No. 23-40217

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Texas Medical Association; Tyler Regional Hospital, L.L.C.; Doctor Adam Corley,
Plaintiffs-Appellees,
v.
United States Department of Health and Human Services; Department of Labor; Department of the Treasury; Xavier Becerra, Secretary, U.S. Department of Health and Human Services; Julie A. Su, Acting Secretary, U.S. Department of Labor; Janet Yellen, Secretary, U.S. Department of Treasury,
Defendants-Appellants.

LifeNet, Incorporated; East Texas Air One, L.L.C.,
Plaintiffs-Appellees,
v.
United States Department of Health and Human Services; Xavier Becerra, Secretary, U.S. Department of Health and Human Services; United States Department of the Treasury; Janet Yellen, Secretary, U.S. Department of Treasury; United States Department of Labor; Julie A. Su, Acting Secretary, U.S. Department of Labor; United States Office of Personnel Management; Kiran Ahuja,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Texas

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INTRODUCTION AND SUMMARY

When Congress enacted the No Surprises Act to shield patients from often devastating surprise medical bills, it recognized that some aspects of the new statutory scheme were not self-effectuating. With respect to the Act's creation of a process through which health plans and medical providers can resolve certain payment disputes through arbitration, Congress expressly directed the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (collectively, the Departments) to, among other things, "establish by regulation one independent dispute resolution process . . . under which . . . [an arbitrator] . . . determines . . . the amount of payment" for services the Act covers. 42 U.S.C. § 300gg-111(c)(2)(A). This was not a mere grant of authority but a statutory mandate. Because Congress knew that the framework it had established required elaboration, Congress specified that the Departments were to issue implementing regulations within "1 year." *Id.* The Departments properly discharged the responsibility Congress placed upon them when promulgating the regulatory provisions at issue in this litigation. *See Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (Aug. 26, 2022) (ROA.970-1007).

Plaintiffs fail to give proper effect to this statutory directive. On their telling, Congress afforded the Departments leeway to do little more than adopt

"rules parroting the statutory instruction[s]" to arbitrators. TMA Br. 41. On that view, even a rule that directs arbitrators to begin their analysis with the first factor identified in the statute and to "then" consider what the statute itself terms "additional" factors is somehow impermissible. Likewise, even modest procedural rules that direct arbitrators to disregard information that is non-credible or irrelevant "usurps the discretion that Congress deliberately conferred on the independent arbitrators, rather than the Departments." TMA Br. 63. But it is plaintiffs' own cramped view of Congress's express grant of rulemaking authority that disregards the statutory design. Congress does not direct agencies to expend the considerable resources that go into developing implementing regulations on the expectation that the result will be a copy-paste from the U.S. Code into the Code of Federal Regulations.

Plaintiffs have not only failed to show that the Departments exceeded their express rulemaking authority with these modest regulatory provisions, but they have also failed even to demonstrate the constitutionally minimal injury necessary to support standing. Plaintiffs' theory of standing turns on the premise that the challenged regulatory provisions will lead arbitrators to grant excessive weight to one statutory factor (the "qualifying payment amount" or QPA) in determining the fair value of plaintiffs' services. But the challenged rule expressly directs arbitrators not to apply any presumption in favor of the

QPA, and plaintiffs' speculation that arbitrators will disregard that instruction is unsupported. No remedy—let alone universal vacatur—was appropriate.

ARGUMENT

I. Plaintiffs lack standing.

The Departments demonstrated in their opening brief that plaintiffs lack Article III standing. Plaintiffs' theory of injury hinges on the assumption that even though the rule is indisputably permissible in directing arbitrators to select the value that the arbitrator determines "best represents the value" of the item or service at issue, 45 C.F.R. § 149.510(c)(4)(ii)(A), a handful of subsidiary provisions will lead arbitrators to undercompensate providers. But plaintiffs still fail to identify a cognizable procedural injury, and they have not carried their burden to establish financial injury.

A. As an initial matter, plaintiffs' own description of their alleged procedural injury reveals that it necessarily depends on their ability to establish a likelihood of financial harm attributable to the challenged provisions. Plaintiffs claim to "have standing because the Final Rule deprives them of the process guaranteed by the [Act] and *replaces it with one that threatens plaintiffs' financial interests*." TMA Br. 28 (emphasis added). But as described further below, plaintiffs have failed to establish the predicate for this claim because they have not shown that the challenged provisions actually threaten their

financial interests. And without a non-speculative showing of financial injury, plaintiffs assert, at most, "a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*," which is "insufficient to create Article III standing." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009).

Plaintiffs are also mistaken in asserting they are "excuse[d]" "from 'meeting all the normal standards for redressability and immediacy'" that establish the constitutional minimum for federal jurisdiction. TMA Br. 29 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 572 n.7 (1992)); *see also* Air Ambulance Br. 22-24. Under the procedural injury doctrine on which plaintiffs seek to rely, "the government's failure to comply with the relevant procedural requirements," *Sierra Club v. Glickman*, 156 F.3d 606, 613 (5th Cir. 1998), can be redressed even if a litigant cannot "'prove that if he had received the procedure the substantive result would have been altered,'" *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) (quoting *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002)). In those cases, a litigant who has a concrete injury and establishes that the government has failed to follow a required process, such as notice-and-comment rulemaking, could obtain a court order effectively compelling an agency do-over under the proper procedures—without having to also show that the agency would necessarily

ultimately take a different action after following the correct process. *See, e.g.*, *id.* at 518 (explaining that standing in procedural-injury cases is premised on the "possibility" that, after following proper procedures, the defendant would "reconsider" the substantive "decision" at issue).

Plaintiffs here, by contrast, have asserted a substantive challenge to the Departments' regulations. And they seek a substantive remedy that is a far cry from a redo on procedural grounds: an order vacating the challenged provisions as inconsistent with the No Surprises Act. To obtain that remedy, plaintiffs must satisfy the ordinary standards for redressability and immediacy. Because plaintiffs have "not identified a procedural requirement" that the Departments "violated" and for which they seek a procedural remedy, "this case is not a 'procedural injury' case." *Defenders of Wildlife v. Perciasepe*, 714 F.3d 1317, 1323 (D.C. Cir. 2013).

Plaintiffs mistakenly contend that *Texas v. United States*, 497 F.3d 491 (5th Cir. 2007), concerned "precisely these circumstances." TMA Br. 30. In that case, the State of Texas had suffered the concrete "injury of being compelled to participate in an invalid administrative process." *Texas*, 497 F.3d at 496-98; *see also Axon Enter., Inc. v. FTC*, 598 U.S. 175, 191 (2023) (recognizing that "subjection to an illegitimate [administrative] proceeding" is a cognizable injury). And the redressability requirement was satisfied because

"a judicial invalidation of the [challenged regulations] would give Texas direct relief from being effectively forced to participate in this process." *Texas*, 497 F.3d at 496-98; *see also New Mexico v. Department of Interior*, 854 F.3d 1207, 1217-18 (10th Cir. 2017) (reaching similar conclusion in challenge to these regulations brought by the State of New Mexico). Here, by contrast, it was Congress, not the Departments, that directed plaintiffs and other medical providers to participate in negotiation and arbitration processes to resolve certain disputes regarding compensation for out-of-network health care. And plaintiffs have failed to demonstrate that line-editing the Departments' instructions to arbitrators as to how those proceedings should be conducted would redress any concrete injury.

B. Plaintiffs fare no better in contending that they have established cognizable financial harm. At summary judgment, plaintiffs bore the burden of "'set[ting] forth by affidavit or other evidence specific facts'" demonstrating "'each element [of standing].'" *Texas v. EEOC*, 933 F.3d 433, 446 (5th Cir. 2019) (second alteration in original) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 (1996)). The evidence plaintiffs point to, however, concerns only providers' expectations that their own offers in arbitration will generally be higher than and farther from the QPA than the offers submitted by health plans. *See* TMA Br. 31 (citing ROA.188, 194, 201); Air Ambulance Br. 19-20 (citing ROA.728-

729, 281-287).[1] But that possibility concerns just one of several steps that underpin plaintiffs' claimed financial harm, and plaintiffs' allegations of harm depend on the wholly unsubstantiated assertion that the challenged regulations will lead arbitrators to select values closer to the QPA than they otherwise would have.

Plaintiffs can provide no data that average arbitration awards dropped following adoption of the challenged provisions or otherwise substantiating their claimed financial injury. Instead, they offer only bare assertions that the challenged provisions will adversely affect them. But these assertions are difficult to credit, particularly in light of the fact that plaintiffs do not "take issue" with the Departments' overarching instruction to arbitrators: to select whichever party's offer "'best represents the value'" of the item or service at issue. TMA Br. 41 (quoting 45 C.F.R. § 149.510(c)(4)(ii)(A)). And as the Departments have explained (Opening Br. 25-26), unsupported assertions that arbitrators will understand the regulations to impermissibly favor the QPA cannot be reconciled with the final rule's explicit contrary directive to

[1] The qualifying payment amount, or QPA, is a statutory term of art for a quantitative value approximating the rate the applicable health plan pays its in-network providers for the relevant service. Generally, it is calculated as "the median of the contracted rates recognized by" the health plan on January 31, 2019, adjusted for inflation, 42 U.S.C. § 300gg-111(a)(3)(E)(i). *See* Opening Br. 9-10.

arbitrators *not* to apply a presumption in favor of the QPA. *See, e.g.*, 87 Fed. Reg. at 52,628 (ROA.980). The speculative nature of plaintiffs' injury is further underscored by the modesty of the procedural requirements at issue.

Plaintiffs' evidentiary shortcoming does not "'go[] to the merits rather than standing.'" TMA Br. 31-32 (quoting *Glen v. American Airlines, Inc.*, 7 F.4th 331, 335 (5th Cir. 2021)). This Court cannot simply take plaintiffs' word for it that the challenged provisions "privilege[] the QPA" (TMA Br. 32) in a manner that will predictably affect the decisions of independent arbitrators. Instead, plaintiffs bear the burden of identifying a non-speculative mechanism through which the modest guardrails they sought to vacate will lead arbitrators to systemically disregard the Departments' express directive not to apply any presumption in favor of the QPA, thereby causing plaintiffs financial harm. They have not done so.

Nor can plaintiffs seek refuge (Air Ambulance Br. 16-18) in cases recognizing that standing may be more readily established when "the plaintiff is himself an object of the action (or forgone action) at issue." *Lujan*, 504 U.S. at 561. As those cases recognize, when a challenged agency regulation operates directly on the plaintiff, "there is ordinarily little question" that the regulation "caused [the plaintiff] injury, and that a judgment preventing" that regulation from being applied "will redress" this injury. *Id.* at 561-62. The

regulatory provisions challenged in this case, however, concern the standards to be applied by arbitrators. And as plaintiffs recognize, arbitrators, not providers such as plaintiffs, are the entities that "are legally required to apply" the regulatory provisions at issue in this case. TMA Br. 32. As a result, "much more is needed" to support standing here, as in other cases where the alleged injury depends on decisions of third parties: "causation and redressability . . . hinge on the response" of the arbitrators to the rules set forth in the challenged regulations, and courts "cannot presume either to control or to predict" how the specific provisions plaintiffs challenged will affect arbitrators' "exercise of broad and legitimate discretion," *Lujan*, 504 U.S. at 562 (quotation marks omitted); *see also California v. Texas*, 141 S. Ct. 2104, 2117 (2021). Without evidence that arbitrators' discretionary assessments will be skewed by the challenged regulatory provisions (in contravention of the Departments' express contrary instructions), plaintiffs fail to satisfy Article III's requirements.[2]

[2] In district court, the Departments argued that one of the air ambulance plaintiffs (LifeNet, Inc.) lacks standing for additional reasons. Because it is undisputed that these reasons do not apply to the other air ambulance plaintiff (East Texas Air One, LLC), the Departments have not renewed that argument on appeal. *See Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006); *see also* Air Ambulance Br. 24-25.

II. The final rule comports with the No Surprises Act.

Even if plaintiffs had standing, their claims fail on the merits.

A. The final rule effectuates Congress's instruction to establish "one" arbitration process.

The final rule properly gives effect to Congress's express mandate to the Departments. Congress enacted the No Surprises Act to shield patients from ruinous medical bills after receiving out-of-network care in situations they cannot control, while allowing providers to obtain compensation directly from patients' health plans. To that end, Congress directed that, between the enactment of the No Surprises Act and its effective date, the Departments "shall establish by regulation one independent dispute resolution process . . . under which . . . [an arbitrator] . . . determines . . . the amount of payment" for services covered by the Act, "in accordance with the succeeding provisions" of the Act addressing the dispute resolution process. 42 U.S.C. § 300gg-111(c)(2)(A).

Plaintiffs believe that a variety of details in the final rule, and even isolated words, are inconsistent with Congress's directions. The overarching flaw in plaintiffs' assertions, however, is that they fail to grapple with the Departments' obligation to set forth regulations establishing "*one* independent dispute resolution process." 42 U.S.C. § 300gg-111(c)(2)(A) (emphasis added). Congress recognized that its new statutory scheme would be best served by

ensuring that the details of that process do not vary across the separate private arbitration entities. And Congress placed the responsibility on the Departments to flesh out the details of that single process. The modest regulatory provisions at issue in this litigation further Congress's intent to foster fair, predictable, and transparent arbitration outcomes—which will in turn promote the efficient resolution of plan-provider payment disputes voluntarily. *See, e.g.*, Amicus Br. of America's Health Insurance Plans 8-10 (discussing features of the statute that reflect this congressional purpose). Plaintiffs may wish Congress had left "no room" (TMA Br. 4, 26, 33, 34) for the Departments to set forth sensible and uniform rules for government-certified arbitrators to follow, but that desire is contradicted by the text Congress enacted. As the Departments demonstrated in their opening brief and plaintiffs have failed to rebut, the provisions plaintiffs challenged, both individually and in concert, are all "reasonable in light of the text, nature, and purpose of the statute," *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 276-77 (2016).

The final rule does not "'rewrite clear statutory terms'" or improperly supplement "a 'comprehensive' statutory scheme." TMA Br. 33-34 (first quoting *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014); and then quoting *National Pork Producers Council v. EPA*, 635 F.3d 738, 753 (5th Cir.

2011)). As explained in detail below, each of the challenged provisions is entirely consistent with the statutory provisions detailing the factors that arbitrators "shall consider" as well as factors they "shall not consider." 42 U.S.C. § 300gg-111(c)(5)(C)(i), (c)(5)(D). This appeal therefore bears no resemblance to the cases upon which plaintiffs seek to rely, which involved circumstances in which courts have invalidated agency regulations on the grounds that they: "replaced" a statute's "precise numerical thresholds" with far higher thresholds "of [the agency's] own choosing," *Utility Air Regulatory Grp.*, 573 U.S. at 325-26; "create[d] from whole cloth new liability provisions" for which agency penalties could be imposed beyond a statute's specific list of circumstances where the agency could hold regulated parties liable, *National Pork Producers Council*, 635 F.3d at 752-53; "tack[ed] on additional criteria" to qualify for a statutory exemption beyond the specific criteria Congress had set forth, *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016); or asserted the authority "to grant lawful presence and work authorization" to millions of non-citizens who did not qualify for such relief under Congress's "intricate system of immigration classifications and employment eligibility," *Texas v. United States*, 809 F.3d 134, 184 (5th Cir. 2015), *aff'd by equally divided Court*, 579 U.S. 547 (2016).

In this case, the Departments straightforwardly exercised the authority Congress charged them with fulfilling to ensure that arbitrators would follow a uniform process when resolving disputes consistent with the terms of the No Surprises Act. The Departments used their expressly delegated authority to give a primary directive to arbitrators—to "select the offer that the [arbitrator] determines best represents the value of the . . . item or service" at issue, 45 C.F.R. § 149.510(c)(4)(ii)(A)—that plaintiffs acknowledge was proper. TMA Br. 41. The Departments also gave arbitrators modest subsidiary instructions regarding the process arbitrators should use when weighing the statutory factors relevant to that determination. While plaintiffs disagree with some of these subsidiary instructions, none of these instructions directly conflicts with any provision of the statute. Nothing in the statute indicates that Congress intended for arbitrators to place weight on information that the arbitrator finds irrelevant, non-credible, or duplicative, nor does any statutory provision preclude the Departments from directing those arbitrators to sequence their analysis in a manner consistent with the statute and to provide adequate written explanations of their decisions. Congress has therefore not "directly spoken to the precise question at issue" in this case, *National Pork Producers Council*, 635 F.3d at 752 (quotation marks omitted).

Plaintiffs do not advance their argument by contending that "Congress gave decision[-]making power directly to the *arbitrators*, not to the Departments." TMA Br. 36; *see also* TMA Br. 37-38. Nothing in the rule purports to "dictat[e] how arbitrators should weigh the statutory factors," TMA Br. 36. Instead, the rule repeatedly reaffirms that the arbitrator is the one responsible for making a judgment as to which offer "best represents the value" of the item or service at issue, 45 C.F.R. § 149.510(c)(4)(ii)(A)—a discretionary determination for arbitrators to make, taking into account each of the factors Congress listed, each of which is reiterated in the rule.

Plaintiffs likewise draw the incorrect inference from statutory provisions reflecting other "targeted gaps for the Departments to fill." TMA Br. 35 & n.6. Notably, Congress did not limit the Departments' regulatory authority to the task of filling the specific gaps listed by plaintiffs. Rather, Congress saw fit to grant the Departments additional authority to adopt rules establishing a single dispute resolution process. If Congress had meant to confine the Departments' regulatory authority to filling the handful of expressly identified gaps, it would not have granted the Departments the general regulatory authority at issue in this case.

Finally, plaintiffs fail to identify a material difference between the regulations at issue in this case and the numerous other contexts in which

courts have upheld an agency's reasonable procedural and evidentiary rules to govern adjudications. *See* Opening Br. 48-49. Just as in "agency-conducted adjudications," TMA Br. 38, Congress has assigned the Departments a responsibility to administer the dispute resolution process under the No Surprises Act. Just because the adjudications themselves are conducted by independent arbitrators does not mean Congress left the Departments devoid of any tools to impose "some degree of order" on the processes they have been tasked with administering. *American Hosp. Ass'n v. NLRB*, 499 U.S. 606, 612 (1991) (quotation marks omitted).

B. Each of the challenged provisions is reasonable in light of the text, nature, and purpose of the No Surprises Act

A provision-by-provision analysis confirms that all of the challenged regulatory language falls well within the scope of the Departments' express rulemaking authority.

1. The rule, like the statute, begins with the QPA.

Plaintiffs argue that the Departments lacked authority to instruct arbitrators to consider the first factor listed in the statute—the QPA—and to "then" consider information regarding what Congress itself termed "[a]dditional circumstances." 45 C.F.R. § 149.510(c)(4)(iii)(B); 42 U.S.C. § 300gg-111(c)(5)(C)(i)-(ii). But the Departments were expected to do more than parrot the statute, and plaintiffs are wrong to insist that they were entitled

to have a single word ("then") taken out of the regulatory text, apparently because that word is not in the statute in that location.

As the Departments have explained (Opening Br. 32-33), the regulation simply tracks the statute's structure and sets forth an order of operations that ensures proper effect is given to the various factors listed in the statute and duplicated in the rule. Moreover, in the context of this particular scheme, the Departments recognized that there was good reason to direct arbitrators to begin with the QPA, a figure that—unlike the other factors—(1) is necessarily quantitative, (2) is determinative with respect to patient cost-sharing responsibilities in the contexts relevant to this case, and (3) is not optional for the parties to submit. *See* Opening Br. 10-12. Plaintiffs' objection to the single word "then"—and the district court's agreement—illustrates just how far their arguments go toward effectively nullifying Congress's mandate to the Departments to set out the applicable processes through regulation.

Plaintiffs do not advance their argument by insisting that "Congress knows how to say that one factor in a list is the most important" but did not do so here. TMA Br. 51. As the rule repeatedly makes clear, arbitrators have an obligation *not* to presume that the QPA is the most important consideration while carrying out their task of "select[ing] the offer that . . . best represents the value" of the item or service, 45 C.F.R. § 149.510(c)(4)(ii)(A). *See* 87 Fed. Reg.

at 52,627 (ROA.979) (no "rebuttable presumption in favor of the QPA"); *see also id.* at 52,628 (ROA.980) (reiterating that the final rule does "not require [arbitrators] to default to the offer closest to the QPA or to apply a presumption in favor of that offer"); *id.* at 52,631 (ROA.983) (same). Any analysis of multiple factors will necessarily begin somewhere, and plaintiffs are mistaken to conflate the common-sense instruction to start with the QPA as a direction to give that factor more weight than the "additional" factors arbitrators must also consider, assuming information beyond the QPA is even submitted.

2. The rule appropriately includes the same sort of common-sense evidentiary rules that often apply in dispute resolution processes.

As the Departments have explained (Opening Br. 35-40), several of the provisions plaintiffs challenged simply reflect the same sorts of common-sense guardrails that are found in many dispute resolution processes. These include the rule's directives to avoid placing weight on information that is non-credible, irrelevant, or duplicative. *See* 45 C.F.R. § 149.510(c)(4)(iii)(E); *see also, e.g.*, Fed. R. Evid. 402, 403, 611(b) (provisions of Federal Rules of Evidence that include similar directives); 5 U.S.C. § 556(d) (providing that, in connection with agency hearings conducted under the Administrative Procedure Act (APA), "the agency as a matter of policy shall provide for the

exclusion of irrelevant, immaterial, or unduly repetitious evidence"). Plaintiffs persuaded the district court to conclude that these common-sense directions to arbitrators somehow defy Congress's enactment, but there can be no serious argument that Congress intended to require arbitrators to give weight to submissions of these types. The Departments acted well within their statutory authority in directing arbitrators to adhere to these requirements.

Plaintiffs acknowledge that the Departments had ample authority to promulgate, at a minimum, "rules that make explicit a principle that implicitly constrains any decisionmaker's discretion," TMA Br. 41. Plaintiffs fail to demonstrate, however, that the challenged provisions do anything more than make such common-sense principles explicit—let alone to establish that Congress's express grant of rulemaking authority left the Departments with "no room" (TMA Br. 4, 26, 33, 34) to supplement the statute with reasonable rules such as the ones at issue here. Each challenged provision reflects a reasonable exercise of the Departments' express grant of rulemaking authority.

Credibility requirement. Plaintiffs object to the rule's direction that arbitrators should "evaluate whether" information on non-QPA factors "is credible" and "should not give weight to information to the extent it is not credible." 45 C.F.R. § 149.510(c)(4)(iii)(E). As plaintiffs acknowledge, however, the Departments had ample authority to issue regulations that

include a "prohibition on considering information that is not credible." TMA Br. 41-42; *see also* TMA Br. 58. That concession alone reflects that the district court erred in setting aside the regulatory text providing precisely such a prohibition.

Plaintiffs nevertheless persuaded the district court to delete this requirement because, in their view, the rule should have further directed arbitrators to similarly evaluate the credibility of the QPA on a case-by-case basis. TMA Br. 58-60. Specifically, plaintiffs insist that the credibility requirement is not "evenhanded" because the rule does not direct arbitrators to "consider[] whether the QPA was correctly calculated." TMA Br. 58-59. But as the Departments have explained, it is not the arbitrator's job to police the accuracy of a health plan's QPA calculations—Congress specifically assigned that responsibility to the Departments. Opening Br. 39-40; *see also* 42 U.S.C. § 300gg-111(a)(2)(A). Moreover, as the rule repeatedly makes equally clear, it *is* the arbitrator's job to determine the appropriate payment amount—and to do so without improperly privileging the QPA. 87 Fed. Reg. at 52,627 (ROA.979); *id.* at 52,628 (ROA.980); *id.* at 52,631 (ROA.983). Nothing in the rule precludes providers from submitting evidence that the QPA does not reflect the fair value of their services, nor does the rule inhibit arbitrators from

concluding that the information properly presented to them in the context of a given dispute reflects that the QPA is not the appropriate payment amount.

Plaintiffs' focus on the specter of "incorrectly calculated" QPAs, TMA Br. 59, also suggests that their true concerns have nothing to do with the regulatory provisions challenged in this case. Plaintiffs and their amici harp on several aspects of the "QPA-calculation methodology," TMA Br. 15-16, 47-48; Amicus Br. of Am. Soc'y of Anesthesiologists 13-19; Amicus Br. of Am. Hosp. Ass'n 21-25; Amicus Br. of Physicians Advocacy Inst. 11-14; Amicus Br. of Emergency Dep't Practice Mgmt. Ass'n 17-24. But plaintiffs filed a separate APA lawsuit challenging the same features of that methodology. *See Texas Med. Ass'n v. HHS* (*TMA III*), No. 6:22-cv-450-JDK, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023) (vacating certain aspects of that methodology). The QPA-calculation methodology is not at issue in this appeal, and the specific mechanics through which the figure is calculated have no bearing on the separate procedural and evidentiary provisions that plaintiffs chose to challenge in this earlier-filed case.[3]

Relevance requirement. Plaintiffs have likewise identified no viable basis for deleting the neighboring provisions directing arbitrators to "evaluate

[3] The Departments disagree with the district court's *TMA III* decision and plan to appeal to this Court.

whether" information on non-QPA factors "relates to the offer submitted" by a health plan or provider and that arbitrators then "should not give weight to information to the extent . . . it does not relate to either party's offer for the payment amount" for the particular item or service at issue. 45 C.F.R. § 149.510(c)(4)(iii)(E). Plaintiffs' challenge rests on the premise that the rule "requires arbitrators to ignore evidence" Congress directed them to consider. TMA Br. 54-55. But Congress plainly did not require arbitrators to place weight on information that—in the arbitrator's view, and in the context of the particular dispute before the arbitrator—is irrelevant to the arbitrator's analysis. Indeed, such a requirement would be unfathomable. Plaintiffs thus err in contending there is any "direct[] conflict" between the rule's relevance requirement and "the statutory text," TMA Br. 56.

In attempting to conjure up a conflict with the statute, plaintiffs contend that Congress categorically determined that any information pertaining to the non-QPA factors listed in the statute is "*always*" entitled to meaningful weight in the arbitrator's analysis, leaving no room for an arbitrator's case-specific analysis of relevance. TMA Br. 56. In plaintiffs' view, for example, "a provider's training and experience are always relevant to the appropriate reimbursement rate." TMA Br. 57. Nothing in the Act indicates, however, that when Congress listed several factors for arbitrators to consider in

connection with each dispute, Congress divested the arbitrators of any discretion to reach their own conclusion that, with respect to the specific item or service at issue, one or more of the factors listed in the statute may not meaningfully affect the arbitrator's conclusion regarding the appropriate payment amount. The statute does not, for example, affirmatively require the parties to a given dispute to submit information bearing on each and every one of the often qualitative statutory "[a]dditional circumstances" beyond the QPA. *See* 42 U.S.C. § 300gg-111(c)(5)(C)(ii). It would make little sense to conclude that Congress left it entirely to the parties to determine whether they believe such information is relevant, granting the arbitrators no leeway to conclude in the context of a specific dispute that one or more of these optional pieces of information is ultimately irrelevant to the specific dispute before them.[4]

Perhaps because there is not a viable basis for deleting the relevance requirement itself, plaintiffs also nitpick the rule's second illustrative example, which they believe reflects "an indefensibly narrow reading," TMA Br. 55, 57,

[4] Plaintiffs do not dispute that there was no need for the final rule to specify a similar relevance requirement with respect to the QPA. As the final rule explains, the QPA is relevant to the arbitrator's analysis "'in all cases,'" Opening Br. 37 (quoting 87 Fed. Reg. at 52,627 (ROA.979)). *See* TMA Br. 54 (acknowledging that a "properly calculated" QPA will always be relevant to the arbitrator).

of the regulatory text's relevance requirement. But that example—like the rest of the rule—makes clear that the judgment regarding relevance is vested in "the certified IDR entity," *i.e.*, the arbitrator. 45 C.F.R. § 149.510(c)(4)(iv)(B)(1). Plaintiffs fail in their effort to defend the district court's decision to delete the relevance requirement entirely by quibbling with one of the rule's five concrete examples of how an arbitrator might view a situation described in a set of hypothetical, stylized facts.

Double-counting provision. The rule likewise reasonably directs arbitrators to avoid giving weight to information bearing on the non-QPA factors if the arbitrator finds that such information "is already accounted for by the [QPA] . . . or other credible information" regarding the non-QPA factors. 45 C.F.R. § 149.510(c)(4)(iii)(E). As with the relevance requirement, plaintiffs have failed (TMA Br. 43-45) to identify any conflict between this provision and the No Surprises Act's provisions regarding factors for arbitrators to consider. Congress did not, for example, specify that arbitrators must give information additional weight if the same underlying information is reflected in multiple statutory factors. Nothing in the statutory language compels, or even supports, that counterintuitive result. And as with the credibility requirement, the double-counting provision does not improperly "elevat[e] the QPA." TMA Br. 46. Instead, the double-counting provision works in concert with the rule's

other reasonable provisions to provide arbitrators with a consistent methodology for making their discretionary determinations regarding the appropriate payment amount. As the Departments have explained (Opening Br. 37-38), because the rule permissibly directs arbitrators to begin their analysis with the QPA, the double-counting provision simply reminds arbitrators that as they move through their analysis, they should not place additional weight on information they have already taken into account—whether they took that information into account through the QPA at the first step of their analysis or through their analysis of any of the other factors they may have considered after the QPA.

Plaintiffs' concerns that the double-counting provision is "unworkable" (TMA Br. 46, 47-49) are likewise misplaced. Plaintiffs believe that arbitrators will be unable to apply this provision because health plans (not arbitrators or providers) calculate QPAs, and plaintiffs speculate that arbitrators will be "given almost no information about how the QPA was calculated" and will have "*no way to tell*" whether non-QPA information is duplicative. TMA Br. 46; *see also* TMA Br. 15, 47-49. These assumptions are unsupported and fail to give proper effect to the governing disclosure requirements. *See, e.g.*, 87 Fed. Reg. at 52,625-26 (ROA.977-978) (describing QPA-related disclosure requirements in effect before the final rule and explaining why the same final

rule challenged in this case also included new disclosure requirements in connection with QPAs). Moreover, even if plaintiffs' guesswork were borne out in the context of any particular arbitration, plaintiffs fail to explain why the result would be to "inevitably skew results toward the QPA." TMA Br. 46. If an arbitrator were hypothetically unable to discern whether certain information was already reflected in the QPA submitted in a particular case, the double-counting provision would not even be triggered. *See* 45 C.F.R. § 149.510(c)(4)(iii)(E) (directing arbitrators not to double-count information that, in the context of the arbitrator's analysis, "is already accounted for"—a condition that would not be satisfied if an arbitrator were unable to discern what information the QPA accounted for).

3. The Departments invoked ample authority to direct arbitrators to adequately explain their decisions in writing.

Plaintiffs' challenge to the rule's written-decision requirement is likewise meritless. As the Departments have explained (Opening Br. 41-45), the entire requirement for arbitrators to explain the basis for their decisions should be sustained for two independent reasons, neither of which plaintiffs have persuasively rebutted.

As an initial matter, the Departments appropriately exercised their express statutory authority to direct government-certified arbitration entities to

"submit to the Secretary [*i.e.*, the Departments] such information as the Secretary determines necessary to carry out" the Departments' obligations, 42 U.S.C. § 300gg-111(c)(7)(C). Although the Departments detailed this independent basis for the requirement in both the rule and in their district court briefing, *see* 87 Fed Reg. at 52,631-32 (ROA.983-984); ROA.643, 951-952, the district court did not refer to this source of statutory authority and did not explain how its holding could be reconciled with the provision. *See* ROA.1859. Plaintiffs' efforts to fill that void are unavailing. On plaintiffs' telling, the Departments' reliance on this provision is "incoherent" because, in plaintiffs' view, Congress did not specifically direct the Departments to collect information illuminating "*why* the arbitrator gave weight to non-QPA factors or *why* the arbitrator selected the offer it did." TMA Br. 49-50. But Congress left it to the "the Secretary" to identify the information "necessary to carry out" the Departments' obligations under the No Surprises Act. 42 U.S.C. § 300gg-111(c)(7)(C). And as the Departments have explained, *see* Opening Br. 43-44, the Departments reasonably determined that they would best be able to fulfill several overlapping statutory duties by directing arbitrators to provide an explanation that comprehensively accounts for the arbitrator's rationale in each case.

Moreover, the challenged requirement is independently appropriate as a direct consequence of the reasonable sequencing and double-counting provisions discussed above in Part II.B.2. Plaintiffs do not dispute that the rule permissibly directs a government-certified arbitrator to submit a written decision to the Departments, nor do they take issue with the provision requiring these written decisions to include the "information the [arbitrator] determined demonstrated that the offer selected . . . best represents the value of the [item or service at issue], including the weight given to the [QPA] and any additional credible information" considered as part of the analysis of the non-QPA factors. 45 C.F.R. § 149.510(c)(4)(vi)(A)-(B). Plaintiffs object only to the next sentence of the rule, which states that "[i]f the [arbitrator] relies on information [about the non-QPA factors] in selecting an offer, the written decision must include an explanation of why the [arbitrator] concluded that this information was not already reflected in the [QPA]." *Id.* § 149.510(c)(4)(vi)(B). But an arbitrator who follows the rule's other reasonable provisions and determines that the QPA does not best represent the value of the item or service at issue would necessarily need to include such an explanation to properly satisfy the undisputedly permissible general instruction in the preceding sentence: a description of what information the arbitrator

relied upon to demonstrate that the offer selected best represents the value of the item or service at issue.

Plaintiffs are therefore mistaken in arguing that the rule imposes a "discriminatory," "QPA-favoring explanatory burden." TMA Br. 47, 49. The arbitrator is always required to include an adequate explanation of why the offer selected best represents the value of the item or service at issue. That modest "burden" applies in all cases, not just those where the arbitrator wishes to "give weight to any factor other than the QPA." TMA Br. 46-47. The single challenged sentence merely provides additional clarity as to what that explanation must include in cases where the arbitrator determines that the QPA does not best represent the value of the item or service at issue.

C. Plaintiffs fail to give effect to the Departments' considered decision to excise any QPA presumption.

Plaintiffs' challenge largely hinges on their view that, "taken together," the isolated words and phrases they plucked from the final rule to cobble together the challenge in this case establish a "QPA-centric" arbitration process that differs from the arbitration process Congress set forth. TMA Br. 60-67. Not so. As the rule repeatedly makes clear, arbitrators are under no obligation to defer to the QPA under the final rule. *See, e.g.*, 87 Fed. Reg. at 52,627 (ROA.979) (disclaiming any "rebuttable presumption in favor of the QPA"); *id.* at 52,628 (ROA.980) (reiterating that the final rule does "not

require [arbitrators] to default to the offer closest to the QPA or to apply a presumption in favor of that offer"); *id.* at 52,631 (ROA.983) (same).

These clear directions to arbitrators are hardly "immaterial," nor would arbitrators be free to cavalierly disregard the rule's governing provisions as paying mere "lip service" to the breadth of arbitrators' discretion. TMA Br. 63. To the contrary, the Court is required to apply "a presumption of regularity," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), in evaluating the Departments' assurances that the rule was not implicitly privileging the QPA over the other factors that arbitrators are also required to account for in their analyses. The rule repeatedly highlights the numerous changes the Departments carefully made when superseding the Departments' interim rule. Plaintiffs cannot effectively render those considered amendments a nullity by attacking the strawman of a "QPA-centric" rule. Plaintiffs' challenges ring particularly hollow given that independent arbitrators—not the Departments—are required to apply the final rule's terms as written. Plaintiffs offer no basis to presume that arbitrators would "skew" the process toward the QPA, TMA Br. 60, notwithstanding the rule's repeated instructions to consider each of the statutory factors without placing a thumb on the scale in favor of the QPA.

Nor are plaintiffs correct that the rule replaces the text Congress enacted "with terms that Congress considered and rejected." TMA Br. 66-67; *see also* TMA Br. 12-14 (discussing details of "congressional deliberation"); TMA Br. 36 (referring to Congress's "prolonged and focused legislative debate"); TMA Br. 52 (referring again to "rejected bills that would have subordinated the other factors to the QPA"). Even assuming a QPA presumption would conflict with the No Surprises Act (an issue this Court need not resolve), the final rule at issue in this case expressly excised any such presumption. And the text of the statute Congress ultimately enacted tasked the Departments with the responsibility to issue implementing regulations. That plaintiffs cannot support their arguments even after mining the legislative record—and, of course, "no amount of legislative history can defeat unambiguous statutory text," *Franco v. Mabe Trucking Co.*, 3 F.4th 788, 795 (5th Cir. 2021)—just serves to underscore how flawed their arguments are.

Plaintiffs and their amici also fret that the final rule would place downward "pressure" on healthcare costs. TMA Br. 64; Air Ambulance Br. 20-22; Amicus Br. of Am. Soc'y of Anesthesiologists 19-29; Amicus Br. of Am. Hosp. Ass'n 31-35; Amicus Br. of Physicians Advocacy Inst. 22-26; Amicus Br. of Emergency Dep't Practice Mgmt. Ass'n 24-27. They have failed to demonstrate, however, that any such consequences would be attributable to

the rule rather than the underlying statute. A key impetus for the No Surprises Act, after all, was a "market failure" that was particularly acute in medical specialties where patients had little to no choice in their provider, such as emergency medicine: before the No Surprises Act, a patient's inability to choose a provider in these circumstances led to "highly inflated payment rates," in turn leading to "costs . . . directly felt through higher out-of-pocket expenses and exorbitant surprise bills for out-of-network care, as well as by all consumers who share in rising overall health care costs through higher premiums." H.R. Rep. No. 116-615, pt. 1, at 53 (2020) (ROA.1060); *see also, e.g.*, Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 Am. J. Managed Care 401, 401, 403 (2020) (ROA.1387, 1389) (explaining that "the ability to surprise-bill" for particular services such as emergency care "creates leverage that enables . . . providers" in practice areas conducive to surprise out-of-network billing "to obtain higher in-network payments," and finding that this leverage "has broader effects on health care spending—resulting in commercial health insurance premiums as much as 5% higher than they otherwise would be in the absence of this market failure"); Amicus Br. of Patient and Consumer Advocacy Organizations 12-20 (detailing numerous mechanisms through which out-of-network medical bills can harm patients and consumers). To the extent certain medical providers are

concerned about payment rates that they deem "artificially low" as compared to "pre-[No Surprises Act] rates," Amicus Br. of Emergency Dep't Practice Mgmt. Ass'n 8, they should direct their concerns to Congress, not the courts. *See, e.g.*, 42 U.S.C. § 300gg-111(c)(5)(D) (prohibiting arbitrators from considering, among other things, "usual and customary charges" or "the amount that would have been billed" if the No Surprises Act's protections had "not applied").

III. At the very least, the district court erred in issuing overbroad relief.

As explained, *see* Opening Br. 53-55, the district court's universal vacatur was erroneous.

Even assuming vacatur were an available remedy for a successful APA challenge to a regulation, *but see United States v. Texas*, 143 S. Ct. 1964, 1980-85 (2023) (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment), it does not follow that plaintiffs justified that equitable remedy in the circumstances of this case. Instead, the matter should have been remanded to the Departments without vacatur of the challenged provisions in light of the "disruptive" consequences of vacatur. *See, e.g.*, *Central & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding without vacatur). Consistent with Congress's intent, the district court should have preserved these provisions rather than inviting the costlier and less predictable

proceedings that will occur following the wholesale deletion of the challenged provisions. *See, e.g.*, Amicus Br. of Patient and Consumer Advocacy Organizations 24-27 (discussing the likely consequences for patients and consumers that would flow from leaving the district court's vacatur in effect).

In any event, even assuming vacatur was an appropriate remedy here, the district court erred by extending relief beyond the parties, in contravention of constitutional and equitable principles. Regardless of whether courts *may* vacate agency action universally, they "should 'think twice—and perhaps twice again—before granting' such sweeping relief." *Texas*, 143 S. Ct. at 1985 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) (quoting *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring)). If "party-specific relief can adequately protect the plaintiff's interests," then "an appellate court should not hesitate to hold that broader relief is an abuse of discretion." *Id.* at 1986. That is the case here because nothing about the injuries plaintiffs claim required extending the equitable relief they sought to non-parties.

Plaintiffs contend (TMA Br. 71) that vacatur under the APA inherently operates universally and cannot be limited to specific parties. But no such prohibition on tailored relief appears in the text of the APA, and plaintiffs' position would require a radical departure from "the bedrock practice of case-

by-case judgments with respect to the parties in each case." *Arizona*, 40 F.4th at 396 (Sutton, C.J., concurring). Regardless, if plaintiffs were correct that vacatur must operate universally, that would only underscore that the district court should have forgone vacatur in favor of party-specific equitable remedies. *See* 5 U.S.C. § 703 (authorizing courts reviewing agency action to consider, among other things, "declaratory judgments" or "injunction[s]"). Plaintiffs strain credulity in contending that universal vacatur of the challenged regulatory provisions was somehow "'a less drastic remedy'" than party-specific relief. TMA Br. 71 (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010)). Plaintiffs' authority referred to vacatur as "a less drastic remedy" when compared with the remedy of vacatur paired with the "additional" relief of a redundant nationwide injunction. *Monsanto*, 561 U.S. at 165-66.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

s/ Kevin B. Soter
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CERTIFICATE OF COMPLIANCE

This brief complies with this Court's October 4, 2023 Order permitting a reply brief not to exceed 7,500 words because it contains 7,424 words, excluding the parts of the brief exempted under Rule 32(f). This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Calisto MT 14-point font, a proportionally spaced typeface.

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