weight. *See* Mot. 20. To the contrary, they cut *against* the Departments' reading because Congress notably did *not* impose these requirements on the parties when reporting their offers to the IDR entity. *Compare* 42 U.S.C. § 300gg-111(c)(5)(B)(i)(I) (requiring parties to submit to the IDR entity "an offer for a payment amount" without any requirement to specify its relation to the QPA), *with id.* § 300gg-111(c)(7)(B)(iii) (requiring the Departments to publicly report the parties' offers "expressed as a percentage of the [QPA]"). Had Congress intended the QPA to exert a gravitational pull within the IDR process, this drafting choice would make little sense. The much better inference is that Congress did not require the parties to report their offers to the IDR entity as a percentage of the QPA because it did not want IDR entities to treat the QPA as the "anchor" for their decisions.

The Departments find it "difficult to imagine" that IDR entities could proceed in any other way. Opp. 21. This says more about the Departments' imagination than it does about the statute. IDR entities can easily treat the QPA as a relevant data point representing a proxy (albeit a significantly flawed one, *see* Compl. ¶¶ 68–71) for the median *in-network* rate for comparable services,

[6] The House Report the Departments cite *passim* related to one of these rejected bills, H.R. 5800. *See* H.R. Rep. No. 116-615 (Dec. 2, 2020).

without treating it as the presumptively correct *out-of-network* rate for the particular services at issue. Even if Congress intended the QPA to be a reasonable "proxy for the in-network price," Opp. 20, nothing supports the Departments' extrapolation that the statute "equates the [QPA] with the reasonable amount of payment" for out-of-network services, *id.* Among other things, "[p]roviders often agree to lower contracted rates in exchange for reimbursement certainty and administrative efficiencies that attend being in a network." Br. for EDPMA *et al.*, Doc. 41, at 13. Additionally, "[i]n exchange for higher volume that comes from being in-network with the payer, providers agree to a lower price per service." Br. for Health Policy Experts, Doc. 85, at 4–5. Thus, comparing in-network and out-of-network rates is not an apples-to-apples comparison. Congress, at least, did not think so. If it had, it could easily have set out-of-network reimbursement at the QPA or made the QPA the default payment amount subject to adjustment only in the event of "extenuating circumstances." But Congress considered and rejected those approaches.

Likewise, if Congress had believed the QPA adequately accounted for the additional factors in the context of a "typical" out-of-network service, Opp. 21, it could easily have constrained IDR entities' consideration of those factors by including the language the Departments have now superimposed on the statute or otherwise indicating that those factors should weigh in IDR entities' decisions only in "unusual cases," *id.*, or "rare instances," 86 Fed. Reg. at 55,997. Or Congress could have subordinated the additional factors to the QPA by making their consideration discretionary such that they need be considered only when the IDR entity concludes that circumstances warrant. Instead, Congress—through the use of the mandatory "shall consider" that applies equally to the QPA and the other factors—required IDR entities to consider the additional circumstances in every case, without any need to clear a heightened burden. *Contra* 86 Fed. Reg. at 56,060 (characterizing the additional factors as "permissible factors" to be considered "when appropriate").

Nor is there any basis for the Departments' assertion that the statute's purpose would be frustrated "if arbitrators were to systematically set out-of-network payment rates higher than the [QPA]." Opp. 22. If that occurred, it would only be because independent arbitrators systematically concluded that the QPA understates the true fair market value of the out-of-network services that come before them. Nothing in the NSA reflects a congressional intent to drive healthcare provider compensation for out-of-network services below fair market value rates. And doing so would trigger a cascade of negative consequences, including fewer in-network providers, industry consolidation that increases healthcare costs, and diminished patient access to care. *See*, *e.g.*, Br. of EDPMA *et al*., Doc. 41, at 14–15; Br. of Action for Health, Inc., Doc. 32, at 4–7; Br. of Physicians Advocacy Inst. *et al*., Doc. 34, at 10–15. Indeed, the Departments themselves recognized that "undercompensation could threaten the viability" of healthcare providers, "lead to additional industry consolidation, potentially driving health costs higher," and result in patients "not receiving needed medical care, undermining the goals of the No Surprises Act." 86 Fed. Reg. at 56,044.

D. The Departments' "interpretation" is not entitled to *Chevron* deference.

The Departments' plea for *Chevron* deference also fails. *Chevron* comes into play only if ambiguity remains after "exhausting all the traditional tools of construction." *Gulf Fishermens Ass'n v. Nat'l Marine Fisheries Serv.*, 968 F.3d 454, 460 (5th Cir. 2020) (cleaned up). There is no ambiguity here—the statute cannot reasonably be read to impose the QPA presumption the Departments engrafted onto it. The Departments' rules do not permit IDR entities to decide cases "in accordance with" the statute's provisions, 42 U.S.C. § 300gg-111(c)(2)(A), but instead impose extrastatutory constraints on IDR entities' ability to consider and give effect to the non-QPA factors. In so doing, they strip IDR entities of the discretion Congress granted them, improperly require them to treat one factor as presumptively controlling, and fundamentally change the "independent," balanced process Congress created into a rubber stamp for the offer closest to the QPA

(which will almost invariably be the payor's offer). Extending *Chevron* to allow agencies to add transformative terms to statutes under the guise of "interpreting" them would stretch the doctrine's constitutional underpinnings—already suspect[7]—beyond the breaking point.

Nor is there any "gap to fill." Opp. 24. Initially, the Departments cannot defend the presumption as an exercise of gap-filling authority because their theory in the rule was that Congress implicitly imposed the presumption in the statute, not that Congress failed to address the issue and so the agencies were free to fill up the "gap." *See Chenery*, 332 U.S. at 196. Regardless, the absence of any provision in the statute requiring IDR entities to treat the QPA as presumptively controlling does not create a "gap." It means the requirement does not exist. *Chevron* does not license agencies to impose new statutory requirements that Congress declined to impose. A statute forbidding "motor vehicles" in a park might allow the administering agency to issue a rule setting forth what counts as a "motor vehicle"; but it would not allow the agency to issue a rule forbidding pets in the park on the theory that Congress left a "gap" regarding pets. So too here. That Congress did not assign weights to the factors does not allow the Departments to make the QPA (or any other factor) presumptively controlling. The Departments' "nothing-equals-something argument is barred by [binding] precedent." *Gulf Fishermens*, 968 F.3d at 460; *see also Earl v. Boeing Co.*, 515 F. Supp. 3d 590, 618 (E.D. Tex. 2021) (explaining the "basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted" (quoting *Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618, 625 (1978))).

[7] *See, e.g.*, *Pereira v. Sessions*, 138 S. Ct. 2105, 2121 (2018) (Kennedy, J., concurring); *Michigan v. EPA*, 576 U.S. 743, 760 (2015) (Thomas, J., concurring); *Gutierrez–Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring). While this Court is of course bound by *Chevron*, plaintiffs preserve for further review the validity of the doctrine if it is applied here.

Chevron deference is inappropriate for two additional reasons. *First*, Congress did not authorize the Departments to issue legislative rules regarding IDR entities' weighing of the statutory factors. *See* Mot. 21–22.[8] The Departments cite their authority to issues rules establishing the IDR process, Opp. 26, but they ignore that Congress carefully specified where implementing rules were needed, Mot. 22 n.7, and did not authorize any rules addressing IDR entities' determination of the payment amount, instead requiring that determination to be made "in accordance with" the provisions Congress itself enacted. 42 U.S.C. § 300gg-111(c)(2)(A). *Second*, "*Chevron* deference is not warranted where the regulation is 'procedurally defective'—that is, where the agency errs by failing to follow the correct procedures in issuing the regulation." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016); *see also N.H. Hosp. Ass'n v. Azar*, 887 F.3d 62, 76 (1st Cir. 2018); *People for the Ethical Treatment of Animals v. U.S. Dep't of Agric.*, 861 F.3d 502, 506–07 (4th Cir. 2017). And, as discussed below, the presumption rules are procedurally defective because they were issued without the notice and comment required by the APA.

E. The policy arguments of the Departments and their *amici* are unavailing.

Finally, the policy arguments advanced by the Departments and their *amici* do nothing to justify the QPA presumption. The question is one of statutory interpretation, and in interpreting statutes, "[i]t is hardly this Court's"—or the Departments'—"place to pick and choose among competing policy arguments" or engage in "freewheeling … policymaking." *Pereida v. Wilkinson*, 141 S. Ct. 754, 766–67 (2021). Congress made the relevant policy choice when it required IDR entities to consider all the statutory factors without presumptions, and "[o]nly that policy choice, embodied in the terms of the law Congress adopted, commands this Court's respect." *Id.* at 767.

[8] The TMA comment letter the Departments cite, *see* Opp. 28, said nothing about the scope of the Departments' authority to issue legislative rules on the weighing of the factors, and in any event would not give rise to any estoppel because TMA's "preferred approach [was not] adopted by the agency." *S. Coast Air Quality Mgmt. Dist.*, 472 F.3d at 892.

That is especially so because the NSA's core policy objective—protecting patients from balance bills and removing them from billing disputes—is not at issue here, only reimbursement disputes between healthcare providers and payors. The Departments and their *amici*, without identifying any language in the statute so providing, contend the NSA was also designed to regulate health insurance premiums. Even if so, that would provide no support for the Departments' rules. Although the Departments' lawyers now assert (in their "Statement of Undisputed Material Facts," no less) that insurers pass on higher reimbursement rates in the form of higher premiums, Opp. 5, the Departments made no finding in the rule that the QPA presumption would have any effect on premiums. *See* 86 Fed. Reg. at 55,996 (stating only that the QPA presumption "will help limit the indirect impact" on premiums "that would occur *if* plans and issuers were to pass higher costs on to individuals in the form of increases in premiums" (emphasis added)); *id.* at 56,060 ("If certified IDR entities choose amounts that are above median in-network rates, this *could* result in a *potential* increase in costs and premiums." (emphases added)). The Departments cannot now ask this Court to uphold their rules based on findings regarding disputed facts that they never made. *See Chenery*, 332 U.S. at 196; *see also* Br. for EDPMA *et al.*, Doc. 41, at 15 (citing evidence of *lower* than average premiums in states whose laws provide for fair reimbursement).

Likewise, the Congressional Budget Office ("CBO") analyses touted by the Departments and their *amici* provide no support for the QPA presumption. The CBO is not Congress, and neither its analyses of proposed bills that never passed nor its post-enactment predictions about how IDR entities would resolve cases have any bearing on the meaning of the statutory text. Moreover, as the Departments explained in the rule, neither the CBO's prediction that the NSA would reduce premiums nor the analysis of CMS's Office of the Actuary predicting that the NSA would increase premiums purported to "isolate the effect attributable to the Federal IDR process," 86 Fed. Reg. at

56,059—let alone the effect attributable to the role of the QPA within the IDR process. The most that can possibly be said is that the CBO assumed out-of-network rates for some healthcare providers would move toward the in-network median, which would hardly be surprising given that the QPA is one of the factors IDR entities must consider. There is no basis to conclude that the CBO scored the law based on the assumption that IDR entities would be required to presume that the QPA is the appropriate out-of-network rate in all cases or to select the offer closest to the QPA unless that presumption is rebutted. *See California v. Texas*, 141 S. Ct. 2104, 2118–19 (2021) (rejecting reliance on CBO predictions that did not "adequately trace the necessary connection").

III. The Departments Unlawfully Bypassed Notice And Comment.

In response to plaintiffs' showing that the Departments lacked good cause for skipping notice and comment, the Departments raise three arguments: (1) that they were not required to provide notice of their proposed rules and consider comments, Opp. 29–31; (2) that doing so would have been impracticable and contrary to the public interest, Opp. 31–25; and (3) that their failure to do so was harmless, Opp. 35–36. All of these arguments are wrong.

A. The Departments' organic statutes do not override the APA's notice-and-comment requirement.

The Departments first contend that they were not required to provide notice or consider comments because their organic statutes authorize them to "promulgate any interim final rules as the Secretary determines are appropriate to carry out" the respective statutes. Opp. 29 (quoting 42 U.S.C. § 300gg-92). This argument has been rejected by every court to consider it. *See Pennsylvania v. President of the U.S.*, 930 F.3d 543, 565–67 (3d Cir. 2019), *rev'd on other grounds sub nom.* 140 S. Ct. 2367 (2020); *California v. Azar*, 911 F.3d 558, 578–80 (9th Cir. 2018); *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 17–19 (D.D.C. 2010). These decisions are correct, and the Departments' recycled arguments here do nothing to undermine them.

The APA itself provides the standard for assessing whether a "[s]ubsequent statute may … be held to supersede or modify" the APA's notice-and-comment requirement—only when "it does so expressly." 5 U.S.C. § 559. The "import of the § 559 instruction is that Congress's *intent to make a substantive change* be clear." *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 745 F.2d 677, 686 (D.C. Cir. 1984) (Scalia, J.); *see also Marcello v. Bonds*, 349 U.S. 302, 310 (1955) (exceptions to the APA "are not lightly to be presumed"). The organic statutes here do not satisfy this exacting standard because they "neither contain express language exempting agencies from the APA nor provide alternative procedures that could reasonably be understood as departing from the APA." *California*, 911 F.3d at 579.

Indeed, the statutory language here contrasts conspicuously with the kind of "express" language Congress uses when it overrides the APA. The Omnibus Consolidated Appropriations Act of 1997, for example, authorized regulations "in the form of an interim final rule" that "shall not be subject to the provisions of section 533 [sic] of title 5, United States Code, regarding notice or opportunity for comment." Pub. L. No. 104-208 § 577, 110 Stat. 3009, 3009-688 (1996); *see also* Pub. L. No. 115-218 § 3, 132 Stat. 1547, 1554 (2018) (directing agency to issue an "interim final rule" within 180 days "[n]otwithstanding the requirements under section 553(b) of title 5"). Similarly, the statutes in the cases the Departments cite expressly provided that the comment period would occur *after* the rules issued. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1236–37 & n.18 (D.C. Cir. 1994); *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998).[9]

[9] The Departments also cite *National Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Service*, 416 F. Supp. 2d 92 (D.D.C. 2006). But that case determined that good cause existed, not that notice and comment were not required. *Id.* at 105.

Against this, the Departments make two arguments, neither of which comes close to showing that their organic statutes expressly override the APA. *First*, they contend that the plain meaning of "interim final rule" just is "a rule issued without notice and comment." Opp. 30–31. Not so. The word "interim" means "temporary" or "provisional." *See, e.g.*, *Interim*, *American Heritage Dictionary of the English Language* (5th ed. 2022). An "interim final rule," therefore, is simply a rule that an agency has officially adopted (making it "final") on a temporary or provisional basis. Such a rule may or may not be preceded by notice and comment. *See, e.g.*, 60 Fed. Reg. 67,298 (Dec. 29, 1995) (interim final rule issued after notice and comment); 56 Fed. Reg. 54,920 (Oct. 23, 1991) (same); 55 Fed. Reg. 50,500 (Dec. 6, 1990) (same). Thus, when Congress authorizes an agency to issue an "interim final rule" without notice and comment, it does not just use that term, but expressly exempts the agency from compliance with the APA. *See supra*, at 21 (citing statutes).

Second, the Departments contend that unless the organic statutes' authorization to issue interim final rules is read to override the APA's notice-and-comment requirement, the authorization would be "surplusage" because the APA already authorizes them to issue interim final rules. Opp. 30. But the APA does not expressly address agencies' authority to issue temporary rules, nor does it provide a standard for when they may be issued. The organic statutes do both, by providing express authority and making clear that it may be exercised whenever the Departments determine that temporary rules "are appropriate to carry out" the statute. 42 U.S.C. § 300gg-92. Moreover, as the Third and Ninth Circuits explained, the interim final rule authorization—again, unlike the APA—exempts the Departments' temporary rules from the interagency consistency requirement that would otherwise apply under the provision's first sentence. *See California*, 911 F.3d at 579–80; *Pennsylvania*, 930 F.3d at 566. The Departments identify no flaw in these courts' reasoning.

Accordingly, the APA's notice-and-comment requirement is fully applicable here, and thus the Departments were required to provide notice and an opportunity for interested parties to comment unless they validly determined that good cause existed for not doing so.[10]

B. The Departments lacked good cause for bypassing notice and comment.

In seeking to defend their good cause determination, the Departments err at the outset by arguing that this Court's review should be "highly deferential." Opp. 15. *Contra* Mot. 12–13 (citing authority for de novo review). The Departments cite *United States v. Johnson*, 632 F.3d 912 (5th Cir. 2011), but while the opinion in that case did not expressly specify whether it was applying the "arbitrary and capricious" or "not in accordance of law" prong of 5 U.S.C. § 706(2)(A), it rejected the agency's good cause determination as "not … persuasive," 632 F.3d at 928—not the sort of language courts typically use when conducting deferential review. And the case law more generally bears out what then-Judge Ginsburg explained long ago—that given the importance of notice and comment and the narrowness of the good cause exception, a reviewing court's "inquiry should be a close one." *Mid-Tex Elec. Coop., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987).

Regardless, under any standard, good cause is lacking here. In arguing to the contrary, the Departments rely extensively on the asserted good cause for parts of the IDR rules not challenged here. *See* Opp. 32–33 (discussing the rules regarding how to initiate the IDR process, what information must be provided, and how IDR entities become certified). Whether there was good cause for other parts of the September IFR is irrelevant. The good cause inquiry is not all-or-nothing; good cause must independently exist for the challenged rules. *See United States v. Garner*, 767

[10] Although they do not themselves so argue, the Departments assert that plaintiffs claimed the challenged rules are merely "[i]nterpretive rules" exempt from the APA's notice-and-comment requirement. Opp. 28 n.8. Plaintiffs never so claimed. The challenged rules are plainly substantive rules because they "effec[t] a substantive change in existing law," *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014), and the Departments "intend[ed] to speak with the force of law," *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 19 (D.C. Cir. 2019).

F.2d 104, 120 (5th Cir. 1985) (not determining whether good cause existed for the "vast number of the [subject] regulations" because it did not exist for the challenged regulation, and a "regulation otherwise subject to section 553 procedures [cannot] piggyback on regulations properly issued" without notice and comment). At least where, as here, the challenged rules are severable from the remainder—as the Departments properly concede they are, *see* Opp. 37—allowing rules for which good cause does not independently exist to "piggyback" on rules for which good cause does exist would allow agencies to evade the APA's foundational notice-and-comment requirement rather than "adher[ing] to [it] scrupulously." *Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015), *aff'd per curiam by an equally divided court*, 136 S. Ct. 2271 (2016) (mem.).

The only rationale the Departments offer that is even arguably aimed at the QPA presumption is their assertion that immediate action was necessary to give insurers sufficient time "to account for the provisions of the interim final rule 'in establishing premium or contribution rates and in making other changes to benefits designs.'" Opp. 32 (quoting 86 Fed. Reg. at 56,044). But as plaintiffs already explained, a desire to provide regulatory guidance sooner is not good cause. *See* Mot. 29–30. The Departments claim that doing so "was required to avoid increasing health care premiums." Opp. 32. But they made no such finding in the rule and thus cannot rely on it here. *See Chenery*, 332 U.S. at 196. And, in any event, a desire to "reduce the costs of health insurance" is "insufficient to establish good cause." *California*, 911 F.3d at 576. Not every worthy policy objective constitutes good cause. Accepting the Departments' contentions here would significantly water down the good cause requirement, which is "intended for true emergencies only," *United States v. Rainbow Family*, 695 F. Supp. 294, 305 (E.D. Tex. 1988), where delay would "do real harm," *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979); *see* Mot. 24 & n.8.

The Departments also have no persuasive response to plaintiffs' other points. As plaintiffs showed, the full year Congress gave the Departments to issue IDR rules was more than sufficient time to allow for notice and comment, and the Departments cannot rely on their own nine-month delay to create good cause. *See* Mot. 25–26. Nowhere in the rule did the Departments assert they "could [not] … have acted sooner" or that the rules establishing the QPA methodology had to be in place "before [the Departments] could move on to incorporate the [QPA] into the rulemaking for the arbitration process." Opp. 34. Even now, the Departments do not explain why they could not have worked on the issues in parallel. In any event, after the July IFR issued, there were still nearly six months until the statutory deadline, enough time to provide notice and comment. The Departments cite statistics showing that on average rulemaking takes longer. *Id.* But they do not explain why they could not have acted faster here. Neither the IDR rules generally nor the QPA presumption rules challenged here are especially "comple[x]," *id.*, especially given the lengths to which Congress went to specify the rules for the process itself, *see* Mot. 6–8. And a year (or even six months) is not an especially "short time frame." Opp. 34. (citing *Petry v. Block*, 737 F.2d 1193, 1200–01 (D.C. Cir. 1984), in which the statutory deadline was 60 days after enactment); *cf. U.S. Steel*, 595 F.2d at 211 (60-day deadline did not provide good cause); *Johnson*, 632 F.3d at 929 (seven months sufficient); *Rainbow Family*, 695 F. Supp. at 305 (six months sufficient).

The Departments' attempt to invoke the statutory deadline is especially misplaced because they issued the September IFR three months *before* the deadline, and five months—or, according to the Departments, *six* months, *see* Opp. 2 (stating arbitrations will begin in April)—before IDR entities would begin hearing cases. In asserting that parties needed "months of lead time," Opp. 32, the Departments do not explain why they should be allowed to second guess Congress's determination that IDR rules issued by December 27, 2021, would provide sufficient lead time. *See*

Mot. 26–27. They point to no changed circumstances Congress was not aware of when it set the deadline. And they provide no other explanation of why they could not have used the three months between release of the September IFR and the statutory deadline to provide notice and comment.

In short, the Departments have identified nothing remotely approaching good cause. Providing notice and comment was neither impracticable nor contrary to the public interest.

C. The error was not harmless.

Nor was the violation harmless. Bypassing notice and comment can be deemed harmless only when "it is clear that the lack of notice and comment did not prejudice the petitioner." *Johnson*, 632 F.3d at 931; *accord U.S. Steel*, 595 F.2d at 215. "An utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure." *Safari Club Int'l v. Zinke*, 878 F.3d 316, 335 (D.C. Cir. 2017). Courts "fin[d] harmless error rarely because the vast majority of agency rulemaking, which produces nuanced and detailed regulations, greatly benefits from expert and regulated entity participation." *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at *5 (E.D. Tex. Jan. 25, 2017) (cleaned up).

The error here was not harmless because it deprived plaintiffs of notice of and an opportunity to comment on both the Departments' proposed rules and the asserted justifications for them. Had the Departments properly noticed proposed rules, plaintiffs could have explained—as they have done in this case—why the statute does not permit the Departments to impose the QPA presumption and why their asserted justifications for doing so are sorely lacking. The Departments' suggestion that notice and comment exist only to allow parties to raise "factual or policy issues," Opp. 36, is misplaced. Parties have every right to raise "purely legal argument[s]," *id.*, regarding the statute's meaning and the scope of an agency's authority, and agencies are obligated to consider and respond to those comments just as they are any others. Here, the Departments did not address *any* objections to their "interpretation," let alone all the points and authorities plaintiffs have raised

here, because they never gave parties an opportunity to raise those objections. *Cf. Johnson*, 632 F.3d at 932 (finding violation harmless where the agency "nevertheless considered the arguments Johnson has asserted and responded to those arguments during the interim rulemaking"). Nor, for that matter, did the Departments address the many significant factual and policy issues raised, *e.g.*, by plaintiffs' *amici* in this case. *See, e.g.*, Br. of Action for Health, Inc., Doc. 32, at 8.

The Departments point to TMA's comment on the July IFR. Opp. 36. But that letter did not and could not respond specifically to the Departments' proposed QPA presumption or the asserted basis for it because TMA had no notice of them. *See Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 382 (5th Cir. 2021) (even when the public is generally aware an agency is considering a matter, "[t]he agency's rationale for the rule must be made clear and subjected to public comment"); *California*, 911 F.3d at 580 (opportunities to comment in a prior rulemaking "are irrelevant" where the "prior rules were materially different").

For the same reason, the Departments err in relying on *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). There, the agency had given notice of its proposed action through a notice issued in a related proceeding, the comments in that proceeding "raised the very issues now raised before this court," and there was not "a single argument" presented to the court "that was not considered by" the agency. *Id.* at 244–45. None of that is true here. *See Dialysis Patient*, 2017 WL 365271, at *5 (rejecting reliance on *City of Arlington* where agency gave no notice at all); *Paulsen v. Daniels*, 413 F.3d 999, 1007 (9th Cir. 2005) (rejecting harmless error because plaintiffs received "no notice of any kind until after" the rule issued).

The Departments wrongly contend that plaintiffs have not suffered prejudice because they did not submit a comment on the September IFR. Opp. 35. TMA did join a comment letter on the September IFR urging the Departments to rescind the QPA presumption as inconsistent with the

statute. *See Concerns with Interim Final Rule Requirements Related to Surprise Billing: Part II implementing the No Surprises Act (NSA)*, Comment ID: CMS-2021-0156-2470 (Nov. 17, 2021). In any event, plaintiffs need not identify any comment they made or would have made had the Departments solicited pre-promulgation comments. "There is no such requirement for harmless error analysis." *California*, 911 F.3d at 580; *accord Johnson*, 632 F.3d at 933; *Safari Club*, 878 F.3d at 335; *United States v. Brewer*, 766 F.3d 884, 891 (8th Cir. 2014). And "'an opportunity to protest an *already-effective rule*' does not render an APA violation harmless." *California*, 911 F.3d at 580–81 (quoting *Paulsen*, 413 F.3d at 1007); *accord U.S. Steel*, 595 F.2d at 214.

In the end, the Departments are left to assert that the error was harmless because "there is no indication that [their] conclusions would have been materially different had they first engaged in notice and comment." Opp. 36. But plaintiffs do not have to identify any "indication" that the Departments would have changed course had they provided notice and comment. That would be an impossible burden and would make notice-and-comment violations virtually always harmless, "gutting the APA's procedural requirements." *Paulsen*, 413 F.3d at 1006; *see id.* ("[A]n agency could always claim that it would have adopted the same rule even if it had complied with the APA procedures."). This is not a case where the result was inevitable because the agency already considered the plaintiff's objections in issuing the rule, *see Johnson*, 632 F.3d at 932; *City of Arlington*, 668 F.3d at 244–45, or because "to heed adverse comments the agency would have had to violate the controlling statute," *United States v. Ross*, 848 F.3d 1129, 1133 (D.C. Cir. 2017). To the contrary, the Department's QPA presumption is *precluded* by the statute, as plaintiffs could have explained to the Departments had they been given notice and an opportunity to comment.

IV. The Court Should Vacate The Challenged Provisions.

If the Court grants summary judgment to plaintiffs on either count, it should vacate the challenged rules. *See* 5 U.S.C. § 706(2) ("[t]he reviewing court shall … hold unlawful and set

aside agency action … found to be" unlawful). In an APA case, vacatur is "by default … the appropriate remedy." *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021), *petition for cert. filed* (U.S. Dec. 29, 2021) (No. 21-954); *see also United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) ("The ordinary practice is to vacate unlawful agency action.").

The Departments ask for remand without vacatur, Opp. 37, but that remedy is reserved for "rare cases," *United Steel*, 925 F.3d at 1287. In assessing such a request, courts consider two main factors: "(1) the seriousness of the deficiencies of the action, that is, how likely it is the agency will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." *Texas*, 20 F.4th at 1000. Both factors strongly militate against remand without vacatur here.

First, the Departments' errors are serious. As to the statutory issue, there is *no* possibility the Departments on remand could justify the challenged rules—the statute precludes them. And as to the notice issue, while the Departments have now taken comment on the September IFR, vacatur is appropriate in light of the seriousness of the error and the need to allow the Departments to consider the issue afresh, without the pressure to continue in effect an approach that IDR entities will already have begun applying. Moreover, if remand without vacatur became the standard remedy in these circumstances, agencies would have no incentive to comply with the requirement that notice and comment must precede the final rule—a requirement designed to allow parties to be heard before the agency has already made up its mind and put a rule into effect. Thus, courts routinely vacate rules, including interim final rules, issued without notice and comment. *See*, *e.g.*, *U.S. Steel*, 595 F.2d at 218 ; *Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir.

2013); *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95–96 (D.C. Cir. 2012); *Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 258 (3d Cir. 2010); *Dialysis Patient*, 2017 WL 365271, at *6.[11]

Second, vacating the challenged rules will not cause disruption. IDR entities have not yet begun hearing cases. And when they do, the only consequence of vacatur will be that they will decide cases under the statute as written without having their hands tied by the Departments' QPA presumption. That is precisely what Congress mandated when it *itself* provided all the guidance to IDR entities it deemed necessary. Regardless, even if additional direction on the weighing of the factors were permissible, its absence is hardly the sort of "serious disruption" that would weigh in favor of allowing an unlawfully issued rule to remain in effect. *Council Tree*, 619 F.3d at 258.

As for the Departments' request for a "tailored" remedy, Opp. 36–37, the request makes no sense where, as here, the remedy sought is vacatur, not an injunction.[12] Vacatur is not a party-specific remedy; it renders the vacated rule null and void and hence unenforceable in all circumstances. *See, e.g.*, *Texas*, 20 F.4th at 957; *Texas v. Biden*, No. 2:21-CV-067, 2021 WL 3603341, at *23–24 & n.12 (N.D. Tex. Aug. 13, 2021); *Am. Min. Cong. v. U.S. Army Corps of Eng'rs*, 962 F. Supp. 2, 4–5 (D.D.C. 1997). Accordingly, if the challenged rules are vacated, they will not bind any IDR entities, regardless of their location or the identity of the parties that come before them.

CONCLUSION

The Court should vacate the challenged provisions of the September IFR.

[11] The error in *Texas Association of Manufacturers*, cited by the Departments, was less serious than the error here. There, the agency provided notice of the proposed rule and took comment, but relied on a different justification in the final rule than in the proposal. *See* 989 F.3d at 381–83. Here, the Departments provided no notice at all before issuing the September IFR, so plaintiffs were unable to comment on either the proposed rule itself or the asserted justifications for it.

[12] Plaintiffs are not currently asking for an injunction because they believe vacatur provides all the relief they need. If the Court vacates the challenged rules but the Departments nonetheless seek to enforce them, plaintiffs will reassess the need for an injunction.

Dated: January 24, 2022

Respectfully submitted,

/s/ *Penny P. Reid*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served on all counsel of record in accordance with the Federal Rules of Civil Procedure and this Court's CM/ECF filing system on January 24, 2022.

/s/ *Penny P. Reid*
Penny P. Reid

EXHIBIT A

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*.	Case No.: 6:21-cv-00425-JDK

DECLARATION OF DR. CHRISTOPHER RYAN COOK

I, Dr. Christopher Ryan Cook, solemnly declare under penalty of perjury and to the best of my knowledge, information, and belief as follows:

1. I am over 18 years of age and with capacity, and I provide this declaration based on my personal knowledge.

2. I am a board certified anesthesiologist, and subspecialty fellowship trained in regional anesthesia, and a member of the Texas Medical Association. I have been in private practice for 12 years, and the last 3.5 years in independent practice in Dallas–Fort Worth. I have cared for and delivered both general anesthetics and regional blocks for orthopedic trauma patients at a Level I Trauma Center, orthopedic oncology patients, patients for cardiac electrophysiology procedures, chronic pain patients for interventional pain procedures to minimize outpatient opioid usage, and morbidly obese patients for robotic bariatric services. A

number of these cases required complex airway management, rapid blood transfusion, and invasive intravascular access. In addition, regional anesthesia was often necessary to avoid general anesthesia, minimize opioid use, and decrease the risk of opioid addiction. The surgeries in which I furnish anesthesia services are often lengthy procedures that can stretch late into the night.

3. I own 100% of Anesthesia and Acute Pain Experts Plano PLLC. My compensation model is based on billing and collecting minus overhead expenses for anesthesia services rendered. This compensation varies based on a number of factors including: volume of cases, payor mixture (e.g., private health insurance versus Medicare), billing company expenses, malpractice premiums, corporate taxation, benefit expenses (including health insurance), accounting, transportation expenses, attorneys' fees, and medical school debt payments.

4. All of the services I provide out-of-network are subject to the No Surprises Act's ("NSA") balance billing prohibition for patients with health insurance covered by the No Surprises Act, such as Texas patients with coverage through an ERISA plan. Some of the out-of-network services I provide qualify as "emergency services" covered under the NSA. Other out-of-network services I provide are non-emergency medical services in which I am out-of-network, but the facility in which I am providing the services is in-network for my patient. Under the NSA, patients cannot consent to being balanced billed for either emergency services or "ancillary services" such as the anesthesiology services I furnish.

5. I routinely see commercially insured patients in my practice, the large majority of whom have coverage that is subject to the NSA's balance billing prohibition, and some of these patients are out-of-network. For example, on January 7, 2022, I provided out-of-network

anesthesia services to four patients covered by ERISA plans. I will continue to provide out-of-network services that are subject to reimbursement through the NSA's IDR process.

6. I have made repeated efforts to enter into network agreements with the commercial insurers of these out-of-network patients, as well as other commercial insurers, but they have not negotiated with me in good faith. For example, attached as Exhibit 1 is a rejection notice I received from a major commercial insurer after recently applying to be an in-network provider.

7. Although I plan to attempt to engage in the NSA's open negotiation process with out-of-network insurers for a reasonable out-of-network reimbursement rate, I expect that open negotiation will not always successfully resolve disagreements over an appropriate rate. In these circumstances, I will work with my administrative staff to submit claims to the NSA's IDR process. A certified IDR entity will then determine the reimbursement rate I receive, as set forth in the NSA and the Departments' regulations.

8. I also expect that the offers I submit for payment amounts will in most cases not be the bid closest to the QPA—this bid will generally be the payor's bid. Indeed, health insurance companies have already indicated they plan to submit bids equal to the QPA. *See, e.g.*, Br. of America's Health Insurance Plans, Doc. 75, at 3 (describing the Departments' "QPA-centric" approach to the IDR process and praising it for making out-of-network rates "more predictable," because "most cases can be resolved by reference to the QPA alone").

9. I do not expect that the question of a reasonable reimbursement rate for the out-of-network services I furnish can in most cases be resolved solely by reference to the QPA. My bid for a reasonable out-of-network reimbursement rate will in most cases be above the QPA for several reasons, including because the manner in which the QPA is calculated will not always

accurately reflect my cost of providing services. Indeed, the QPA will often be well below the true median contracted rate as paid out in the market where I work, Dallas–Fort Worth. In my region, the QPA will reflect the median contracted rate in the Dallas–Fort Worth–Arlington Metropolitan Statistical Area ("MSA"), which spans 11 counties and encompasses "a multitude of urban and rural healthcare settings with very different economic and healthcare market conditions." Comment Letter of Texas Society of Anesthesiology to September 30 IFR, CMS-2021-0156-5267. My costs are higher than those of the rural doctors in this MSA "due to differences in the price of delivering care, patient morbidity, or access to healthcare" in urban versus rural areas in Texas. *Id.* But the QPA does not account for these differences. In addition, I expect to often submit bids for a reimbursement rate above the QPA because many of my patients are covered by health insurance plans with large market shares—especially compared to my market share—and these payors have not engaged in good faith efforts to enter into network agreements with me. I also have broader concerns about the accuracy of QPA calculations. *See Fremont Emergency Services (Mandavia), et al. v. UnitedHealth Group, Inc. et al.*, No. A-19-792978-B (8th Jud. Dist., Clark Cty., Nev.).

10. My experiences are consistent with the descriptions submitted by other physician groups of how the rebuttable presumption in favor of the QPA will drive out-of-network reimbursement rates to the QPA as a de facto benchmark, resulting in financial harm to physicians. *See also, e.g.*, *id.* at 3 (explaining why the "QPA does not accurately capture the broad range of costs, complexities, and acuity of care that underpins in-network contract negotiations").

11. The "rebuttable presumption" in favor of the QPA adopted in the September IFR will therefore make it more challenging for my bid to be selected as the winning bid, as

compared to a process in which IDR entities are free to consider all the statutory factors, without a presumption that the QPA is an appropriate reimbursement amount.

12. Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will thus result in lower reimbursement rates for my services and, correspondingly, will cause my compensation to decrease. In fact, I fear the lower rates will further threaten the viability of small practices like mine, which will likely close in the next six months. Ultimately, this will lead to a loss of access to anesthesiology services as large groups or academic departments will not and cannot fill this void.

13. The "rebuttable presumption" therefore directly harms my financial interests.

Pursuant to the requirements of 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: 1/24/2022

DocuSigned by:
Christopher Cook
125B6B23611E4C7...

Dr. Christopher Ryan Cook

EXHIBIT 1

Begin forwarded message:

From: Aetna Provider Communications <Aetna_ProviderCommunications@provider.aetna.com>
Date: January 19, 2022 at 3:50:35 PM CST
To: [redacted]
Subject: Thank you for your interest in joining Aetna
Reply-To: Provider <reply-fec813787164067f-92_HTML-302321778-515007887-2573@provider.aetna.com>

Trouble viewing this? **Read this email online.**

Thank you for your interest in becoming a participating provider with Aetna.

Request ID: [redacted]
NPI: [redacted]

Dear Healthcare Professional:

Thank you for your interest in becoming a participating provider with Aetna. We regret to inform you that the network in your area is currently at capacity, and we are not accepting new providers in your field of practice at this time.

However, Aetna is constantly evaluating the needs of its networks, and at some point, may decide to add providers in your specialty. In the future, if you would like to find out if we are considering accepting new providers in your specialty, please do not hesitate to contact Credentialing Customer Service at 1-800-353-1232.

Have you thought about joining our First Health network? If interested, please access the application online, and follow the path for First Health which is located in our Other network section.

Again, thank you for your interest in Aetna.

Sincerely,
Network Services

EXHIBIT B

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*.	)	Case No.: 6:21-cv-00425-JDK

DECLARATION OF DR. TU X. DAO

I, Dr. Tu X. Dao, solemnly declare under penalty of perjury and to the best of my knowledge, information, and belief as follows:

1. I am over 18 years of age and with capacity, and I provide this declaration based on my personal knowledge.

2. I am an anesthesiologist, a resident of Dallas, Texas, and a member of the Texas Medical Association. As an anesthesiologist, I provide services at the Level I Trauma Center at the Medical City Plano Hospital. The Trauma Center includes orthopedic, gastrointestinal, and vascular services, as well as interventional cardiac and burn units.

3. I work through, and own, OrthoMed Staffing, LLC ("OrthoMed"), a practice group that provides anesthesiology services, including at Level I Trauma Centers and in rural areas. The rural areas where we provide services—including Yuma, Arizona; Fayetteville,

Arkansas; Paris, Texas; Stockbridge, Georgia; and Murray, Utah—are underserved and have high indigent populations.

4. I own 100% of OrthoMed. The compensation I receive for the medical services I provide is based on the total collections minus expenses received by OrthoMed.

5. All of the services I provide out-of-network are subject to the No Surprises Act's ("NSA") balance billing prohibition for patients with health insurance covered by the No Surprises Act, such as Texas patients with coverage through an ERISA plan. Some of the out-of-network services I provide qualify as "emergency services" covered under the NSA. Other out-of-network services I provide are non-emergency medical services in which I am out-of-network, but the facility in which I am providing the services is in-network for my patient. Under the NSA, patients cannot consent to being balanced billed for either emergency services or "ancillary services" such as the anesthesiology services I furnish.

6. OrthoMed furnishes services to approximately 500 patients per week, and provides out-of-network services to approximately 200 of those patients. At least 60% of those out-of-network patients, such as patients covered by ERISA plans, are now covered by the NSA's rules for out-of-network reimbursement.

7. Since January 1, 2022, after the NSA went into effect, I and other providers who work through OrthoMed have provided out-of-network anesthesiology services subject to reimbursement through the NSA's IDR process, and we will continue to provide out-of-network anesthesiology services that are subject to reimbursement through the NSA's IDR process.

8. Although OrthoMed plans to attempt to engage in open negotiation with these patients' out-of-network insurers for a reasonable out-of-network reimbursement rate, I expect that open negotiation will not always successfully resolve disagreements over an appropriate

rate. In these circumstances, I will work with the OrthoMed administrative staff to submit claims to the NSA's IDR process. A certified IDR entity will then determine the reimbursement rate that OrthoMed receives, as set forth in the NSA and the Departments' regulations.

9. Indeed, because I am certain that I will soon need to use the NSA's IDR process, on January 3, 2022, I preemptively attempted to file a sample request to initiate the IDR Process through a government website. I entered a sample claim and found the website full of errors and nonfunctional tabs. I called the help support desk and the agent did not know the process enough to assist. A supervisor was listening on the line and finally chimed in and apologized for the inadequate portal. In the end, I was only able to enter my name, my email address and phone number, and upload one sample supporting document. I was told I would be contacted by an analyst, which has yet to happen. We were then contacted by the Department of Health and Human Services team the following week to help them troubleshoot the website. I am actively engaging with the Centers for Medicare & Medicaid Services about flaws I encountered in the system during that test.

10. I also expect that the offers I submit for payment amounts will generally not be the bid closest to the QPA—this bid will generally be the payor's bid. Indeed, health insurance companies have already indicated they plan to submit bids tethered to the QPA. *See, e.g.*, Br. of America's Health Insurance Plans, Doc. 75, at 3 (describing the Departments' "QPA-centric" approach to the IDR process and praising it for making out-of-network rates "more predictable," because "most cases can be resolved by reference to the QPA alone"). I do not expect that the question of a reasonable reimbursement rate for out-of-network services furnished by OrthoMed healthcare providers can in most cases be resolved solely by reference to the QPA. My level of training, and the level of training of other OrthoMed doctors, many of whom are fellowship-

trained, is above-average, and the services I provide at a Level I Trauma Center are of above average complexity, including because the acuity of the trauma patients is significant.

11. This is particularly true because the QPA will often be well below the true median contracted rate as paid out in the marketplace. In my practice, this is because the QPA does not take into account the severity of the patient or the difficulty of the surgery, and I treat the patients in the sickest lines of service at a Level I Trauma Center. *See also, e.g.*, Comment Letter of Texas Society of Anesthesiology to September 30 IFR, CMS-2021-0156-5267 (explaining why the "QPA does not accurately capture the broad range of costs, complexities, and acuity of care that underpins in-network contract negotiations").

12. The "rebuttable presumption" in favor of the QPA adopted in the September IFR will therefore make it more challenging for my bid to win, compared to a process in which IDR entities are free to consider all the statutory factors without a presumption that the QPA is an appropriate reimbursement amount.

13. Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will thus result in lower reimbursement rates for my services and, correspondingly, will cause my compensation to decrease.

14. The "rebuttable presumption" therefore directly harms my financial interests.

Pursuant to the requirements of 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: 1/24/2022

Dr. Tu X. Dao

EXHIBIT C

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*.	Case No.: 6:21-cv-00425-JDK

DECLARATION OF DR. STEVEN FORD

I, Dr. Steven Ford, solemnly declare under penalty of perjury and to the best of my knowledge, information, and belief as follows:

1. I am over 18 years of age and with capacity, and I provide this declaration based on my personal knowledge.

2. I am a neuro-anesthesiologist, a resident of Dallas, Texas, and a member of the Texas Medical Association. As a neuro-anesthesiologist, I perform the anesthesia for operations on the brain and spine, while a neurosurgeon performs the surgery. The anesthesia for neurosurgical operation, whether brain or spine, commonly require special anesthesia techniques to facilitate intraoperative neuro-monitoring, which is totally unique to these types of operations and often requires invasive monitoring to maintain hemodynamic stability and manage blood loss. None of these caregiving services are ever provided as telemedicine or from a laptop at

home; they all require in-person, intensive one-on-one interactions between the neuro-anesthesiologist and patient, which begins at the time the patient leaves the preoperative area, continues through the completion of the operation, and remains ongoing while the patient is transferred to a post-anesthesia care unit or intensive care unit after the operation.

3. I work at Optima Anesthesia PLLC, a small practice of four physicians that provide M.D.-only anesthesia services. All physicians are board certified, two of the physicians have had additional formal fellowship training, and I have additional board certification in critical care medicine. Two of us, including myself, were on faculty at large medical schools in the U.S. in the past at the Assistant Professor or Associate Professor level. I received my anesthesia and critical care training from Stanford University.

4. I am one of three owners of this small medical practice. After all expenses are paid—including but not limited to credentialing expenses, scheduling expenses, revenue cycle management expenses, malpractice premiums, cross coverage expenses, profit sharing expenses, legal expenses, banking fees, accounting expenses, hospital privilege expenses, state franchise taxes, arbitration fees, and mediation fees—the remaining revenue is distributed to the three separate professional associations of the three owners. Each professional association has many additional expenses including but not limited to continuing medical education expenses, health insurance premium expenses, transportation expenses, legal expenses, banking expenses, accounting expenses, and retirement plan expenses.

5. All of the caregiving that I and other physicians furnish through Optima Anesthesia PLLC, if provided out-of-network, is subject to the No Surprises Act's ("NSA") balance billing prohibition for patients with health insurance covered through an ERISA plan. Out-of-network non-ERISA patients are generally subject to SB 1264, which is the State of

Texas' version of the NSA and is implemented by the Texas Department of Insurance. Some of the out-of-network services I provide qualify as "emergency services" covered under the NSA. Other out-of-network services I provide are non-emergency medical services in which I am out-of-network, but the facility in which I am providing the services is in-network for my patient. Under the NSA, patients cannot consent to being balanced billed for either emergency services or "ancillary services" such as the anesthesiology services I furnish.

6. Optima Anesthesia PLLC furnishes caregiving services to approximately 40 to 50 patients per week, and provides out-of-network services to approximately 50% of those patients. About 80% of those out-of-network patients are patients covered by ERISA plans, and accordingly they are now covered by the NSA's rules for out-of-network reimbursement.

7. On January 1, 2022, after the NSA went into effect, I and other members of Optima Anesthesia PLLC provided an out-of-network anesthesia caregiving service that is subject to reimbursement through the NSA's IDR process. I will continue to provide out-of-network services that are subject to reimbursement through the NSA's IDR process. In the first two weeks of January 2022, I have personally provided anesthesia caregiving services for operations for multiple patients who were out-of- network and covered by ERISA plans, and my out-of-network reimbursement rate for those caregiving services is subject to the NSA's IDR process. For example, I personally performed one-on-one anesthesia caregiving services for an operation for a total knee replacement performed on a patient with severe degenerative joint disease with multiple coexisting medical problems (including morbid obesity and obstructive sleep apnea). I also personally performed anesthesia caregiving services for a patient as part of an operation to resect a severe chronic lesion involving the patient's skull.

8. Although my medical practice plans to attempt to engage in open negotiation with these patients' out-of-network insurers for a reasonable out-of-network reimbursement rate, I expect that open negotiation will not always successfully resolve disagreements over an appropriate rate. In these circumstances, I will work with Optima Anesthesia PLLC's Revenue Cycle Management, the other physicians in our practice, and our practice management staff to submit claims to the NSA's IDR process. A certified IDR entity will then determine the reimbursement rate that Optima Anesthesia PLLC receives, according to processes set forth in the NSA and the Departments' regulations.

9. I also expect that the offers I would want to submit for reasonable payment amounts will generally not be the bid closest to the QPA—this bid will generally be the payor's bid. Indeed, commercial payors have already indicated they plan to submit bids equal to the QPA. *See*, *e.g.*, Br. of America's Health Insurance Plans, Doc. 75, at 3 (describing the Departments' "QPA-centric" approach to the IDR process and praising it for making out-of-network rates "more predictable," because "most cases can be resolved by reference to the QPA alone"). Commercial health insurance companies create networks for their unjust enrichment. *See Fremont Emergency Services (Mandavia), et al. v. UnitedHealth Group, Inc. et al.*, No. A-19-792978-B (8th Jud. Dist., Clark Cty., Nev.). In my experience, these same commercial payors have been manipulating the in-network median rate in anticipation of the NSA and the IFR. In my experience, they have done so by terminating contracts of providers that have contracted rates not to their liking, unless the physician caregiver agrees to drop their contracted rate, to a deflated rate that is 10, 20, or even 30% less. Our small business medical practice has already seen the effects of this. The median reimbursement rate from commercial payors in the Dallas metroplex (as captured by the Fair Health database for the 50% in-network median

allowed commercial payor rate in the "752" geozip) has dropped by 11% just in the last six months, despite spiking inflation.

10. I anticipate that the bid I would like to make for a reasonable out-of-network reimbursement rate will in many cases be above the QPA, including because the QPA will not always reflect the complexity of the caregiving services provided by myself and other physicians at Optima Anesthesia PLLC or the acuity of the patient. In addition, in my experience, commercial payors often have very large market shares—particularly as compared to my medical practice—and refuse to negotiate appropriate in network payment rates. Despite my good faith efforts, I have been unable to enter network agreements with some of the commercial payors who insure the patients seen by Optima Anesthesia PLLC physicians.

11. My views and experiences are consistent with the descriptions submitted by other physician groups of how the rebuttable presumption in favor of the QPA will drive out-of-network reimbursement rates to the QPA as a de facto benchmark, resulting in financial harm to physicians. *See also, e.g.*, Comment Letter of Texas Society of Anesthesiology to September 30 IFR, CMS-2021-0156-5267 (explaining why the "QPA does not accurately capture the broad range of costs, complexities, and acuity of care that underpins in-network contract negotiations"). The long-term effects on physicians' ability to provide care to patients will be disastrous.

12. The "rebuttable presumption" in favor of the QPA adopted in the September IFR will therefore make it more challenging for my bid to win, compared to a process in which IDR entities are free to consider all the statutory factors without a presumption that the QPA is an appropriate reimbursement amount.

13. Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will thus result in lower reimbursement rates for my services and, correspondingly, will cause my compensation to decrease.

14. The "rebuttable presumption" therefore directly harms my financial interests.

Pursuant to the requirements of 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on:
JANUARY 21ST, 2022

Dr. Steven Ford

Dr. Steven Ford

EXHIBIT D

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*.	)	Case No.: 6:21-cv-00425-JDK

SUPPLEMENTAL DECLARATION OF DR. ADAM CORLEY

I, Dr. Adam Corley, solemnly declare under penalty of perjury and to the best of my knowledge, information, and belief as follows:

1. I am over 18 years of age and with capacity, and I provide this declaration based on my personal knowledge.

2. I am an emergency room physician who resides and practices in Tyler, Texas.

3. I work through Precision Emergency Physicians, PLLC ("Precision"), for which I receive hourly reimbursement for providing emergency medical services. I also own a percentage of a freestanding emergency department in Tyler, Texas ("Tyler FSED"), doing business as Hospitality Health ER, and I receive dividends based on profits from the facility.

4. The services furnished out-of-network by myself and the Tyler FSED are defined as "emergency services" under the No Surprises Act ("NSA") and subject to the NSA's balance

billing prohibition for patients with health insurance covered by the No Surprises Act, such as Texas patients with coverage through an ERISA plan.

5. On a typical day in which I or the Tyler FSED furnish emergency services, at least some of the patients served are commercially insured, out-of-network patients, and of those patients, some are covered by health plans subject to the NSA's balance billing restriction and IDR process.

6. I expect that open negotiation with insurance companies over out-of-network emergency services provided by myself or the Tyler FSED will not always successfully resolve disagreements over an appropriate reimbursement rate. In these circumstances, Precision and the Tyler FSED will submit claims to the NSA's IDR process. A certified IDR entity will then determine the reimbursement rate, according to processes set forth in the NSA and the Departments' regulations.

7. I also expect that the offers submitted for these out-of-network emergency services will in many cases not be the bid closest to the QPA—this bid will generally be the payor's bid. Indeed, health insurance companies have already indicated they plan to submit bids equal to the QPA. *See, e.g.*, Br. of America's Health Insurance Plans, Doc. 75, at 3 (describing the Departments' "QPA-centric" approach to the IDR process and praising it for making out-of-network rates "more predictable," because "most cases can be resolved by reference to the QPA alone").

8. The bid for a reasonable out-of-network reimbursement rate for emergency services provided by myself or the Tyler FSED will in many cases be above the QPA, among other reasons because the Tyler FSED has attempted to become in-network with multiple ERISA plans, but they have refused to negotiate in good faith, including by refusing to return calls or

emails. Many of those ERISA plans also have high market shares, especially as compared to the Tyler FSED. Additionally, in at least some cases, the QPA will not reflect the acuity of the patient who received the emergency services or the complexity of furnishing the emergency services to that patient. *See also, e.g.*, Comment Letter of National Association of Freestanding Emergency Centers to September 30 IFR, CMS-2021-0156-4990.

9. The "rebuttable presumption" in favor of the QPA adopted in the September IFR will therefore make it more challenging for Precision's and the Tyler FSED's bids to win, compared to a process in which IDR entities are free to consider all the statutory factors without a presumption that the QPA is an appropriate reimbursement amount.

10. Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will thus result in lower reimbursement rates for my services and for the services of the Tyler FSED and, correspondingly, will cause my hourly compensation and the value of my stake in the Tyler FSED to decrease.

11. The "rebuttable presumption" therefore directly harms my financial interests.

Pursuant to the requirements of 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: 1/24/2022

Dr. Adam Corley

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*.	)	Case No.: 6:21-cv-00425-JDK

[PROPOSED] ORDER DENYING DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Before the Court is defendants' cross-motion for summary judgment. Being fully advised in the premises, the Court finds that the motion should be **DENIED**.

It is, therefore, **ORDERED** that the motion is hereby **DENIED**.