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,
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

BRIEF FOR APPELLANTS

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CERTIFICATE OF INTERESTED PERSONS

A certificate of interested persons is not required, as defendants-appellants are all governmental parties. 5th Cir. R. 28.2.1.

s/ Kevin B. Soter
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STATEMENT REGARDING ORAL ARGUMENT

In 2020, Congress enacted the No Surprises Act to shield consumers from the often-devastating effects of surprise medical bills. Invoking that Act's express delegation of rulemaking authority, the government promulgated the regulations at issue in this case. The district court entered a universal vacatur of the challenged provisions of the regulations, which address an important aspect of the Act's implementation. Given the importance of the issues raised, the government believes that oral argument would assist the Court.

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INTRODUCTION

In 2020, Congress enacted the No Surprises Act to shield patients from the often-crippling surprise medical bills that could result from circumstances beyond their control, such as receiving emergency care from a provider outside the patient's health insurance network. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2757-2890 (2020). The Act limits individual patients' potential liability for surprise medical bills while allowing medical providers to seek further compensation from their patients' health plans. To that end, the Act creates a procedure for resolving potential disputes between providers and health plans whereby independent arbitrators determine the value of the relevant services and how much compensation a provider is entitled to receive from a health plan if providers and plans cannot agree.

The statute provides the basic framework for how these arbitrations should proceed and includes, among other things, a list of factors arbitrators must consider when determining the value of a given service. But rather than comprehensively detailing all the procedures applicable to these arbitrations, Congress delegated to the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (the Departments) the task of devising the implementing regulations necessary to

make the arbitration program functional. Specifically, Congress expressly directed the Departments that within one year of the statute's enactment, they must "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 appeal arises from a challenge to the Departments' fulfillment of that Congressional directive. Consistent with Congress's specification that there should be "one" independent dispute resolution process, the Departments devised modest procedural and evidentiary rules for arbitrators to follow in conducting adjudications. These rules are designed to promote uniformity and predictability across arbitrations. The challenged regulations specify that arbitrators should base their determinations of the value of the medical services at issue on precisely the same factors Congress identified in the No Surprises Act itself. The regulations also direct arbitrators to begin by considering the first factor Congress listed and to "then" consider what Congress itself termed "additional factors." And the Departments further directed that an arbitrator should not give weight to evidence regarding those additional factors if the arbitrator finds such evidence not credible, irrelevant, or duplicative.

Plaintiffs, a group of medical providers and providers of air ambulance services, persuaded the district court that the Departments were without statutory authority to promulgate the challenged regulatory provisions. But plaintiffs offer only speculation that the challenged provisions would adversely affect them and, accordingly, plaintiffs cannot establish standing. In any case, the Departments acted well within their express rulemaking authority in providing reasonable guidance to arbitrators that is entirely consistent with Congress's design of the arbitration program. The district court erred in concluding that Congress had left the Departments no role in devising procedures for determining the value of services. And it compounded that error by issuing a universal vacatur of the challenged provisions.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331, 1346(a), 2201-2202, and 5 U.S.C. §§ 704-706. ROA.30 ¶ 21; ROA.660 ¶¶ 20-21. The district court entered judgment for plaintiffs on February 6, 2023. ROA.1869-1870, 2162-2163. The government timely appealed on April 6, 2023. ROA.1871-1872, 2164-2165. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether plaintiffs lack Article III standing to challenge evidentiary and procedural rules regarding arbitrations under the No Surprises Act when plaintiffs' summary judgment evidence does not establish a non-speculative link between the challenged provisions and harm to plaintiffs.

2. Whether the Departments acted within their delegated rulemaking authority in promulgating the challenged evidentiary and procedural provisions.

3. Whether the district court erred in entering a universal vacatur of the challenged provisions.

STATEMENT OF THE CASE

A. Statutory Background

1. Medical services are not provided under uniform pricing models. One provider may charge different patients substantially different amounts for the same services. The amount that a provider will charge for care to a given patient is often dependent on whether the patient has health insurance and, if so, whether the provider has entered into a contract with the patient's health

plan agreeing to provide services to the plan's customers at particular pre-negotiated rates.[1]

The pre-negotiation of rates between plans and providers is a common feature of the health care market. Most health plans have a network of providers who have contractually agreed to accept pre-negotiated payment amounts for particular items or services. *See Requirements Related to Surprise Billing; Part* I, 86 Fed. Reg. 36,872, 36,874 (July 13, 2021) (ROA.1604). These pre-negotiated rates benefit both plan members (who receive lower rates through these negotiated contracts) and providers (who receive preferred access to or patient steering of the potential customer base consisting of the plan's members).

Plans encourage their members to receive care from these "in-network" providers, and when they do so, the patients' financial obligations are limited by the terms of their health plans. When, however, a patient receives care from an out-of-network provider, the provider generally will not have agreed to accept a particular negotiated rate for the service. Moreover, the patient's health plan may decline to pay the provider or may pay an amount lower than

[1] For ease of reference, this brief generally uses "health plans" or "plans" to refer to both group health plans and health insurance issuers, and generally uses "providers" to refer to providers (including providers of air ambulance services) and health care facilities.

the provider's billed charges, leaving the patient potentially responsible for the balance of the bill. *See* 86 Fed. Reg. at 36,874 (ROA.1604). And because the rate charged was not pre-negotiated by the patient's health plan, this practice of "balance billing" may result in the patient being personally held responsible for immensely more than the same service would have cost had a pre-negotiated rate been applicable.

Balance billing of individual patients raises particular concerns in circumstances where the patient has little or no opportunity to choose between an in-network and out-of-network provider. A patient in an emergency situation will often be unable to choose whether to receive care from an in-network provider. Likewise, even patients who try to receive services from an in-network facility (like a hospital) will sometimes nonetheless receive care from an out-of-network provider (such as a radiologist or anesthesiologist) who is working as an independent contractor at the in-network facility. Under those circumstances, a patient with health insurance could receive a potentially crippling surprise medical bill. *See* 86 Fed. Reg. at 36,874 (ROA.1604).

"The financial liability imposed on patients by surprise medical bills can be staggering." H.R. Rep. No. 116-615, pt. 1, at 52 (2020) (ROA.1059). As Congress recognized, "[t]hese unexpected medical bills can result in financial ruin, as nearly four in ten American adults are unable to cover a $400

emergency expense, yet the average surprise balance bill by emergency physicians in 2014 and 2015 was an estimated $620 greater than the Medicare rate for the same service." *Id.* (citations omitted). The potentially devastating effects on patients are well documented. *See, e.g.*, *id.* (referring to a "shocking" example of "a spinal surgery patient who received a bill of $101,000 despite having confirmed that her surgeon was in-network"); Erin C. Fuse Brown et al., *The Unfinished Business of Air Ambulance Bills*, Health Affairs Forefront (Mar. 26, 2021) (ROA.1422) (noting that "[m]edian charges for a rotary-wing air ambulance transport spiked over the past decade, nearly tripling from $12,500 to $35,900 between 2008 and 2017"). Moreover, surprise billing can systematically cause health care costs to spiral upward for all consumers, including those who do not themselves receive out-of-network services. *See, e.g.*, Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 Am. J. Managed Care 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").

During the 2010s, the phenomenon of surprise medical billing was on the rise. *See, e.g.*, Eric C. Sun et al., *Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals*, 179 JAMA Internal Med. 1543, 1544 (2019) (ROA.1568) (study finding that out-of-network billing had "becom[e] more common and potentially more costly" between 2010 and 2016).

2. In 2020, Congress enacted the No Surprises Act to combat the growing crisis of surprise medical bills. 134 Stat. at 2757-2890 (codified in relevant part at 42 U.S.C. § 300gg-111 *et seq.*).[2] The No Surprises Act protects insured patients from unexpected liabilities arising from common forms of balance billing. As described further below, in circumstances where it applies, the No Surprises Act caps an individual patient's share of liability to an out-of-network provider at an amount comparable to what the individual would have

[2] For ease of reference, this brief cites the Act's amendments to the Public Health Service Act and the regulations implemented by HHS. The Act made parallel amendments to the Employee Retirement Income Security Act (administered by the Department of Labor) and the Internal Revenue Code (administered by the Department of the Treasury), and the implementing regulations likewise contain parallel provisions implemented by the different Departments. The Act also affects the Office of Personnel Management (OPM) by requiring, in a provision not directly relevant to this case, that OPM's contracts with the Federal Employees Health Benefits Program require the carrier to comply with applicable provisions of the No Surprises Act. *See* 5 U.S.C. § 8902(p).

owed had she received care from an in-network provider.[3] The No Surprises Act also creates procedures that allow the provider to seek further compensation from the patient's health plan. Those separate procedures further Congress's goal of "taking the consumer out of the middle" of billing disputes. *See* H.R. Rep. No. 116-615, pt. 1, at 55 (ROA.1062) (quotation marks omitted).

Because provider rates are usually not standardized, and because the Act is specifically addressed to circumstances in which the provider and health plan have not pre-negotiated the applicable rates, Congress devised a means for establishing the amounts that could be recovered by the provider from the individual patient and the health plan respectively.[4] Congress determined that a relevant consideration in each of these calculations would be what the statute

[3] The circumstances where these protections apply include: (1) when an insured patient receives emergency care, *see* 42 U.S.C. § 300gg-131; (2) when an insured patient receives certain non-emergency services at an in-network facility but is nevertheless furnished certain services by an out-of-network provider such as an anesthesiologist or radiologist, *see id.* § 300gg-132; and (3) when an insured patient is transported in an air ambulance by an out-of-network provider, *see id.* § 300gg-135.

[4] In some circumstances, the No Surprises Act looks to State law or to a State All-Payer Model Agreement under 42 U.S.C. § 1315a to supply the relevant payment rates. *See* 42 U.S.C. § 300gg-111(a)(3)(H)(i), (iii), (a)(3)(K)(i), (iii). This appeal concerns circumstances where those provisions are inapplicable; accordingly, the discussion that follows does not address circumstances where those provisions are applicable.

terms the "qualifying payment amount" or "QPA," which for a given health plan and service is generally "the median of the contracted rates recognized by" the health plan on January 31, 2019 (before the Act went into effect), adjusted for inflation. 42 U.S.C. § 300gg-111(a)(3)(E)(i). The QPA essentially approximates the total amount that the provider would have received under the terms of the patient's health plan had the provider been in-network. It is typically derived from the amounts the applicable health plan actually agreed to pay its in-network providers for the relevant service before the Act's protections against surprise billing took effect, selecting from those amounts a representative value (the median), and adjusting that representative value for inflation.

The QPA is a factor in determining the respective payment obligations of both patients and health plans under the No Surprises Act, but it is used differently in these two determinations. As to patients, the QPA plays a dispositive role in determining the patient's cost-sharing responsibility. A patient's cost-sharing requirement must be calculated as if the total charge were no greater than the QPA, and the patient's cost-sharing requirement cannot exceed the requirement that would apply if the services had been provided by an in-network provider. 42 U.S.C. § 300gg-111(a)(1)(C)(ii)-(iii), (a)(3)(H)(ii),

(b)(1)(A)-(B).[5] For example, if the QPA for a given service is $1,000 and the patient's health insurance policy would have required her to pay a coinsurance rate of 20% for receiving that service in-network, the patient's responsibility would be capped at $200, assuming she had met her deductible.[6]

The Act's procedures for determining a health plan's payment obligation include additional steps, and also use the QPA as a significant consideration. After a provider submits a bill for its out-of-network service to the health plan, the plan must respond by either issuing an initial payment or a notice of denial of payment; if the provider is dissatisfied with the plan's response, the provider may initiate a "30-day period" of "open negotiation." 42 U.S.C. § 300gg-

[5] Separate provisions of the Act create a parallel process applicable to air ambulance providers. 42 U.S.C. § 300gg-112. Many of the parallel statutory requirements are identical in relevant part. For air ambulance services, the Act specifies that a patient's cost-sharing responsibilities are calculated based on the rates "that would apply" to in-network air ambulance services. *Id.* § 300gg-112(a)(1). Through a regulation not at issue in this case, the Departments have specified that the QPA should be used as the maximum rate that would apply when determining the patient's responsibility for air ambulance services. 45 C.F.R. § 149.130(b)(2).

[6] The patient's responsibility in this example would be less than $200 if the provider had billed the service at an amount lower than the QPA of $1,000. *See* 42 U.S.C. § 300gg-111(a)(1)(C)(iii), (b)(1)(B) (requiring calculation of the cost-sharing requirement "as if the total amount that would have been charged . . . were equal to the recognized amount," a term of art under the statute); 45 C.F.R. § 149.30 (defining "recognized amount" for the purposes relevant to this case as "the lesser of" the QPA or the "amount billed by the provider or facility").

111(a)(1)(C)(iv), (b)(1)(C), (c)(1)(A). The Act thus reflects Congress's recognition that a negotiated resolution between the provider and the health plan may be an efficient method for determining a payment amount.

When, however, the dispute remains unresolved after the open negotiation period, the plan and provider may proceed to an independent dispute resolution process, where an arbitrator working for an entity certified under a government-established process will establish how much the plan is to pay the provider. 42 U.S.C. § 300gg-111(c)(1)(B), (c)(4)(A). The Act relies on "baseball-style" arbitration: the provider and the health plan each propose a payment amount, along with their justification, and the arbitrator is required to select one of the two proposals. *Id.* § 300gg-111(c)(5)(A)(i).

Congress directed that in determining which of the two proposals to select, arbitrators "shall consider—(I) the [QPAs] for the applicable year for items or services that are comparable" to the item or service at issue; "and (II) . . . information on any circumstance described in" a list of "[a]dditional circumstances," as well as any information "relating to" a party's offer that is either requested by the arbitrator or submitted by the party. 42 U.S.C. § 300gg-111(c)(5)(C)(i)-(ii), (c)(5)(B)(i)(II), (c)(5)(B)(ii). The list of "[a]dditional circumstances" for arbitrators to consider includes, for example, the provider's level of training and experience and the acuity of the patient or complexity of

the procedure. *Id.* § 300gg-111(c)(5)(C)(ii).[7] The arbitrator's decision is binding on the parties and is not subject to judicial review except under circumstances described in the Federal Arbitration Act. *Id.* §§ 300gg-111(c)(5)(E), 300gg-112(b)(5)(D).

Once a final amount has been identified either through agreement between the parties or an arbitration decision, the health plan must pay the provider the final identified value for the services, offset by the patient's cost-sharing obligation and any amounts already paid by the plan. 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D). Thus, to return to the example of a service where the patient's coinsurance obligation is 20% and the QPA is $1,000 (and the amount billed by the provider is more than $1,000), the negotiation and arbitration process would have no effect on the patient's $200 obligation; the patient has been taken out of the middle of the billing dispute, and what is instead at stake is the amount that the plan owes the provider.

B. Regulatory Background and Prior Proceedings

Congress, recognizing that the statutory provisions creating the independent dispute resolution process would require further elaboration,

[7] The list of the specific "additional circumstances" for arbitrators to consider in resolving disputes regarding air ambulance services differs somewhat, though there is some overlap. *See* 42 U.S.C. § 300gg-112(b)(5)(C)(ii).

expressly directed the Departments to flesh out certain details. For example, Congress directed the Departments to "establish through rulemaking" the methodology for calculating QPAs. 42 U.S.C. § 300gg-111(a)(2)(B). Congress also directed the Departments to "establish a process to certify" independent dispute resolution entities that would conduct the arbitrations called for under the Act. *Id.* § 300gg-111(c)(4). And, as most relevant here, Congress required that within one year of the No Surprises Act's enactment, the Departments must "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. *Id.* § 300gg-111(c)(2)(A). This litigation involves a challenge to regulatory provisions promulgated pursuant to that express statutory authority.

1. In October 2021, the Departments promulgated an interim final rule establishing the arbitration process for resolving payments between health plans and providers. *See Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021). This October 2021 rule included what the Departments described as a "rebuttable presumption that the QPA is the appropriate payment amount." *Id.* at 56,060. Specifically, the regulatory text provided that in selecting between a plan's offer and a provider's offer,

arbitrators "must select the offer closest to the [QPA] unless the [arbitrator] determines that credible information submitted by either party . . . clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate," or unless "the offers are equally distant from the [QPA] but in opposing directions," in which case the arbitrator should select the offer that "best represents the value" of the item or service. *Id.* at 56,128 (provision previously codified at 45 C.F.R. § 149.510(c)(4)(ii)(A)).

The October 2021 rule was successfully challenged in litigation filed by several medical providers (who overlap with plaintiffs here). *See Texas Med. Ass'n v. HHS* (*TMA I*), 587 F. Supp. 3d 528, 549 (E.D. Tex. 2022); *LifeNet, Inc. v. HHS* (*LifeNet I*), 617 F. Supp. 3d 547, 563 (E.D. Tex. 2022). As relevant here, the district court in that prior litigation held that the Act's provision requiring arbitrators to consider both the QPA and any information regarding the "additional considerations" listed in the statute precluded the regulation's rebuttable presumption that the QPA was the appropriate payment amount. *See TMA I*, 587 F. Supp. 3d at 535-36. The district court entered a universal vacatur of the provisions of the rule that effectuated this presumption in favor of the QPA, as well as parallel provisions of the air ambulance-specific rule that had been challenged in a separate lawsuit. *See id.* at 549; *LifeNet I*, 617 F. Supp. 3d at 563.

2. In response to those district court decisions as well as comments on the interim final rule, the Departments promulgated the August 2022 final rule at issue in this case. *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (Aug. 26, 2022) (ROA.970-1007). The final rule supersedes the provisions at issue in the prior litigation and "does not include the provisions that the District Court" in *TMA I* and *LifeNet I* had vacated. *Id.* at 52,627 (ROA.979). And the final rule explains that it is "not intended to impose a rebuttable presumption" in favor of the QPA. *Id.* Under the final rule, the overarching standard for arbitrators directs them to "select the offer that the [arbitrator] determines best represents the value" of the item or service. 45 C.F.R. § 149.510(c)(4)(ii)(A).

To provide arbitrators with guidance in making these determinations, and to "encourage[] a consistent methodology for evaluation of information when making a payment determination," 87 Fed. Reg. at 52,627 (ROA.979), the final rule sets forth certain procedures arbitrators must follow in assessing which offer best reflects the value of the services at issue. Three sets of provisions are most relevant to this case.

First, the arbitrator is to consider the QPA and "then" consider information regarding the additional statutory factors, if the parties elect to submit any such additional information. 45 C.F.R. § 149.510(c)(4)(iii)(A)-(B).

Second, in considering additional evidence beyond the QPA, the arbitrator "should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount . . . or it is already accounted for by the [QPA]." 45 C.F.R. § 149.510(c)(4)(iii)(E); *see also id.* § 149.520(b)(3) (similar language contained in parallel provision that is specific to air ambulance arbitrations). Based on these requirements, the rule also includes certain illustrative examples of when it would or would not be appropriate for the arbitrator to select an offer equal to the QPA depending on whether additional information submitted by a party is credible, relevant, and not otherwise accounted for in the QPA. *Id.* § 149.510(c)(4)(iv). The rules include five illustrative examples in total, only two of which describe circumstances where the QPA identified as applicable by the health plan would accurately reflect the value of the services. *See id.* § 149.510(c)(4)(iv)(B), (C).

Finally, if the arbitrator relies on information beyond the QPA, the arbitrator's written decision "must include an explanation of why the [arbitrator] concluded that this information was not already reflected in the [QPA]." 45 C.F.R. § 149.510(c)(4)(vi).

3. Plaintiffs, who include a trade association of Texas medical providers, two medical providers, and two air ambulance providers, brought

suit under the Administrative Procedure Act (APA) challenging the provisions of the August 2022 final rule described above (including the illustrative examples and the analogous provisions applicable to air ambulance providers). Plaintiffs alleged that the Departments were without regulatory authority to promulgate the challenged provisions.

On cross-motions for summary judgment, the district court granted summary judgment to plaintiffs and entered a universal vacatur of each of the challenged provisions. After concluding that plaintiffs had established Article III standing based on procedural and financial injuries, ROA.1850-1856, the court held that the challenged regulatory provisions exceeded the Departments' authority under the Act, ROA.1857-1864. In the district court's view, the rule impermissibly "place[s] a thumb on the scale for the QPA." ROA.1860. The court acknowledged that the final rule lacks any "explicit presumption in favor of the QPA." ROA.1860. But the court believed that the Departments "have not relinquished their goal of privileging the QPA, tilting arbitrations in favor of insurers, and thereby lowering payments to providers." ROA.1864. The court concluded that whereas the Act "requires arbitrators to consider all the specified information in determining which offer to select" (that is, the quantitative QPA as well as the generally qualitative additional circumstances listed in the statute), the final rule privileges the QPA "by

requiring arbitrators to begin with the QPA and then imposing restrictions on the non-QPA factors that appear nowhere in the statute." ROA.1859-1860. The court rejected the Departments' argument that the final rule merely establishes "'reasonable evidentiary and procedural rules'"—for example, directing arbitrators not to place weight on information that is not credible, not relevant, or double-counts information already reflected in the QPA. ROA.1861. Finally, the court granted plaintiffs' request for universal vacatur of the challenged provisions. ROA.1864-1866.

SUMMARY OF ARGUMENT

Congress expressly tasked the Departments with developing the implementing regulations necessary to make the No Surprises Act's arbitration system operative. Consistent with that directive, and in furtherance of Congress's desire for a uniform arbitration system, the Departments promulgated modest procedural and evidentiary rules to guide arbitrators in applying the factors that the No Surprises Act itself identifies as pertinent to the determination of the value of medical services. These rules were duly promulgated through the APA's rulemaking procedures. And there is no allegation that any provision of the regulations is in express conflict with any provision of the statute.

Plaintiffs do not challenge the final rule's overarching direction that arbitrators should exercise their discretion to select the offer that best represents the value of the disputed item or service, nor do they challenge its requirement that arbitrators explain their decisions. Instead, they persuaded the district court to vacate provisions that, in plaintiffs' view, improperly elaborate on the arbitration process set forth in the statute. The district court agreed, concluding that Congress left the Departments no room to guide arbitrators in applying the statutory factors, notwithstanding Congress's express directive to the Departments to craft implementing regulations.

As an initial matter, plaintiffs failed to establish Article III standing. Plaintiffs themselves recognize that at least some of the challenged provisions—which, for example, direct arbitrators not to consider information that is not credible or not relevant—merely require arbitrators to analyze disputes the same way they would have even without the rule. Plaintiffs speculate that the provisions may nonetheless systematically skew arbitration outcomes, but they offer no evidence to support that assertion. And plaintiffs cannot fall back on an alleged procedural injury; they have substantively attacked the outcome of a rulemaking process and are not making a challenge to the process by which the rule was promulgated.

On the merits, the Departments acted well within the express rulemaking authority Congress directed them to exercise. The modest provisions at issue provide reasonable guidance to arbitrators and do not in any respect conflict with Congress's design of the Act's arbitration program. Plaintiffs' objections to these provisions share a common flaw: under black-letter administrative law principles, when a statute expressly delegates authority to an agency to flesh out the details of a government program through rulemaking, an agency has the authority—indeed, in this case, the statutory mandate—to adopt "rules that are 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). That principle should have led the district court to reject plaintiffs' challenges. But instead, the court relied on an unduly narrow view of the Departments' rulemaking authority. The district court appears to have treated the final rule with skepticism because the interim final rule that it replaced had included an evidentiary presumption that plaintiffs believed was still lurking beneath the surface of the final rule. But that reasoning fails to give proper effect to the Departments' considered judgment to explicitly remove that very evidentiary presumption and to emphasize this deletion as a key feature of the final rule.

Finally, the district court compounded these errors by issuing the unwarranted remedy of universal vacatur of the challenged provisions.

STANDARD OF REVIEW

In challenges to agency action, this Court reviews the district court's grant of summary judgment de novo, applying the standards of the APA. *Texas Sav. & Cmty. Bankers Ass'n v. Federal Hous. Fin. Bd.*, 201 F.3d 551, 553-54 (5th Cir. 2000). Agency actions pursuant to an "express delegation of authority" must be "given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Easom v. U.S. Well Servs., Inc.*, 37 F.4th 238, 245 (5th Cir. 2022) (quotation marks omitted); *see also* 5 U.S.C. § 706(2)(A).

ARGUMENT

I. Plaintiffs lack Article III standing to challenge provisions of a rule whose effect on plaintiffs is at best speculative.

To invoke the federal courts' jurisdiction, plaintiffs "must satisfy the familiar tripartite test for Article III standing: (A) an injury in fact; (B) that's fairly traceable to the defendant's conduct; and (C) that's likely redressable by a favorable decision." *E.T. v. Paxton*, 41 F.4th 709, 714 (5th Cir. 2022) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). As the parties invoking federal jurisdiction, plaintiffs bear the burden of supporting each element of their standing in accordance "'with the manner and degree of evidence required at'" this "'stage[] of the litigation.'" *Texas v. EEOC*, 933 F.3d 433, 446 (5th Cir. 2019) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 (1996)). At

the summary judgment stage, plaintiffs bore the burden of "'set[ting] forth by affidavit or other evidence specific facts" demonstrating "'each element [of standing].'" *Id.* (second alteration in original) (quoting *Lewis*, 518 U.S. at 358). The district court concluded that plaintiffs had adequately established standing through their assertions of both procedural and financial injury from the Departments' promulgation of final regulations implementing the No Surprises Act. ROA.1852-1855. Neither theory withstands scrutiny.

A. The district court first found that plaintiffs had adequately alleged standing through their claim of the procedural injury of being "deprive[d] . . . of the arbitration process established by the Act." ROA.1852 (quotation marks omitted). But the district court misunderstood the scope of the "procedural injury" strand of standing doctrine. That body of law stands for the proposition that certain standing requirements are applied less stringently when a plaintiff alleges that an agency failed to follow the correct procedures when taking the challenged agency action. *See Texas v. EEOC*, 933 F.3d at 447. A paradigmatic example of a procedural injury is an alleged "violation of the APA's notice-and-comment requirements." *Id.*

Here, by contrast, plaintiffs allege no defect in the procedures through which the challenged rule was promulgated. There is no dispute that the August 2022 final rule was issued after accounting for comments on an earlier

interim final rule and that the Departments followed the APA's procedural requirements in promulgating the final rule. Plaintiffs' objections to the final rule are strictly substantive. The happenstance that the disputed substantive provisions of the rule relate to the procedures to be used in arbitrations conducted under the No Surprises Act does not mean that plaintiffs have alleged a procedural injury.

B. Plaintiffs' evidence also does not establish standing based on financial harm. Plaintiffs' theory of injury involves the role played in arbitrations by the QPA—the approximation of how much the health plan pays its in-network providers and the first of the factors that the No Surprises Act directs arbitrators to consider when determining the value of items and services. *See* 42 U.S.C. § 300gg-111(c)(5)(C)(i)(I). Plaintiffs' belief that they will be harmed financially depends on the supposition that the challenged provisions of the final rule will make arbitrators more likely than they would be in the absence of these regulatory provisions to determine that the QPA represents the fair value of the services at issue. Because providers generally expect to claim values that are higher than and farther from the QPA than the offers submitted by health plans, providers would allegedly be injured by a rule that privileged the QPA. *See, e.g.*, ROA.201-202 ¶¶ 12-13, 17.

Plaintiffs have not carried their burden of establishing injury because their argument is entirely speculative. *See Lujan*, 504 U.S. at 560 (finding "conjectural" and "hypothetical" injury insufficient to establish standing (quotation marks omitted)). In this pre-enforcement challenge, plaintiffs could not and did not produce any evidence that the challenged provisions of the final rule have actually led arbitrators to systematically select offers closer to the QPA or to otherwise award lower provider reimbursements than might prevail in the absence of the challenged provisions. And in the absence of such evidence, plaintiffs cannot establish injury because the Departments have explicitly stated that the challenged rules "do not require [arbitrators] to default to the offer closest to the QPA or to apply a presumption in favor of that offer." 87 Fed. Reg. at 52,628 (ROA.980). Instead, the "final rules specify that [arbitrators] should select the offer that best represents the value of the item or service under dispute after considering the QPA *and all permissible information submitted by the parties*." *Id.* (emphasis added).

In the face of these express disclaimers, plaintiffs contend that arbitrators will nonetheless understand the rules to impose a stealth QPA presumption. They object to provisions of the final rule stating that: (1) the arbitrator should begin her analysis with the first factor listed in the statute—the QPA—and "then" consider the other factors; (2) in considering those additional factors,

the arbitrator "should not give weight" to information that is irrelevant, non-credible, or duplicative; and (3) the arbitrator who has followed this order of operations and concluded that information on the non-QPA factors affects the appropriate payment amount should include in the written decision an explanation of why the arbitrator reached that conclusion. *See* 45 C.F.R. § 149.510(c)(4)(iii)(A)-(B), (c)(4)(iii)(E), (c)(4)(iv), (c)(4)(vi)(B); *id.* § 149.520(b)(3). But given the Departments' express disclaimers, these modest procedural requirements (which are derived in significant part from the statute itself) cannot simply be presumed to have the effect on independent arbitrators that plaintiffs posit. *Cf. California v. Texas*, 141 S. Ct. 2104, 2117 (2021) (recognizing that where the alleged injury "depends upon the decision of an independent third party," plaintiffs "must show at the least 'that third parties will likely react in predictable ways'" (quoting *Department of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019))).

Plaintiffs' submissions, if anything, underscore that their injury is speculative: Even plaintiffs admit that "surely arbitrators will not give weight to information they deem noncredible," ROA.173, which is a tacit acknowledgment that the final rule's directive that arbitrators "not give weight to" non-"credible" evidence will have no systemic effect on arbitration results, 45 C.F.R. § 149.510(c)(4)(iii)(E). It is similarly unlikely that decisions would

be systematically skewed by the rule's instructions to avoid giving weight to irrelevant or duplicative evidence, the rule's inclusion of the single word "then" in the clause introducing the list of non-QPA factors, or the rule's requirement that the arbitrator's written explanation be sufficiently comprehensive to allow the parties and the Departments to accurately understand the basis for the decision. *See infra* Part II.A.1-3 (discussing in further detail each of the challenged provisions of the final rule). Because plaintiffs have no evidence supporting their contrary assertions, they lack standing.

II. The final rule is consistent with the Departments' authority and obligations under the No Surprises Act.

Even if plaintiffs had standing, their claims fail on the merits because the challenged regulations are a valid exercise of express rulemaking authority.

A. The final rule's modest procedural and evidentiary guardrails properly effectuate Congress's directive to issue regulations establishing a single arbitration process.

In the No Surprises Act, Congress established a general framework for resolving payment disputes between health plans and providers through arbitration. Congress recognized, however, that the statute failed to supply all the necessary specifics and that the independent dispute resolution process would need further elaboration to function properly. Congress accordingly expressly directed that, within one year of the Act's enactment, 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).

Consistent with that Congressional directive, the Departments promulgated regulations to ensure that arbitrations would proceed under a uniform set of procedures. For example, the Departments exercised their rulemaking authority to establish requirements governing the manner in which a party must provide notice that it wishes to initiate the independent dispute resolution process and the contents of that notice, 45 C.F.R. § 149.510(b)(2)(iii); to create an online "portal" and require parties to use it throughout the dispute resolution process, *see id.* § 149.510(b)(2)(iii)(C), (c)(1)(iii), (c)(1)(iv), (c)(2)(i), (g)(2); and to establish recordkeeping requirements for arbitration entities under which they would be required to maintain certain records for six years, *id.* § 149.510(c)(4)(viii). There is no dispute that the Departments acted within their statutory authority by issuing regulations generally, and it is similarly undisputed that many of the specific provisions of those regulations consist of reasonable exercises of the authority expressly delegated by Congress.

Plaintiffs allege, however, that the Departments were nonetheless without authority to adopt procedural and evidentiary guidelines to ensure that arbitrators would apply uniform procedures in conducting arbitrations and analyzing claims. Plaintiffs do not challenge the final rule's overarching direction 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). And though the regulations direct arbitrators to consider particular types of evidence in identifying the offer that best reflects the value of the disputed service, these factors are drawn directly from the statute. *Compare, e.g.*, *id.* § 149.510(c)(4)(iii)(A)-(B), *with* 42 U.S.C. § 300gg-111(c)(5)(C)(i)-(ii). Accordingly, plaintiffs cannot (and do not) argue the Departments were without authority to direct arbitrators to consider such factors as the QPA and the level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the disputed services.

Instead, plaintiffs object to ancillary provisions of the final rule, such as a directive in the rule specifying that arbitrators should begin by considering the first factor listed in the statute and rule and "then" consider what the statute calls "additional circumstances." In plaintiffs' view, because the statute identifies factors that arbitrators are to consider, the Departments are without

meaningful authority to provide guidance as to how those factors should be applied or the procedures that arbitrators should use when considering them.

While plaintiffs object to several different provisions (or even isolated words) in the final rule, their objections share a common flaw. Under basic tenets of administrative law, when a "statute 'expressly authorizes'" an agency "'to engage in the process of rulemaking' to address" a "gap" in the statutory scheme, courts interpret the statute "as granting the agency leeway to enact rules that are 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) (alterations omitted) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001)) (upholding an agency's regulation promulgated to effectuate Congress's directive to issue "'regulations . . . establishing and governing'" proceedings administered by the agency (alteration in original) (quoting 35 U.S.C. § 316(a)(4))). Agency regulations exercising such express delegations of authority are accordingly "give[n] controlling weight" as long as those regulations are "not arbitrary, capricious, or manifestly contrary to" the statute. *Easom v. U.S. Well Servs., Inc.*, 37 F.4th 238, 245 (5th Cir. 2022) ("giv[ing] controlling weight" to a regulation promulgated to implement Congress's express directive to "'prescribe such regulations as may be necessary to carry out'" the relevant statute (quoting 29 U.S.C. § 2107(a))).

When an agency that has explicitly been tasked by Congress with fleshing out the details of a program through rulemaking discharges that responsibility through the issuance of reasonable regulations that are consistent with Congress's design, it does not exceed the bounds of its authority. And because the statute at issue in this case "contains an express and clear conferral of authority" to promulgate the type of regulations at issue, this scenario does not implicate the distinct issues presented when courts defer to an agency's decision based on the assumption that Congress gave "an *implicit* delegation of power to an administrative agency." *Cuozzo*, 579 U.S. at 286 (Thomas, J., concurring) (emphasis added).

That principle should have led the district court to reject plaintiffs' challenge. The regulatory provisions at issue are modest elaborations on the framework described in the No Surprises Act itself. They do not conflict with the statute. And an analysis of these provisions shows that they are each "reasonable in light of the text, nature, and purpose of the statute," *Cuozzo*, 579 U.S. at 277.

1. The rule reasonably instructs arbitrators to consider the QPA first.

The rule instructs arbitrators to consider the QPA and to "then" consider information that relates to additional circumstances listed in both the statute and the rule. 45 C.F.R. § 149.510(c)(4)(iii)(B). (As noted above, the QPA is a

value that approximates the rate the applicable health plan pays its in-network providers for the relevant service. *See supra* pp. 9-10.) The district court held that the single word "then" must be excised from this regulatory text, ROA.1867, but the regulation reflects an eminently reasonable way to direct arbitrators to structure their decision-making processes under the No Surprises Act.

Recall that the Act directs that, in determining which party's payment offer to select, arbitrators "shall consider—(I) the [QPAs] for the applicable year for items or services that are comparable" to the item or service at issue; "and (II) . . . information on any circumstance described in" a list of "[a]dditional circumstances," such as the provider's level of training and experience and the acuity of the patient or complexity of the procedure if a party chooses to provide any such additional information. 42 U.S.C. § 300gg-111(c)(5)(C)(i)-(ii). The structure of the statute, like the rule, directs arbitrators to the QPA first, and to other circumstances second. And the statute, like the rule, makes clear that the QPA is the starting point for the analysis: arbitrators shall consider the QPA plus "information on any circumstance described" in a clause titled "[a]dditional circumstances." *Id.* By identifying the non-QPA circumstances as "[a]dditional," Congress directed that the analysis properly

begins with the QPA and is then supplemented by assessment of those additional circumstances.

As the Departments explained in the final rule's preamble, this order of operations makes sense in light of the role played by the respective factors in any given arbitration decision. The QPA is "a quantitative figure, like the offers that will be submitted" by the plan and provider, and it will be relevant to the arbitrator "in all cases" because "it represents the typical payment amount" that would apply to the item or service if it had been provided in-network. 87 Fed. Reg. at 52,627 (ROA.979). The additional circumstances such as the provider's level of training and experience, by contrast, "will often be qualitative and open to subjective evaluation," and may consist of "voluminous and complex information" that need not be submitted by the parties in every case and may, in any event, not necessarily be relevant to the value of the item or service. *See id.* Thus, in structuring the arbitrator's analysis of the appropriate payment amount—a "quantitative figure" like the QPA and often unlike "the additional, likely-qualitative factors," *id.*—it makes sense that both the statute and the rule list the QPA first, and that the rule captures the statute's structure and treatment of other factors as "[a]dditional" by using the word "then" in clarifying the sequence of the required analysis.

The rule takes pains to emphasize that considering the QPA first does not give arbitrators permission to discount relevant information regarding the additional circumstances. The rule's overarching standard, which has not been challenged here, directs arbitrators to "select the offer that . . . best represents the value" of the item or service. 45 C.F.R. § 149.510(c)(4)(ii)(A). In the same paragraph of the rule's preamble explaining why the Departments found it reasonable to direct arbitrators to consider the QPA first, the Departments emphasized that "the amount that best represents the value" of an item or service "may be more or less than the QPA due to additional circumstances" that arbitrators should also account for under both the statute and the rule. 87 Fed. Reg. at 52,627 (ROA.979). The Departments thus made clear that beginning the analysis with the QPA—an input that must be provided to the arbitrator in every case and is always relevant to the arbitrator's decision—does not give arbitrators leeway to fail to account for relevant information on "[a]dditional circumstances," 42 U.S.C. § 300gg-111(c)(5)(C)(ii), in instances where such information is submitted.

The direction to arbitrators to follow a uniform analytical process (one that tracks the statute itself) does not conflict with the statute or exceed the Departments' express rulemaking authority.

2. The rule reasonably instructs arbitrators to avoid giving weight to information that is not credible, not relevant, or duplicative.

The rule also instructs arbitrators that, in weighing information on the "[a]dditional circumstances" listed in the statute and repeated in the regulation, arbitrators "should evaluate whether the information is credible and relates to the offer submitted by either party." 45 C.F.R. § 149.510(c)(4)(iii)(E). The arbitrators are directed to "not give weight to information to the extent it is not credible, it does not relate to either party's offer . . ., or it is already accounted for by the [QPA] or other credible information" already considered by the arbitrator. *Id.*; *see also id.* § 149.520(b)(3) (similar language specific to air ambulances). And the rule provides arbitrators with a series of concrete examples demonstrating proper application of the rule, including general guidance on how to apply these instructions to particular scenarios where the arbitrator has made a given determination regarding the credibility or relevance of certain evidence. *Id.* § 149.510(c)(4)(iv). Of the rule's five illustrative examples, only two describe circumstances where the QPA identified as applicable by the health plan would best reflect the value of the services. *See id.* § 149.510(c)(4)(iv)(B), (C). (The other three examples describe circumstances where the arbitrator should either determine that an offer other than a plan-identified QPA would best

reflect the value of the services, *id.* § 149.510(c)(4)(iv)(A), (E), or where neither the plan nor the provider submits an offer equal to the QPA, *id.* § 149.510(c)(4)(iv)(D).)[8]

The challenged procedural and evidentiary standards impose common-sense guardrails as a natural component of the single independent dispute resolution process that Congress directed the Departments to "establish by regulation," 42 U.S.C. § 300gg-111(c)(2)(A). The directives to avoid placing weight on information that is irrelevant, non-credible, or duplicative mirror the sort of evidentiary rules that commonly apply in other dispute resolution processes. *See, e.g.*, Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."); Fed. R. Evid. 611(b) (providing that cross-examination of a witness may address "matters affecting the witness's credibility"); Fed. R. Evid. 403 (permitting courts to exclude "needlessly . . . cumulative evidence").

Plaintiffs, perhaps recognizing the oddity of objecting to such common-sense guardrails, acknowledged in district court that "surely arbitrators will not give weight to information they deem noncredible." ROA.173. The same

[8] Plaintiffs' only specific objection to the rule's examples was that they "restate the language of 45 C.F.R. § 149.510(c)(4)(iii)(E)." ROA.672. Accordingly, for purposes of this litigation, the validity of the rule's examples rises or falls with the validity of the rule's provisions regarding credibility, relevance, and double-counting.

could be said for information that is irrelevant to the matter before the arbitrator or duplicative of other information already before the arbitrator. But there is no principle of administrative law that bars agencies from establishing rules on the theory that they are so obvious and sensible that the requirement imposed should go without saying.

Plaintiffs nonetheless persuaded the district court that it was necessary to delete these modest evidentiary standards and the illustrative examples to ensure the rule is "evenhanded," emphasizing that these basic evidentiary standards apply only to the arbitrator's analysis of the "additional" (non-QPA) factors and not to the arbitrator's analysis of the QPA. ROA.173. But the Departments have reasonably explained why arbitrators do not need to scrutinize the QPA on a case-by-case basis in the same manner as the additional evidence. As to the credibility requirement, "to the extent the QPA is calculated in a manner that is consistent with the detailed rules" that govern its calculation (and which were not challenged in this case), "the QPA will meet the credibility requirement." 87 Fed. Reg. at 52,627 (ROA.979). As to the relevance requirement, because the QPA "represents the typical payment amount" that a health plan would pay for an item or service similar to the one subject to the arbitration, it "will be relevant" "in all cases." *Id.* And as to the requirement to avoid relying on duplicative information, because the QPA is

always relevant and may always be considered first, *see supra* Part II.A.1, all the double-counting rule does is ensure that arbitrators recognize they "should not give weight to . . . information if it is already accounted for by any of the other information submitted by the parties" that the arbitrator has already taken into account—whether that information is accounted for in the QPA or in any other information before the arbitrator. 87 Fed. Reg. at 52,628 (ROA.980).[9]

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[9] As the final rule explains, there are many circumstances in which the QPA will already account for the often-qualitative information captured by the non-QPA factors (the additional circumstances listed in the statute). For example, the non-QPA factors include patient acuity and the complexity of furnishing the item or service at issue to that patient. *See* 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(III). And "because the plan or issuer is required to calculate the QPA using median contracted rates for service codes, as well as modifiers (if applicable), and because service codes and modifiers in many cases reflect patient acuity and the complexity of the service provided," those non-QPA factors "will often already be reflected in the QPA." 87 Fed. Reg. at 52,628 (ROA.980); *see also id.* at 52,629 (ROA.981) (explaining the Departments' view "that, in many cases," the non-QPA factors "will already be reflected in the QPA" because "[t]he QPA is generally calculated to include characteristics that affect costs, including medical specialty, geographic region, and patient acuity and case severity").

As the Departments have also explained, however, this does not mean the QPA will necessarily capture all relevant information in any given case: "there are instances when certain factors related to" the "item or service" at issue "may not be adequately reflected in the QPA"—for example, providers "that provide high-acuity care, such as level 1 trauma or neonatal care, may contend that additional factors such as their case mix and the scope of services offered were not accounted for in the QPA." *Id.* at 52,629 (ROA.981); *see* 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(IV) (reflecting that "case mix" and "scope of services" furnished by the facility are among the non-QPA statutory factors).

Continued on next page.

In any event, to the extent plaintiffs' true grievance is not that the "additional" evidence is subject to ordinary evidentiary standards but that the QPA is not similarly subject to case-by-case scrutiny, that only serves to underscore that the relief plaintiffs persuaded the district court to award them in this litigation—deletion of the regulatory text guiding arbitrators in their evaluation of the non-QPA factors—is unwarranted. Indeed, once briefing in this case was underway, plaintiffs filed new lawsuits, which remain pending, challenging the separate regulations governing the calculation of the QPA. *See Texas Med. Ass'n v. HHS* (*TMA III*), No. 6:22-cv-450-JDK (E.D. Tex. Nov. 30. 2022); *LifeNet, Inc. v. HHS* (*LifeNet III*), No. 6:22-cv-00453-JDK (E.D. Tex. Dec. 1, 2022). Plaintiffs failed to seek any changes to the manner in which the QPA is calculated in *this* litigation, and their broader desire for such changes in the implementation of the Act provides no basis for depriving arbitrators of common-sense guidelines to apply when deciding how much weight to accord any additional, non-QPA information. Moreover, as the final rule explains, any effort to have the QPA recalculated by arbitrators—rather than to ensure there are appropriate rules in place for its accurate calculation by health

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Accordingly, under the final rule, arbitrators "are required to consider the QPA and then must consider all additional information submitted by the parties relating to the offer." 87 Fed. Reg. at 52,629 (ROA.981). "To the extent a factor is not already reflected in the QPA, the [arbitrator] should accord that factor appropriate weight . . . ." *Id.*

plans—conflicts with Congress's determination that "it is the Departments' (or applicable State authorities') responsibility, not the [arbitrator's], to monitor the accuracy of the [health plan's] QPA calculation methodology by conducting an audit." 87 Fed. Reg. at 52,627 n.31 (ROA.979); *see* 42 U.S.C. § 300gg-111(a)(2)(A) (requiring the Departments to "establish through rulemaking a process" of auditing health plans to ensure compliance with "the requirement of applying a [QPA]" that is calculated in conformance with the applicable rules).

Though the final rule therefore appropriately does not invite arbitrators to recalculate the QPA or to deem it categorically irrelevant or non-credible, the rule also makes clear that arbitrators are under no obligation to defer to the QPA as the appropriate payment amount. *See, e.g.*, 87 Fed. Reg. at 52,628 (ROA.980) ("The Departments note that these final rules do not require [arbitrators] to default to the offer closest to the QPA or to apply a presumption in favor of that offer. . . . Rather, these final rules specify that [arbitrators] should select the offer that best represents the value of the item or service under dispute after considering the QPA and all permissible information submitted by the parties."); *id.* at 52,631 (ROA.983) (similar).

3. The rule reasonably requires arbitrators to include in their written decisions adequate details to understand the basis for those decisions.

The final provision at issue involves the rule's requirements regarding the arbitrator's explanation for the decision. There is no dispute that the rule appropriately requires an arbitrator to "explain its determination in a written decision submitted to the parties and the [Departments]." 45 C.F.R. § 149.510(c)(4)(vi)(A). Plaintiffs likewise take no issue with the rule's requirement that arbitrators' written decisions "must include an explanation of [the arbitrator's] determination, including what 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. *Id.* § 149.510(c)(4)(vi)(B). Plaintiffs contend that the rule nevertheless went too far, however, in specifying 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.*

Plaintiffs' challenge lacks merit because the written decision requirement, including the challenged portion, reasonably furthers the Departments' statutorily mandated role in establishing and monitoring the No

Surprises Act's dispute resolution process. In addition to directing the Departments to "establish by regulation one independent dispute resolution process," 42 U.S.C. § 300gg-111(c)(2)(A), Congress directed the Departments to: establish the methodology for calculating QPAs, *id.* § 300gg-111(a)(2)(B); establish a process of auditing health plans to ensure compliance with the rules for calculating and applying their QPAs, *id.* § 300gg-111(a)(2)(A); and publish on a quarterly basis a variety of information, including how frequently payment amounts determined or agreed to under the Act "exceed[] the [QPA]," the parties' offer amounts "expressed as a percentage of the [QPA]," and the arbitrator's final offer selections "expressed as a percentage of the [QPA]," *id.* § 300gg-111(c)(7)(A)(v), (c)(7)(B)(iii)-(iv). Congress further specified that certified arbitration entities "shall submit to the [Departments] such information as the [Departments] determine[] necessary to carry out" the Departments' obligations. *Id.* § 300gg-111(c)(7)(C).

As the rule's preamble explains, the Departments "determine[d]" that the entire written decision requirement was "necessary to carry out" the Departments' own obligations under the statute, 42 U.S.C. § 300gg-111(c)(7)(C). *See* 87 Fed. Reg. at 52,631 (ROA.983). Requiring arbitrators to provide a rationale for their decisions in each case is "important to ensure that the parties understand the outcome of a payment determination" as well as to

provide a mechanism for the Departments to collect some of the information Congress required them to publish. *See id.* The modest additional requirement that an arbitrator include, when applicable, "an explanation of why the [arbitrator] concluded that [information on the non-QPA factors] was not already reflected in the [QPA]," 45 C.F.R. § 149.510(c)(4)(vi)(B), simply enables the Departments to "fulfill their statutory functions to monitor and to report on how often, and why, an offer that is selected exceeds the QPA," 87 Fed. Reg. at 52,632 (ROA.984).

Understanding not only the bottom-line numerical results of arbitrations but also the arbitrators' rationales further "provide[s] the Departments with valuable information to inform future policy making, in particular, policy making related to the QPA methodology." 87 Fed. Reg. at 52,632 (ROA.984). That QPA methodology is set out in a separate interim final rule on which comments were received that has not yet been finalized. *See* 86 Fed. Reg. 36,872-36,985 (ROA.1602-1715). The Departments acted well within their statutory authority in determining that, among other things, any future rulemaking on the QPA methodology—including finalization of the still-interim rule that is currently in place—would benefit from a robust case-by-case explanation as to why arbitrators may find in any given case that the QPA does not "best represent[] the value" of the item or service at issue, 45 C.F.R.

§ 149.510(c)(4)(ii)(A). Given the QPA's key role in the No Surprises Act—in addition to serving as an input in every plan-provider arbitration, the QPA itself dictates a patient's payment obligation in the circumstances relevant here regardless of the results of any such negotiation or arbitration, *see supra* pp. 10-11—the Departments acted well within their statutory authority by requiring government-certified arbitrators to provide important information about the QPA's utility in the context of the specific cases that come before them.

The challenged portion of the written decision requirement also should be sustained for the independent reason that it follows from the requirement that arbitrators not rely on additional information that is duplicative of information in the QPA. (Plaintiffs' challenge to the limitation on consideration of duplicative information lacks merit for the reasons explained above in Part II.A.1-2.) Requiring that the written decision confirm that additional information relied upon is non-duplicative simply elaborates on what it means for the arbitrator to follow the rule's overarching—and indisputably appropriate—mandates to select the offer that "best represents the value" of the item or service, 45 C.F.R. § 149.510(c)(4)(ii)(A), and to provide a written decision explaining "what information the [arbitrator] determined demonstrated that the offer selected . . . best represents [that value], including the weight given to the [QPA] and any additional credible information." *id.*

§ 149.510(c)(4)(vi)(B). An arbitrator who begins the analysis with the QPA, then considers any relevant, credible, non-duplicative information on the non-QPA factors, then ultimately "relies on information [about the non-QPA factors] in selecting an offer," has necessarily "concluded that this information" about the non-QPA factors "was not already reflected in the [QPA]." *Id.* The challenged requirement simply directs the arbitrator to "include an explanation of why" the arbitrator reached that conclusion when carrying out the overall task. *Id.*

B. The district court's contrary reasoning was mistaken.

1. The district court relied on an unduly narrow view of the rulemaking authority expressly granted by Congress.

The district court nonetheless struck each provision plaintiffs challenged, concluding that "the challenged provisions of the Final Rule conflict with the unambiguous statutory text" of the No Surprises Act. ROA.1857. To be clear, however, the district court did not identify any respect in which the regulations expressly conflict with the statute. This is not a case where, for example, Congress directed arbitrators not to consider a given factor and the Departments issued regulations specifying that the factor should be considered after all. Instead, the district court believed that *any* elaboration the Departments provided on the analytic framework to be used in arbitrations

would conflict with the statute on the theory that the statute is comprehensive and leaves the Departments no room to provide even modest clarifying guidance. In the court's view, the statute's "detailed rules" reflect that Congress "vest[ed] discretion in the arbitrators—not the Departments—to determine the proper payment amount." ROA.1860-1861; *see also* ROA.1862 (referring to the statute's "meticulous detail").

But the district court's concern with the Departments "invading the adjudicative role assigned by the statute to the arbitrators," ROA.1862, was misplaced. Far from undermining arbitrators' discretion, the rule emphasizes the breadth of that discretion: the arbitrator's task, per the rule, is to "select the offer that . . . best represents the value" of the item or service at issue, 45 C.F.R. § 149.510(c)(4)(ii)(A). The illustrative examples likewise point the arbitrator to reach particular results in given scenarios based on whether the arbitrator—not the Departments—finds the evidentiary submissions to be credible and relevant. *See, e.g.*, *id.* § 149.510(c)(4)(iv)(A)(2) (explaining the appropriate result "[i]f the certified IDR entity [*i.e.*, the arbitrator] determines that it is appropriate to give weight" to particular evidence). And lest there be any doubt about the arbitrator's responsibility to weigh all relevant statutory factors in each case without placing undue weight on the QPA (or any other factor), the Departments made clear in the rule's preamble that the rule "do[es]

not require [arbitrators] to default to the offer closest to the QPA or to apply a presumption in favor of that offer." 87 Fed. Reg. at 52,628 (ROA.980).

In striking the challenged provisions, the district court also failed to honor Congress's choice (and explicit mandate) that the Departments should promulgate precisely the sort of requirements embodied in the final rule. As noted, Congress required the Departments to "establish by regulation one independent dispute resolution process." 42 U.S.C. § 300gg-111(c)(2)(A). Thus, in treating the statute as comprehensive, to the exclusion of any further elaboration from the Departments, the district court failed to properly account for Congress's explicit recognition that the statute did not create a self-effectuating dispute resolution process and expected the Departments to establish uniform procedures. The district court's overly cramped understanding of the No Surprises Act does not protect Congress's judgments from being overridden by an intermeddling agency; rather, the decision itself overrides the Congressional determination reflected in the statute's express grant of rulemaking authority.

In addition to that overarching error, the district court's reasoning regarding individual challenged provisions contained several additional flaws. For example, in concluding that the Departments lacked authority to direct arbitrators to explain decisions crediting evidence beyond the QPA, the district

court did not acknowledge that the Departments identified a variety of permissible reasons for requiring arbitrators to explain their written decisions, including to assist the Departments in fulfilling their own obligations to publish information, to monitor arbitrations under the No Surprises Act, and to engage in rulemaking regarding the methodology for calculating the QPA. *Compare supra* Part II.A.3 (explaining these reasons for the written decision requirement and citing relevant passages of the final rule justifying the requirement), *and* ROA.643, 951-952 (government's district court briefing highlighting these justifications for the written decision requirement)*, with* ROA.1859 (district court rejecting any requirement that it viewed as "creat[ing] procedural hurdles" to the consideration of non-QPA factors without acknowledging these justifications for the challenged requirement).

Similarly, the district court failed to follow precedent recognizing that agencies have broad authority to promulgate procedural and evidentiary rules in the context of "agency-conducted adjudications." ROA.1862 (citing *National Mining Ass'n v. Department of Labor*, 292 F.3d 849 (D.C. Cir. 2002) (per curiam)). The district court dismissed these precedents because they did not involve "independent arbitrations" conducted by non-agency employees. ROA.1862. But regardless of the identity of the adjudicator, when an agency is tasked with establishing adjudicative procedures, that authority necessarily

encompasses the authority to adopt reasonable procedural and evidentiary standards to guide decisionmakers. Nothing in the No Surprises Act prevents the Departments from exercising their express grant of rulemaking authority to adopt reasonable rules designed to "promote consistency and predictability" as different arbitrators employed by different entities undertake to resolve payment disputes consistent with the requirements of the No Surprises Act, 87 Fed. Reg. at 52,627 (ROA.979). *Cf. American Hosp. Ass'n v. NLRB*, 499 U.S. 606, 611-12 (1991) (reasoning that a requirement for a decision-maker to "exercise its discretion in every disputed case cannot fairly or logically be read to command" that decision-maker "to exercise standardless discretion in each case" without the benefit of rules of general applicability "supplanting the original discretionary chaos with some degree of order" (quotation marks omitted)).

2. The district court was mistaken to conclude that the final rule improperly privileges the QPA.

The district court's holding was also rooted in its belief that the challenged provisions "place a thumb on the scale for the QPA." ROA.1860. But even assuming that a QPA presumption would be unlawful (a question that this Court need not decide), the Departments have unambiguously said the opposite, expressly disclaiming that the final rule creates any "rebuttable presumption in favor of the QPA." 87 Fed. Reg. at 52,627 (ROA.979); *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).

The district court appears to have treated the August 2022 final rule with suspicion because the interim final rule that it replaced included a rebuttable presumption in favor of the QPA. The same district court had struck down the interim final rule, *see TMA I*, 587 F. Supp. 3d at 541, and believed that the August 2022 final rule reflected a lingering desire on the part of the Departments to adopt a QPA presumption. *See* ROA.1863-1864 (concluding "that privileging the QPA remains the Department[]s[']' intent behind the Final Rule" and that despite "abandon[ing] the 'rebuttable presumption' term, [the Departments] have not relinquished their goal of privileging the QPA").

But the final rule repeatedly emphasizes that the Departments took heed of the prior district court rulings that any QPA presumption would conflict with the statute—rulings that are discussed at several points throughout the rule's preamble, *see, e.g.*, 87 Fed. Reg. at 52,625, 52,627, 52,631, 52,633 (ROA.977, 979, 983, 985). In assuming that the Departments imposed a stealth QPA presumption—in the face of the Departments' express statements to the contrary—the district court departed from the rule that courts reviewing agency action under the APA are required to apply "a presumption of

regularity." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971); *see also, e.g.*, *Ghedi v. Mayorkas*, 16 F.4th 456, 468 (5th Cir. 2021). The district court erred in theorizing that notwithstanding the rule's express disclaimers of any presumption in favor of the QPA, it remained the Departments' unstated intent for such a presumption to be read into the rule.

Moreover, the district court's focus on the Departments' purported continuing desire to impose a QPA presumption was misplaced because the pertinent regulations are applied to providers such as plaintiffs by arbitrators, not by the Departments themselves. And there is no reason to believe that the arbitrators will not take the Departments at their word when they have disclaimed a QPA presumption. Any such inference would be particularly unwarranted given the Departments' express abandonment of the QPA presumption that had appeared in the interim final rule. *Cf. Ross v. Blake*, 578 U.S. 632, 641-42 (2016) ("When Congress amends legislation, courts must 'presume it intends [the change] to have real and substantial effect.'" (alteration in original) (quoting *Stone v. INS*, 514 U.S. 386, 397 (1995))). Here, where the Departments expressly excised the QPA presumption that had been found in the interim final rule—and explained that the Departments had specifically made this change to account for comments expressing disparate views on the interim final rule's QPA presumption as well as district court

decisions striking down that presumption, *see* 87 Fed. Reg. at 52,623-52,628 (ROA.975-980)—the district court should not have assumed that arbitrators would construe the regulations as if the presumption remained.

Finally, the district court's belief that the Departments harbored a "goal of privileging the QPA," ROA.1864, also does not follow from the premise that, as the district court observed, one of the Departments' goals has been "'to keep costs down,'" ROA.1864 (quoting ROA.1905:22-23). Any belief that the Departments should not have made it their goal to reduce administrative costs incurred in connection with arbitrations conducted in accordance with the statute would be mistaken. The Departments acted well within their discretion in seeking to "lower[] administrative costs" through the final rule, 87 Fed. Reg. at 52,627 (ROA.979), particularly since Congress specifically directed the Departments in other aspects of their regulations to prioritize "efficiency (including minimizing costs) of the [independent dispute resolution] process," 42 U.S.C. § 300gg-111(c)(3)(A). To the extent plaintiffs are dissatisfied with the prospect that the costs of certain medical services as reflected in the final dollar amount reached through either negotiation or arbitration may decline in the wake of the No Surprises Act, plaintiffs' true disagreement is with Congress, not the Departments. It is the statute itself, after all, that was premised on Congress's findings that surprise medical billing reflected a

"market failure" in which "highly inflated payment rates" were 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 (ROA.1060). Even if one consequence of the Departments' rulemaking is a decrease in the cost of medical care, that does not demonstrate that the Departments did anything other than follow Congress's instructions to implement the Act.

III. At a minimum, the rule should not have been vacated, let alone vacated as to non-parties.

Even were the district court's merits decision correct, the court also erred in ordering universal vacatur of the challenged provisions of the final rule. ROA.1864-1866. While this Court's precedents identify vacatur as an available remedy for a successful APA challenge to a regulation, *see, e.g.*, *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374-75 (5th Cir. 2022), the APA itself does not reference vacatur, instead remitting plaintiffs to traditional equitable remedies like injunctions, 5 U.S.C. § 703, and there is little indication that Congress intended to create a new and radically different remedy in providing that courts reviewing agency action should "set aside" agency "action, findings, and conclusions," *id.* § 706(2). *See United States v. Texas*, No. 22-58, 2023 WL 4139000, at *12-16 (U.S. June 23, 2023) (Gorsuch, J., joined

by Thomas and Barrett, JJ., concurring in the judgment) (detailing "serious" arguments that "warrant careful consideration" as to whether the APA "empowers courts to vacate agency action").

In any event, this Court has treated universal vacatur of agency action as a discretionary equitable remedy—not a remedy that is automatic or compelled. *See, e.g.*, *Central & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding without vacatur in light of "disruptive" consequences of vacatur). And in this case, any remedy should have been limited to remand to the Departments without vacating the challenged provisions. Vacatur of the challenged provisions leaves arbitrators to conduct costlier and less predictable proceedings than would exist if the additional overarching rules remained in place pending the outcome of any remand to the Departments. These costs could ultimately be passed along to patients, frustrating Congress's goal of protecting patients and lowering health care costs. *See* H.R. Rep. No. 116-615, pt. 1, at 55, 57 n.48 (ROA.1062, 1064) (noting that health plans "typically pass on to consumers" increased health care costs, including when inflated health care costs are linked to "additional administrative costs incurred" as part of an arbitration process). These equitable interests counsel heavily in favor of remand without vacatur. *Central & S. W. Servs.*, 220 F.3d at 692. At a minimum, any immediately effective relief should have been limited to the

specific plaintiffs who are parties to this lawsuit. Ordinarily principles of Article III standing and equity generally require that a court tailor remedies to address the plaintiff's injury. *See, e.g.*, *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018); *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). Courts should thus "ask[] whether party-specific relief can adequately protect the plaintiff's interests" before entering broader relief. *Texas*, 2023 WL 4139000, at *17 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment). Equitable relief as to the challenged portions of the final rule only with respect to the plaintiffs to this suit would remedy the injuries they claim.

CONCLUSION

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

Respectfully submitted,

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July 2023

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 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
Kevin B. Soter

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,134 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.

s/ Kevin B. Soter
Kevin B. Soter

ADDENDUM

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42 U.S.C. § 300gg-111 (excerpts)

§ 300gg-111. Preventing surprise medical bills

(a) Coverage of emergency services

(1) In general

If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department (as defined in paragraph (3)(D)), the plan or issuer shall cover emergency services (as defined in paragraph (3)(C))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider or a participating emergency facility, as applicable, with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating provider or a nonparticipating emergency facility—

(i) such services will be provided without imposing any requirement under the plan or coverage for prior authorization of services or any limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities with respect to such plan or coverage, respectively;

(ii) the cost-sharing requirement is not greater than the requirement that would apply if such services were provided by a participating provider or a participating emergency facility;

(iii) such cost-sharing requirement is calculated as if the total amount that would have been charged for such services by such participating provider or participating emergency facility were equal to the recognized amount (as defined in paragraph (3)(H)) for such services, plan or coverage, and year;

(iv) the group health plan or health insurance issuer, respectively—

(I) not later than 30 calendar days after the bill for such services is transmitted by such provider or facility, sends to the provider or

facility, as applicable, an initial payment or notice of denial of payment; and

(II) pays a total plan or coverage payment directly to such provider or facility, respectively (in accordance, if applicable, with the timing requirement described in subsection (c)(6)) that is, with application of any initial payment under subclause (I), equal to the amount by which the out-of-network rate (as defined in paragraph (3)(K)) for such services exceeds the cost-sharing amount for such services (as determined in accordance with clauses (ii) and (iii)) and year; and

(v) any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to such emergency services so furnished shall be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage, respectively (and such in-network deductible and out-of-pocket maximums shall be applied) in the same manner as if such cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 300gg-3 of this title, including as incorporated pursuant to section 1185d of title 29 and section 9815 of title 26, and other than applicable cost-sharing).

(2) Audit process and regulations for qualifying payment amounts

(A) Audit process

(i) In general

Not later than October 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking a process, in accordance with clause (ii), under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the Secretary or applicable State authority to ensure that—

(I) such plans and coverage are in compliance with the requirement of applying a qualifying payment amount under this section; and

(II) such qualifying payment amount so applied satisfies the definition under paragraph (3)(E) with respect to the year involved, including with respect to a group health plan or health insurance issuer described in clause (ii) of such paragraph (3)(E).

(ii) Audit samples

Under the process established pursuant to clause (i), the Secretary—

(I) shall conduct audits described in such clause, with respect to a year (beginning with 2022), of a sample with respect to such year of claims data from not more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage; and

(II) may audit any group health plan or health insurance issuer offering group or individual health insurance coverage if the Secretary has received any complaint or other information about such plan or coverage, respectively, that involves the compliance of the plan or coverage, respectively, with either of the requirements described in subclauses (I) and (II) of such clause.

(iii) Reports

Beginning for 2022, the Secretary shall annually submit to Congress a report on the number of plans and issuers with respect to which audits were conducted during such year pursuant to this subparagraph.

(B) Rulemaking

Not later than July 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking—

(i) the methodology the group health plan or health insurance issuer offering group or individual health insurance coverage shall use to determine the qualifying payment amount, differentiating by individual market, large group market, and small group market;

(ii) the information such plan or issuer, respectively, shall share with the nonparticipating provider or nonparticipating facility, as applicable, when making such a determination;

(iii) the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in

rural and underserved areas, including health professional shortage areas, as defined in section 254e of this title; and

(iv) a process to receive complaints of violations of the requirements described in subclauses (I) and (II) of subparagraph (A)(i) by group health plans and health insurance issuers offering group or individual health insurance coverage.

Such rulemaking shall take into account payments that are made by such plan or issuer, respectively, that are not on a fee-for-service basis. Such methodology may account for relevant payment adjustments that take into account quality or facility type (including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities. In carrying out clause (iii), the Secretary shall consult with the National Association of Insurance Commissioners to establish the geographic regions under such clause and shall periodically update such regions, as appropriate, taking into account the findings of the report submitted under section 109(a) of the No Surprises Act.

(3) Definitions

***

(E) Qualifying payment amount

(i) In general

The term "qualifying payment amount" means, subject to clauses (ii) and (iii), with respect to a sponsor of a group health plan and health insurance issuer offering group or individual health insurance coverage—

(I) for an item or service furnished during 2022, the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market (specified in subclause (I), (II), (III), or (IV) of clause (iv)) as the plan or coverage) as the total maximum payment (including the cost-sharing amount imposed for such item or service and the amount to be paid by the plan or issuer, respectively) under such plans or coverage, respectively, on

January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary under paragraph (2)(B), increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over 2019, such percentage increase over 2020, and such percentage increase over 2021; and

(II) for an item or service furnished during 2023 or a subsequent year, the qualifying payment amount determined under this clause for such an item or service furnished in the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over such previous year.

(ii) New plans and coverage

The term "qualifying payment amount" means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which such sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(I) for the first year in which such group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region, a rate (determined in accordance with a methodology established by the Secretary) for items and services that are covered by such plan or coverage and furnished during such first year; and

(II) for each subsequent year such group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region, the qualifying payment amount determined under this clause for such items and services furnished in the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over such previous year.

(iii) Insufficient information; newly covered items and services

In the case of a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage that does not have sufficient information to calculate the median of the

contracted rates described in clause (i)(I) in 2019 (or, in the case of a newly covered item or service (as defined in clause (v)(III)), in the first coverage year (as defined in clause (v)(I)) for such item or service with respect to such plan or coverage) for an item or service (including with respect to provider type, or amount, of claims for items or services (as determined by the Secretary) provided in a particular geographic region (other than in a case with respect to which clause (ii) applies)) the term "qualifying payment amount"—

(I) for an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for such item or service with respect to such plan or coverage), means such rate for such item or service determined by the sponsor or issuer, respectively, through use of any database that is determined, in accordance with rulemaking described in paragraph (2)(B), to not have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for relevant services furnished in the applicable geographic region (such as a State all-payer claims database);

(II) for an item or service furnished in a subsequent year (before the first sufficient information year (as defined in clause (v)(II)) for such item or service with respect to such plan or coverage), means the rate determined under subclause (I) or this subclause, as applicable, for such item or service for the year previous to such subsequent year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over such previous year;

(III) for an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, has the meaning given the term qualifying payment amount in clause (i)(I), except that in applying such clause to such item or service, the reference to "furnished during 2022" shall be treated as a reference to furnished during such first sufficient information year, the reference to "in 2019" [1] shall be treated as a reference to such sufficient information year, and the increase described in such clause shall not be applied; and

(IV) for an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, has the meaning given such term

in clause (i)(II), except that in applying such clause to such item or service, the reference to "furnished during 2023 or a subsequent year" shall be treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(iv) Insurance market

For purposes of clause (i)(I), a health insurance market specified in this clause is one of the following:

(I) The individual market.

(II) The large group market (other than plans described in subclause (IV)).

(III) The small group market (other than plans described in subclause (IV)).

(IV) In the case of a self-insured group health plan, other self-insured group health plans.

(v) Definitions

For purposes of this subparagraph:

(I) First coverage year

The term "first coverage year" means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer and an item or service for which coverage is not offered in 2019 under such plan or coverage, the first year after 2019 for which coverage for such item or service is offered under such plan or health insurance coverage.

(II) First sufficient information year

The term "first sufficient information year" means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(aa) in the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in clause (i)(I) in 2019, the first year subsequent to 2022 for which the sponsor or issuer has such sufficient information to calculate the median of such contracted rates in the year previous to such first subsequent year; and

(bb) in the case of a newly covered item or service, the first year subsequent to the first coverage year for such item or service with respect to such plan or coverage for which the sponsor or issuer has sufficient information to calculate the median of the contracted rates described in clause (i)(I) in the year previous to such first subsequent year.

(III) Newly covered item or service

The term "newly covered item or service" means, with respect to a group health plan or group or individual health insurance issuer offering health insurance coverage, an item or service for which coverage was not offered in 2019 under such plan or coverage, but is offered under such plan or coverage in a year after 2019.

***

(H) Recognized amount

The term "recognized amount" means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility during a year and a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(i) subject to clause (iii), in the case of such item or service furnished in a State that has in effect a specified State law with respect to such plan, coverage, or issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service, the amount determined in accordance with such law;

(ii) subject to clause (iii), in the case of such item or service furnished in a State that does not have in effect a specified State law, with respect to such plan, coverage, or issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service, the amount that is the qualifying payment amount (as defined in subparagraph (E)) for such year and determined in accordance with rulemaking described in paragraph (2)(B)) for such item or service; or

(iii) in the case of such item or service furnished in a State with an All-Payer Model Agreement under section 1115A of the Social Security Act [42 U.S.C. 1315a], the amount that the State approves under such system for such item or service so furnished.

***

(K) Out-of-network rate

The term "out-of-network rate" means, with respect to an item or service furnished in a State during a year to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer receiving such item or service from a nonparticipating provider or nonparticipating emergency facility—

(i) subject to clause (iii), in the case of such item or service furnished in a State that has in effect a specified State law with respect to such plan, coverage, or issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service, the amount determined in accordance with such law;

(ii) subject to clause (iii), in the case such State does not have in effect such a law with respect to such item or service, plan, and provider or facility—

(I) subject to subclause (II), if the provider or facility (as applicable) and such plan or coverage agree on an amount of payment (including if such agreed on amount is the initial payment sent by the plan under subsection (a)(1)(C)(iv)(I), subsection (b)(1)(C), or section 300gg-112(a)(3)(A) of this title, as applicable, or is agreed on through open negotiations under subsection (c)(1)) with respect to such item or service, such agreed on amount; or

(II) if such provider or facility (as applicable) and such plan or coverage enter the independent dispute resolution process under subsection (c) and do not so agree before the date on which a certified IDR entity (as defined in paragraph (4) of such subsection) makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(iii) in the case such State has an All-Payer Model Agreement under section 1115A of the Social Security Act [42 U.S.C. 1315a], the amount that the State approves under such system for such item or service so furnished.

(L) Cost-sharing

The term "cost-sharing" includes copayments, coinsurance, and deductibles.

(b) Coverage of non-emergency services performed by nonparticipating providers at certain participating facilities

(1) In general

In the case of items or services (other than emergency services to which subsection (a) applies) for which any benefits are provided or covered by a group health plan or health insurance issuer offering group or individual health insurance coverage furnished to a participant, beneficiary, or enrollee of such plan or coverage by a nonparticipating provider (as defined in subsection (a)(3)(G)(i)) (and who, with respect to such items and services, has not satisfied the notice and consent criteria of section 300gg-132(d) of this title) with respect to a visit (as defined by the Secretary in accordance with paragraph (2)(B)) at a participating health care facility (as defined in paragraph (2)(A)), with respect to such plan or coverage, respectively, the plan or coverage, respectively—

(A) shall not impose on such participant, beneficiary, or enrollee a cost-sharing requirement for such items and services so furnished that is greater than the cost-sharing requirement that would apply under such plan or coverage, respectively, had such items or services been furnished by a participating provider (as defined in subsection (a)(3)(G)(ii));

(B) shall calculate such cost-sharing requirement as if the total amount that would have been charged for such items and services by such participating provider were equal to the recognized amount (as defined in subsection (a)(3)(H)) for such items and services, plan or coverage, and year;

(C) not later than 30 calendar days after the bill for such services is transmitted by such provider, shall send to the provider an initial payment or notice of denial of payment;

(D) shall pay a total plan or coverage payment directly, in accordance, if applicable, with the timing requirement described in subsection (c)(6), to such provider furnishing such items and services to such participant, beneficiary, or enrollee that is, with application of any initial payment under subparagraph (C), equal to the amount by which the out-of-network rate (as defined in subsection (a)(3)(K)) for such items and

services involved exceeds the cost-sharing amount imposed under the plan or coverage, respectively, for such items and services (as determined in accordance with subparagraphs (A) and (B)) and year; and

(E) shall count toward any in-network deductible and in-network out-of-pocket maximums (as applicable) applied under the plan or coverage, respectively, any cost-sharing payments made by the participant, beneficiary, or enrollee (and such in-network deductible and out-of-pocket maximums shall be applied) with respect to such items and services so furnished in the same manner as if such cost-sharing payments were with respect to items and services furnished by a participating provider.

***

(c) Determination of out-of-network rates to be paid by health plans; independent dispute resolution process

(1) Determination through open negotiation

(A) In general

With respect to an item or service furnished in a year by a nonparticipating provider or a nonparticipating facility, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage, in a State described in subsection (a)(3)(K)(ii) with respect to such plan or coverage and provider or facility, and for which a payment is required to be made by the plan or coverage pursuant to subsection (a)(1) or (b)(1), the provider or facility (as applicable) or plan or coverage may, during the 30-day period beginning on the day the provider or facility receives an initial payment or a notice of denial of payment from the plan or coverage regarding a claim for payment for such item or service, initiate open negotiations under this paragraph between such provider or facility and plan or coverage for purposes of determining, during the open negotiation period, an amount agreed on by such provider or facility, respectively, and such plan or coverage for payment (including any cost-sharing) for such item or service. For purposes of this subsection, the open negotiation period, with respect to an item or service, is the 30-day period beginning on the date of initiation of the negotiations with respect to such item or service.

(B) Accessing independent dispute resolution process in case of failed negotiations

In the case of open negotiations pursuant to subparagraph (A), with respect to an item or service, that do not result in a determination of an amount of payment for such item or service by the last day of the open negotiation period described in such subparagraph with respect to such item or service, the provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage that was party to such negotiations may, during the 4-day period beginning on the day after such open negotiation period, initiate the independent dispute resolution process under paragraph (2) with respect to such item or service. The independent dispute resolution process shall be initiated by a party pursuant to the previous sentence by submission to the other party and to the Secretary of a notification (containing such information as specified by the Secretary) and for purposes of this subsection, the date of initiation of such process shall be the date of such submission or such other date specified by the Secretary pursuant to regulations that is not later than the date of receipt of such notification by both the other party and the Secretary.

(2) Independent dispute resolution process available in case of failed open negotiations

(A) Establishment

Not later than 1 year after December 27, 2020, the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, shall establish by regulation one independent dispute resolution process (referred to in this subsection as the "IDR process") under which, in the case of an item or service with respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (1)(B) (in this subsection referred to as a "qualified IDR item or service"), a certified IDR entity under paragraph (4) determines, subject to subparagraph (B) and in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility.

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(3) Treatment of batching of items and services

(A) In general

Under the IDR process, the Secretary shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of encouraging the efficiency (including minimizing costs) of the IDR process. ***

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(4) Certification and selection of IDR entities

(A) In general

The Secretary, in consultation with the Secretary of Labor and Secretary of the Treasury, shall establish a process to certify (including to recertify) entities under this paragraph. ***

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(5) Payment determination

(A) In general

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) 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; and

(ii) notify the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination of the offer selected under clause (i).

(B) Submission of offers

Not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination—

(i) shall each submit to the certified IDR entity with respect to such determination—

(I) an offer for a payment amount for such item or service furnished by such provider or facility; and

(II) such information as requested by the certified IDR entity relating to such offer; and

(ii) may each submit to the certified IDR entity with respect to such determination any information relating to such offer submitted by either party, including information relating to any circumstance described in subparagraph (C)(ii).

(C) Considerations in determination

(i) In general

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).

(ii) Additional circumstances

For purposes of clause (i)(II), the circumstances described in this clause are, with respect to a qualified IDR item or service of a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer of group or individual health insurance coverage the following:

(I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based

entity authorized in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).

(II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.

(III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.

(IV) The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.

(V) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Prohibition on consideration of certain factors

In determining which offer is the payment to be applied with respect to qualified IDR items and services furnished by a provider or facility, the certified IDR entity with respect to a determination shall not consider usual and customary charges, the amount that would have been billed by such provider or facility with respect to such items and services had the provisions of section 300gg-131 or 300gg1132 of this title (as applicable) not applied, or the payment or reimbursement rate for such items and services furnished by such provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], under the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.], under the Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.], under the TRICARE program under chapter 55 of title 10, or under chapter 17 of title 38.

(E) Effects of determination

(i) In general

A determination of a certified IDR entity under subparagraph (A)—

(I) shall be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved regarding such claim; and

(II) shall not be subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9.

***

(7) Publication of information relating to the IDR process

(A) Publication of information

For each calendar quarter in 2022 and each calendar quarter in a subsequent year, the Secretary shall make available on the public website of the Department of Health and Human Services—

(i) the number of notifications submitted under paragraph (1)(B) during such calendar quarter;

(ii) the size of the provider practices and the size of the facilities submitting notifications under paragraph (1)(B) during such calendar quarter;

(iii) the number of such notifications with respect to which a determination was made under paragraph (5)(A);

(iv) the information described in subparagraph (B) with respect to each notification with respect to which such a determination was so made;

(v) the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount, specified by items and services;

(vi) the amount of expenditures made by the Secretary during such calendar quarter to carry out the IDR process;

(vii) the total amount of fees paid under paragraph (8) during such calendar quarter; and

(viii) the total amount of compensation paid to certified IDR entities under paragraph (5)(F) during such calendar quarter.

(B) Information

For purposes of subparagraph (A), the information described in this subparagraph is, with respect to a notification under paragraph (1)(B) by a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer offering group or individual health insurance coverage—

(i) a description of each item and service included with respect to such notification;

(ii) the geography in which the items and services with respect to such notification were provided;

(iii) the amount of the offer submitted under paragraph (5)(B) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider or nonparticipating emergency facility (as applicable) expressed as a percentage of the qualifying payment amount;

(iv) whether the offer selected by the certified IDR entity under paragraph (5) to be the payment applied was the offer submitted by such plan or issuer (as applicable) or by such provider or facility (as applicable) and the amount of such offer so selected expressed as a percentage of the qualifying payment amount;

(v) the category and practice specialty of each such provider or facility involved in furnishing such items and services;

(vi) the identity of the health plan or health insurance issuer, provider, or facility, with respect to the notification;

(vii) the length of time in making each determination;

(viii) the compensation paid to the certified IDR entity with respect to the settlement or determination; and

(ix) any other information specified by the Secretary.

(C) IDR entity requirements

For 2022 and each subsequent year, an IDR entity, as a condition of certification as an IDR entity, shall submit to the Secretary such information as the Secretary determines necessary to carry out the provisions of this subsection.

(D) Clarification

> The Secretary shall ensure the public reporting under this paragraph does not contain information that would disclose privileged or confidential information of a group health plan or health insurance issuer offering group or individual health insurance coverage or of a provider or facility.

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42 U.S.C. § 300gg-112 (excerpts)

§ 300gg-111. Ending surprise air ambulance bills

(a) In general

In the case of a participant, beneficiary, or enrollee who is in a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who receives air ambulance services from a nonparticipating provider (as defined in section 300gg-111(a)(3)(G) of this title) with respect to such plan or coverage, if such services would be covered if provided by a participating provider (as defined in such section) with respect to such plan or coverage—

(1) the cost-sharing requirement with respect to such services shall be the same requirement that would apply if such services were provided by such a participating provider, and any coinsurance or deductible shall be based on rates that would apply for such services if they were furnished by such a participating provider;

(2) such cost-sharing amounts shall be counted towards the in-network deductible and in-network out-of-pocket maximum amount under the plan or coverage for the plan year (and such in-network deductible shall be applied) with respect to such items and services so furnished in the same manner as if such cost-sharing payments were with respect to items and services furnished by a participating provider; and

(3) the group health plan or health insurance issuer, respectively, shall—

(A) not later than 30 calendar days after the bill for such services is transmitted by such provider, send to the provider, an initial payment or notice of denial of payment; and

(B) pay a total plan or coverage payment, in accordance with, if applicable, subsection (b)(6), directly to such provider furnishing such services to such participant, beneficiary, or enrollee that is, with application of any initial payment under subparagraph (A), equal to the amount by which the out-of-network rate (as defined in section 300gg-111(a)(3)(K) of this title) for such services and year involved exceeds the cost-sharing amount imposed under the plan or coverage, respectively, for such services (as determined in accordance with paragraphs (1) and (2)).

(b) Determination of out-of-network rates to be paid by health plans; independent dispute resolution process

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(5) Payment determination

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(C) Considerations in determination

(i) In general

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 air ambulance service shall consider—

(I) the qualifying payment amounts (as defined in section 300gg-111(a)(3)(E) of this title) for the applicable year for items or services that are comparable to the qualified IDR air ambulance service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR air ambulance service; and

(II) subject to clause (iii), 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).

(ii) Additional circumstances

For purposes of clause (i)(II), the circumstances described in this clause are, with respect to air ambulance services included in the notification submitted under paragraph (1)(B) of a nonparticipating provider, group health plan, or health insurance issuer the following:

(I) The quality and outcomes measurements of the provider that furnished such services.

(II) The acuity of the individual receiving such services or the complexity of furnishing such services to such individual.

(III) The training, experience, and quality of the medical personnel that furnished such services.

(IV) Ambulance vehicle type, including the clinical capability level of such vehicle.

(V) Population density of the pick up location (such as urban, suburban, rural, or frontier).

(VI) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider and the plan or issuer, as applicable, during the previous 4 plan years.

(iii) Prohibition on consideration of certain factors

In determining which offer is the payment amount to be applied with respect to qualified IDR air ambulance services furnished by a provider, the certified IDR entity with respect to such determination shall not consider usual and customary charges, the amount that would have been billed by such provider with respect to such services had the provisions of section 300gg-135 of this title not applied, or the payment or reimbursement rate for such services furnished by such provider payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], under the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.], under the Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.], under the TRICARE program under chapter 55 of title 10, or under chapter 17 of title 38.

(D) Effects of determination

The provisions of section 300gg-111(c)(5)(E) of this title shall apply with respect to a determination of a certified IDR entity under subparagraph (A), the notification submitted with respect to such determination, the services with respect to such notification, and the parties to such notification in the same manner as such provisions apply with respect to a determination of a certified IDR entity under section 300gg-111(c)(5)(E) of this title, the notification submitted with respect to such determination, the items and services with respect to such notification, and the parties to such notification.

45 C.F.R. § 149.510 (excerpts)

§ 149.510 Independent dispute resolution process.

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(c) Federal IDR process following initiation—

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(4) Payment determination for a qualified IDR item or service—

(i) Submission of offers. Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(1) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(2) Information requested by the certified IDR entity relating to the offer.

(3) The following additional information, as applicable—

(i) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(ii) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(iii) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(iv) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) Payment determination and notification. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, weighing only the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) Considerations in determination. In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(1) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(2) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(3) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(4) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(5) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying

payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) Examples. The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) Example 1—

(1) Facts. A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(2) Conclusion. In this paragraph (c)(4)(iv)(A) (Example 1), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating

emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) Example 2—

(1) Facts. A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(2) Conclusion. In this paragraph (c)(4)(iv)(B) (Example 2), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified

IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) Example 3—

(1) Facts. A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(2) Conclusion. In this paragraph (c)(4)(iv)(C) (Example 3), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) Example 4—

(1) Facts. A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written

information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(2) Conclusion. In this paragraph (c)(4)(iv)(D) (Example 4), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) Example 5—

(1) Facts. A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR

service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(2) Conclusion. In this paragraph (c)(4)(iv)(E) (Example 5), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

(v) Prohibition on consideration of certain factors. In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) Written decision.

(A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

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45 C.F.R. § 149.520 (excerpts)

§ 149.510 Independent dispute resolution process for air ambulance services.

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(b) Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process—

(1) In general. Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(2) Considerations for air ambulance services. In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) Weighing considerations. In weighing the considerations described in paragraph (b)(2) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under § 149.510(c)(4)(iii)(A) or other credible information under § 149.510(c)(4)(iii)(B) through (D), except that the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

***

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

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July 13, 2023

Mr. Kevin Benjamin Soter
U.S. Department of Justice
Civil Division, Appellate Section
950 Pennsylvania Avenue, N.W.
Room 7222
Washington, DC 20530

No. 23-40217 Texas Medical Association v. HHS
USDC No. 6:22-CV-372
USDC No. 6:22-CV-373

Dear Mr. Soter,

We have determined that your brief is deficient (for the reasons cited below) and must be corrected within 14 days. We note that our Quality Control Program advised you of some of these deficiencies when you filed the document.

The only attachments allowed to the briefs without leave of court are statutes, rules, regulations, etc. and may not exceed the 15 page limit. See FED. R. APP. P. 28(f). A motion is required to file in excess pages, or the addendum may be filed separately with no page limitation. If you choose to file the addendum separately, the brief must be re-filed according to the paragraph below without the addendum attached.

Note: Once you have prepared your sufficient brief, you must electronically file your 'Proposed Sufficient Brief' by selecting from the Briefs category the event, Proposed Sufficient Brief, via the electronic filing system. Please do not send paper copies of the brief until requested to do so by the clerk's office. The brief is not sufficient until final review by the clerk's office. If the brief is in compliance, paper copies will be requested and you will receive a notice of docket activity advising you that the sufficient brief filing has been accepted and no further corrections are necessary. The certificate of service/proof of service on your proposed sufficient brief **MUST** be dated on the actual date that service is being made. Also, if your brief is sealed, this event automatically seals/restricts any attached documents, therefore you may still use this event to submit a sufficient brief.

Sincerely,

LYLE W. CAYCE, Clerk

Christina Rachal

By: _____
Christina C. Rachal, Deputy Clerk
504-310-7651

cc:
Mr. Brian Boynton
Ms. Anna L. Deffebach
Ms. Brenna Jenny
Ms. Jaime L.M. Jones
Mr. Madeleine Joseph
Mr. Eric Dean McArthur
Mr. Joshua Marc Salzman
Mr. Steven Shepard
Mr. Manuel Valle