

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

_____	)	
TEXAS MEDICAL ASSOCIATION, <i>et al.</i> ,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 6:22-cv-00372-JDK
	)	
U.S. DEPARTMENT OF HEALTH AND	)	Lead Consolidated Case
HUMAN SERVICES, <i>et al.</i> ,	)	
	)	
Defendants.	)	
_____	)	

**DEFENDANTS' REPLY IN SUPPORT OF THEIR  
CROSS-MOTION FOR SUMMARY JUDGMENT**

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## INTRODUCTION

Plaintiffs challenge a final rule issued by the Defendants—the Departments of the Treasury, Labor, and Health and Human Services (the “Departments”)—that establishes a process under which arbitrators will resolve payment disputes between health care providers or facilities and group health plans or health insurance issuers under No Surprises Act (the “NSA” or the “Act”). The Act prohibits health care providers and facilities, in certain circumstances, from balance billing patients for out-of-network items or services. In lieu of recovering reimbursement for those services directly from patients, if the provider and the health insurance plan or issuer cannot agree on a payment amount through negotiation, the Act creates an independent dispute resolution (“IDR”) process in which an arbitrator selects among offers of payment submitted by each party.

Congress left to the Departments the duty to establish by regulation the process under which the arbitrators decide which offer to select. Consistent with that Congressional command, the Departments issued reasonable procedural and evidentiary rules that provide a methodology to guide arbitrators in the decision-making process. The final rule, just like the Act, instructs arbitrators to consider the qualifying payment amount (“QPA”)—a term of art for the median in-network contracted rate for the same item or service and a rough proxy for the fair market rate—and all other permissible information submitted by the parties, but not to give weight to information that is noncredible, irrelevant, or duplicative. The final rule leaves entirely to the discretion of the arbitrators how to weigh credible, relevant and nonduplicative information in carrying out their ultimate task: to select the offer that best represents the value of the item or service at issue. The final rule also follows the statutory directive that places the responsibility for monitoring the accuracy of the QPA with the Departments, not the arbitrators, furthering Congress’s goal of an efficient and cost-effective arbitration process.

Plaintiffs lack standing to challenge the final rule. Because the portions of the final rule that Plaintiffs challenge do not govern which offer the arbitrator should ultimately select, their claim of injury ultimately falls flat: it is sheer speculation that the challenged portions of the final rule will lead arbitrators not to select their offer. Plaintiffs’ claims also fail on the merits. The final rule was well

within the Departments’ statutory authority—indeed, statutory mandate—to establish a uniform IDR process to guide arbitrators’ decision-making. And the challenged provisions of the final rule represent the kind of reasonable procedural and evidentiary guidance that agencies are allowed to promulgate to ensure consistency and reliability in the adjudication process.

Plaintiffs decry any rule that imposes a presumption or preference in favor of the QPA, but the final rule includes no such presumption. Contrary to Plaintiffs’ strained reading, the final rule: (i) requires arbitrators to consider all of the permissible information before them; (ii) does not elevate the QPA above other information or instruct arbitrators to give it any preferential weight; and (iii) leaves entirely up to the discretion of the arbitrators how to weigh credible, relevant, nonduplicative information when selecting an offer. And far from being arbitrary and capricious, and the final rule does not overlook any of Plaintiffs’ claimed “problems” with the QPA and is plainly workable. Plaintiffs’ arguments boil down to the fact that they dislike that the arbitrators must consider the QPA at all, but Plaintiffs cannot escape the fact that it was Congress—not the Departments—that required arbitrators to consider the QPA when making payment determinations in the IDR process.

This Court should grant Defendants’ cross-motion for summary judgment.

## **ARGUMENT**

### **I. Plaintiffs Have Not Shown That They Have Standing To Challenge The Final Rule’s Arbitration Procedures.**

#### **A. None Of The Plaintiffs Have Demonstrated Cognizable, Redressable Injury.**

To establish Article III standing, Plaintiffs must show they have suffered “an invasion of a legally protected interest [that] is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 459 (5th Cir. 2005) (quoting *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 560 (1991)). Plaintiffs argue they will be harmed because the final rule will cause arbitrators to select payers’ offers instead of their offers, but they do not challenge provisions of the final rule that instruct, or even determine, which offer the arbitrator should select. Thus, Defendants’ argument is not that Plaintiffs lack standing because their claims fail on the merits—they lack standing because they challenge provisions of the final rule that could not actually

injure them.

In the lawsuit over the interim final rule, *Texas Medical Association v. United States Department of Health & Human Services* (“*TMA I*”), 587 F. Supp. 3d 528, 540 (E.D. Tex. 2022), the plaintiffs challenged the provisions of the interim final rule that instructed the arbitrator which offer to select. This Court found standing based on the plaintiffs’ affidavits suggesting that the interim final rule’s instruction for arbitrators to select the offer closest to the QPA, unless certain other conditions were met, would necessarily lead the arbitrators to not select the plaintiffs’ offers, because those offers would almost always be further from the QPA. *Id.* at 537-38. The final rule, however, instructs arbitrators to select the offer that “best represents the value of the qualified IDR item or service” and Plaintiffs do not challenge that portion of the final rule. 45 C.F.R. § 149.510(c)(4)(ii)(A).

Instead, here, Plaintiffs’ affidavits speculate about what offers *payers* are likely to submit but that speculation has no bearing on whether *arbitrators* will determine that the payers’ offers will be the ones that best represent the value of the item or service. Thus, Plaintiffs cannot simply claim standing on the same basis as in *TMA I*. The challenged provisions here, unlike the in *TMA I*, do not instruct the arbitrator which offer it should select, and thus cannot cause any injury to Plaintiffs. Plaintiffs instead challenge portions of the final rule that instruct the arbitrator to consider the QPA and “then” “evaluate whether the information is credible and relates to the offer submitted by either party” and to “not give weight to information to the extent it is not credible, it does not related to either party’s offer . . . or is already accounted for by the [QPA] . . . or other credible information.” 45 C.F.R. § 149.510(c)(4)(iii)(B), (E). Additionally, Plaintiffs do not assert that they intend to submit noncredible or irrelevant information to the arbitrators. *TMA Pls.’ Opp’n to Defs.’ Mot. For Summ. J. and Reply in Supp. of Summ. J.* at 5, ECF No. 82 (“*TMA Reply*”). Plaintiffs cannot claim a financial injury based on their speculative and unsupported theory that the final rule will somehow lead arbitrators not to select their offers. *See California v. Texas*, 141 S. Ct. 2104, 2117 (2021) (“[A]t the summary judgment stage, such a party can no longer rest on mere . . . allegations, but must set forth . . . specific facts’ that adequately support their contention.”).

For these same reasons, Plaintiffs have also failed to establish that any claimed injury is

redressable by the relief requested here. Plaintiffs have not shown that a court order vacating the procedural and evidentiary portions of the final rule they challenge will make their offers more likely to “best represent the value of the qualified IDR item or service.” 45 C.F.R. § 149.510(c)(4)(ii)(A). And a victory in this lawsuit would not cure any of Plaintiffs’ claimed problems with the calculation of the QPA (as Plaintiffs admit in their separate lawsuits challenging those regulations, *Texas Medical Association v. United States Department of Health & Human Services*, No. 6:22-cv-450-JDK, ECF No. 1 at 4 (E.D. Tex. Nov. 30, 2022) (“Even if plaintiffs in *TMA II* successfully challenge the Departments’ renewed efforts to anchor arbitration outcomes to the QPA, however, the Departments’ flawed methodology that deflates QPAs will continue to harm physicians.”); see also *LifeNet, Inc. v. United States Department of Health & Human Services*, No. 6:22-cv-00453-JDK (E.D. Tex. Dec. 1, 2022)). Plaintiffs’ argument that they will be injured because the final rule reimposes a presumption in favor of the QPA requires arbitrators to adopt a convoluted reading of the final rule that the Departments themselves, in the rule, have expressly disclaimed. Such speculation does not establish standing. See *Missouri v. Yellen*, 39 F. 4th 1063, 1069 (8th Cir, 2022), *petition for cert. filed*, No. 22-352 (Oct. 14, 2022).

Finally, Plaintiffs cannot claim standing based on the sort of procedural injury the Court found in *TMA I*. 587 F. Supp. 3d at 537. The final rule was promulgated after a period of notice-and-comment rulemaking. And while Plaintiffs gesture at an indeterminate procedural injury based on an alleged “depriv[ation] of the arbitration process established by the Act” TMA Reply at 3, it is settled that a “deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.” *Summers v. Earth Island Inst.*, 555, U.S. 488, 496 (2009). There is no concrete interest—financial or otherwise—impacted by the challenged portions of the final rule. The final rule leaves to the discretion of the arbitrator how to weigh the credible, relevant, nonduplicative information and the ultimate selection of which offer best represents the value of the item or service at issue. Plaintiffs have failed to establish a procedural violation sufficient to confer standing here.

**B. LifeNet Has Still Failed To Demonstrate That It Has Standing.**

LifeNet does not have standing to challenge the final rule because it does not participate in arbitrations conducted under the Act, and its compensation is unaffected by the outcome of such arbitrations. As explained in Defendants' opening brief, because Air Methods Corporation participates in arbitrations involving services provided by LifeNet, only Air Methods has a financial interest in the outcome of those arbitrations; Plaintiff is paid a fixed amount whether or not Air Methods obtains reimbursement from other payers. Defs.' Cross-Mot. For Summ. J. and Mem. in Opp. to Pls.' Summ. J. Mots. at 20-22, ECF No. 63 (Defs.' Mot.). None of LifeNet's arguments are sufficient to show that it has a stake in the outcome of the Act's arbitrations, or that it will suffer any injury as a result of the challenged provisions. LifeNet has entirely failed to show that even if Air Methods stands to do better under revised IDR regulations, it will pass that financial benefit on to LifeNet in any way. *See Summers*, 555 U.S. at 496 (rejecting a standing theory premised on a speculative chain of possibilities). In sum, LifeNet has not demonstrated that it will suffer any injury traceable to the final rule. While Defendants acknowledge that this Court has previously rejected a similar challenge to LifeNet's standing, Defendants respectfully preserve them here to explain why LifeNet remains an improper plaintiff to challenge the final rule.

LifeNet argues that it has standing because it is an "object" of the challenged regulation and has suffered a procedural harm. LifeNet insists that it is "directly regulated" by the rule, as a provider of out-of-network air ambulance services. LifeNet's Opp'n to Defs.' Mot. for Summ. J. and Reply in Supp. of Summ. J. ("LifeNet Reply") at 11, ECF No. 83. Not so. The "provider" that is regulated by the Act's arbitration provisions, or whose interests these provisions (arguably) protect, is the entity that submits the reimbursement claim and that will receive payment in the amount determined by the arbitrator. *See* 42 U.S.C. § 300gg-111(c)(1). That entity is Air Methods. LifeNet itself is not "directly regulated" by these provisions at all. Nor does LifeNet advance its claim to standing by asserting that it suffers a "procedural injury." LifeNet Reply at 13. As noted above, none of the Plaintiffs in this case have shown that they suffer any concrete injury from the regulation. LifeNet therefore cannot claim standing based on a procedural injury or as an "object" of the final rule since it does not participate

in any of the procedures at issue.

LifeNet's contention that it has standing because Air Methods could decide not to renew its contract, LifeNet Reply at 12, is similarly unavailing. *See Kitty Hawk*, 418 F.3d at 459 (rejecting "Kitty Hawk's claims of injury resulting from future contracts" because they rely "on a string of hypotheticals and conjectures"). As a matter of law, LifeNet cannot meet its burden of proof by relying on speculation as to the likelihood that a third party might act in a given way in response to the rule. *See Inclusive Cmty. Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 655-56 (5th Cir. 2019). Even if Air Methods were to someday negotiate less favorable contract terms, LifeNet would have to establish that it is "substantially probable that the challenged acts of the defendant, not of some . . . third party[,] . . . caused the injury." *Ortiz v. Am. Airlines, Inc.*, 5 F.4th 622, 629 (5th Cir. 2021) (quoting *Fla. Audubon Soc. v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996)).

Finally, LifeNet cannot establish that the final rule has caused it a reputational injury sufficient to confer standing. LifeNet may not assert standing on the possibility that it might be disparaged if an arbitrator makes statements about the value of air ambulance services. LifeNet Reply at 13-14. The kind of reputational harm that rises to the level of an injury in fact to support standing are far graver than what LifeNet alleges here—more akin to a libel that is the core of a plaintiff's claimed injury than a collateral reputational consequence from slightly lower compensation for a given item or service. *See, e.g., McBryde v. Comm. to Rev. Cir. Council Conduct & Disability Ords. of Jud. Conf. of U.S.*, 264 F.3d 52, 56-57 (D.C. Cir. 2001) (holding that a statement of public reprimand issued on the Fifth Circuit's website against a district judge was enough of a reputational injury for standing, and noting that "the Supreme Court has strongly suggested, without deciding, that where an effect on reputation is a collateral consequence of a challenged sanction, it is insufficient to support standing"). At any rate, a claim of standing based on a reputational injury must be more than speculative. *See Advanced Mgmt. Tech., Inc. v. F.A.A.*, 211 F.3d 633, 637 (D.C. Cir. 2000). For this same reason, LifeNet's argument that it may someday want to borrow money and might attribute a possible future lower valuation or credit score to the final rule fails to pass muster at summary judgment. On summary judgment, LifeNet "must have adduced evidence to support controverted factual allegations" in support of its standing.

*El Paso Cnty. v. Trump*, 982 F.3d 332, 338 (5th Cir. 2020), *cert. denied*, 141 S. Ct. 2885 (2021). It has failed to do so.

**C. East Texas Air One Is Not A Proper Party, And This Court Should Not Consider Whether It Has Standing.**

This Court should not consider whether East Texas Air One has standing to challenge the final rule here. LifeNet filed an Amended Complaint purporting to add East Texas Air One as a plaintiff only after (indeed, mere hours after) Defendants filed their response to Plaintiffs' motion for summary judgment and cross-motion in support of summary judgment. Am. Compl., ECF No. 64. Defendants therefore had no opportunity to develop or make any arguments as to whether East Texas Air One has standing, or indeed, to develop or make any arguments at all specific to East Texas Air One, including any other potential defenses Defendants might raise. As explained in Defendants' motion to strike, the Amended Complaint was procedurally improper and should be given no legal effect. ECF No. 81 (citing *United States ex rel. Mathews v. HealthSouth Corp.*, 332 F.3d 293, 296 (5th Cir. 2003)). LifeNet cannot rely on its improper attempt to add East Texas Air One to cure the deficiencies in its own standing. If Defendants' motion to strike is denied, Defendants should be afforded an opportunity to brief arguments specific to East Texas Air One.

**II. The Departments Had Statutory Authority—Indeed, A Statutory Obligation— To Promulgate Reasonable Procedural And Evidentiary Rules To Establish The IDR Process.**

The Departments exercised their statutory authority to promulgate regulations governing the IDR process, and the regulations issued under that authority are entitled to deference. Contrary to Plaintiffs' intimation, the Departments did not make up a duty to establish rules governing the IDR process out of whole cloth, but issued the final rule in response to Congress's express instruction to establish, by regulation, a process under which arbitrators make their payment determinations. 42 U.S.C. § 300gg-111(c)(2)(A).<sup>1</sup> Plaintiffs' invocation of cases where agencies tried to find rulemaking authority where none existed are therefore inapposite. See *Gulf Fishermens Ass'n v. Nat'l Marine Fisheries*

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<sup>1</sup> A parallel provision requiring the Departments to establish an arbitration process for air ambulance payments is codified at 42 U.S.C. § 300gg-112(b)(2)(A).

*Serv.*, 968 F.3d 454, 461 (5th Cir. 2020), as revised (Aug. 4, 2020); *Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 753 (5th Cir. 2011). The Departments do not, as Plaintiffs claim, as the Court to “presume a delegation of power absent an express withholding of such power.” *Gulf Fishermens Ass'n*, 968 F.3d at 461. Quite the opposite: the statute requires the Departments to establish by regulation an IDR process for making payment determinations, and that is exactly what they did.

The statute states that the Departments “shall establish by regulation one independent dispute resolution process . . . under which . . . a certified IDR entity . . . 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.” 42 U.S.C. § 300gg-111(c)(2)(A). The statute thus requires the Departments to “establish one independent resolution process” “under which” the IDR entity “determines” the amount of payment in accordance with the statute. *Id.* Although Congress required the Departments to establish regulations for a decision-making process, it did not spell out what procedural rules they must establish or what those rules should look like, other than that the rules should lead the arbitrators to make decisions in accordance with the statute. Congress’s use of the phrase “one . . . process” further suggests that it intended the Departments to establish a process that would be standardized, uniform, or otherwise predictable across all of the IDR entities.

A directive to “establish by regulation” is, of course, a delegation of substantive rulemaking authority. *See In re Avandia Mktg., Sales Pract. & Prod. Liab. Litig.*, 685 F.3d 353, 366 (3d Cir. 2012). Given the sheer volume of payment disputes to be adjudicated under the Act, with over 90,000 arbitrations being initiated in the first few months, the need for procedural regularity is even more pronounced. *See Barnhart v. Walton*, 535 U.S. 212, 225 (2002) (holding that “the vast number of claims that [the statute] engenders, and the consequent need for agency expertise and administrative experience lead us to read the statute as delegating to the Agency considerable authority to fill in, through interpretation, matters of detail related to its administration.”); *Ctrs. for Medicare & Medicaid Servs., Calendar Year 2023 Fee Guidance for the Federal [IDR] Process under the No Surprises Act*, at 5 (Oct. 31, 2022) (over 90,000 arbitrations initiated between April 2022 and September 2022) *available at*

<https://www.cms.gov/cciiio/resources/regulations-and-guidance/downloads/cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf>.

Plaintiffs' focus on statutory provisions that they claim are "unambiguous" does not prove as much as they claim. TMA Reply at 7-8. Although the Act may be unambiguous in some respects (for example, it unambiguously requires the arbitrator to select between the two offers before her), the Act does not specifically describe every detail of the procedures and methodologies the Departments should establish to guide arbitrators in the decisionmaking process. *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (under *Chevron* a court first asks "whether the statute's plain terms 'directly address[s] the precise question at issue.'" (quoting *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984))). A statute can be unambiguous in some respects and ambiguous or silent in others—it is the *precise* question at issue that determines whether there is a statutory gap or ambiguity. *Nat'l Cable & Telecomm. Ass'n*, 545 U.S. at 986. Thus, while as Plaintiffs recognize the Act unambiguously requires an arbitrator to not to consider impermissible information, the statute is not similarly unambiguous on each minute detail of the "one independent resolution process" "under which" the arbitrator reaches her decision. 42 U.S.C. § 300gg-111(c)(2)(A). That the statute may speak unambiguously to other issues not implicated in this litigation is irrelevant to whether the specific portions of the final rule that Plaintiffs have challenged reflect permissible exercises of statutory authority, including to the extent the final rule fills statutory gaps.

The statute therefore leaves a gap, directing the Departments to establish "one . . . process . . . under which . . . an IDR entity determines" payment amounts without spelling out what that deliberative process under which decisions are made should look like. *Id.* In other words, Congress delegated a "specific task" to the Departments "without giving detailed instructions" and therefore "the agency gets to fill the silence." TMA Reply at 9 (quoting *Marlow v. New Food Guy, Inc.*, 861 F.3d 1157, 1163 (10th Cir. 2017)). The statutory scheme here thus bears no resemblance to cases where agencies claim that Congressional silence on an entire topic confers rulemaking authority, *cf. Coffelt v. Fawkes*, 765 F.3d 197, 202 (3rd Cir. 2014) (finding statute that failed to address topic entirely did not create statutory ambiguity), or to a "comprehensive" statutory scheme that is entirely silent on the

regulatory authority claimed by the agency. *See, e.g., Nat'l Pork Producers*, 635 F.3d at 753. For example, in *Gulf Fishermans Association*, where the statute was silent on the entire industry that the agency sought to regulate, the court declined to infer expansive rulemaking authority based on silence alone. 968 F.3d at 465. Here, in contrast, there is an express grant of rulemaking authority (“shall establish”) that leaves gaps for the Departments to fill (“one . . . process” “under which” payment determinations should be made). The Departments were therefore not only authorized, but required, to establish rules setting forth the process for arbitrators to follow in their decision-making, although Congress was silent on what those rules and procedures should look like, other than that they should be in accordance with the statute. *See, e.g., Sweeney v. Westvaco Co.*, 926 F.2d 29, 35 (1st Cir. 1991) (Breyer, J.) (explaining that “in accordance with” is ambiguous and could mean “mandated” by or “not forbid[den]” by); *see also United States v. Curb*, No. 06 CR 324-31, 2019 WL 2017184, at \*4 (N.D. Ill. May 7, 2019) (“To be ‘in accordance’ does not require precise equivalency, but only agreement, conformity, or consistency.”).

This gap, therefore, was left for the Departments to fill. *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (“[s]tatutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency”). And the Departments did just that, creating reasonable procedural rules to help ensure regularity and predictability in the IDR process.

Plaintiffs also seem to argue that, to the extent there is any gap or ambiguity in the decision-making process, it should have been for the certified IDR entities, not the Departments, to fill.<sup>2</sup> TMA Reply at 8-9. But the Departments’ extensive regulation of the IDR entities overall does not logically limit the Departments’ ability to set reasonable procedures for establishing a standardized IDR process

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<sup>2</sup> TMA argues that, because its comment letter urged the Departments to promulgate rules governing how arbitrators would consider the Act’s statutory factors and the QPA in a way that would not prioritize the QPA, the letter is not inconsistent with its position in this litigation. But if the Departments had the authority, as TMA seemed to assume they did, to promulgate rules governing the arbitrators’ consideration of the statutory factors in a way that it likes, TMA’s position necessarily encompassed the view that the Departments have the authority to promulgate rules governing how the arbitrators consider the Act’s statutory factors. *See* Letter from E. Linda Villarreal, President, Tex. Med. Ass’n, et al., to Xavier Becerra, Secretary, U.S. Dep’t of Health & Human Servs., et al., at 16 (Sept. 7, 2021) (AR 7832) (asking Departments to “[r]equire the IDR entity . . . to be provided with direction”).

under the statute. *Id.* at 11. In fact, the “detailed rules” that Congress required the Departments to establish governing IDR entities in other respects strengthens the idea that Congress intended the Departments to closely supervise and regulate the IDR entities to ensure that they follow a standardized process for approaching decision-making in payment disputes. *Id.* Even if Congress could have directed the certified IDR entities to establish their own procedural rules governing arbitrations under the Act, it did not do so. Instead, Congress chose to vest the power to establish a decision-making process with the Departments. *See* 42 U.S.C. § 300gg-111(c)(2)(a) (“the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, shall establish by regulation one independent dispute resolution process. . .”). This shows Congress’s recognition that there should be across-the-board standards, rules, procedures, and methodologies to help ensure that procedures followed in each individual arbitration should not depend on the whims of the particular IDR entity deciding it.

Nevertheless, Plaintiffs ignore that the final rule does not actually prevent arbitrators from considering any permissible information in the first place, nor does it instruct them on *how* to weigh all of the relevant, nonduplicative, and credible information, consistent with this Court’s prior opinions. The final rule leaves a great deal to the discretion of the arbitrators and imposes no procedures or requirements on *how* an arbitrator should weigh the relevant, credible, nonduplicative information when deciding which offer best represents the value of the qualified IDR item or service. On this, the key question before the arbitrator, the Departments left the arbitrator to her own discretion.

### **III. The Challenged Portions Of The Final Rule Are Reasonable Evidentiary And Procedural Regulations Establishing A Predictable And Consistent IDR Process And Are Not Arbitrary Or Capricious.**

As noted above, Plaintiffs do not challenge the portion of the final rule that instructs the arbitrator which offer to select, *see* 45 C.F.R. § 149.510(c)(iv)(2)(A) (directing the arbitrator to select the offer that “best represents the value of the qualified IDR item or service”), but instead challenge ancillary provisions that are intended to “ensure that certified IDR entities have clear guidance on how

to evaluate potentially voluminous and complex information in a methodological and consistent manner.” *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618, 52,627 (Aug. 26, 2022). These portions of the final rule reflect a reasonable interpretation of the statute and is thus entitled to *Chevron* deference.<sup>3</sup>

Although the arbitrators are required by statute to consider the QPA, *see* 42 U.S.C. § 300gg-111(c)(5)(C)(i), the final rule does not prescribe any particular weight that should be given to that amount, consistent with this Court’s prior opinions. *See* 87 Fed. Reg. at 52,627 (“The Departments note that these final rules are not intended to impose a rebuttable presumption for payment determinations in the Federal IDR process.”); *see also id.* (“The regulatory text in these final rules does not include the provisions that the District Court reasoned would have the effect of imposing such a presumption.”). The final rule does not place any greater weight on the QPA than on any other factor (indeed, it repeatedly and expressly disclaims doing so), and it instructs the arbitrator to consider all the permissible information submitted by the parties. The final rule leaves entirely to the discretion of the arbitrator how to weigh credible, relevant, and nonduplicative information. But, the rule explains, arbitrators should not give weight to information that is noncredible, irrelevant to the task at hand, or duplicative. 45 C.F.R. § 149.150(c)(4)(iii)(E).

These basic methodological and procedural rules serve as guardrails to ensure that all IDR entities are following “one independent dispute resolution process,” 42 U.S.C. § 300gg-111(c)(2)(A), and are intended to “promote consistency and predictability in the process[.]” 87 Fed. Reg. at 52,627. Although Plaintiffs argue that the challenged provisions of the final rule are not evidentiary, methodological, or procedural rules, but are in fact more substantive, TMA Reply at 10, the challenged provisions guide the arbitrators in how to evaluate the evidence before them and bear a close resemblance to other evidentiary rules, such as the Federal Rules of Evidence. *Compare* 87 Fed. Reg. at 52,628 (information relates to a party’s offer “if it tends to show that the offer best represents the

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<sup>3</sup> The Plaintiffs hint in a footnote at a potential future challenge to the viability of the *Chevron* doctrine. TMA Reply at 22 n.4. This argument, raised only in a footnote in a reply brief, is waived. *See, e.g., Arbuckle Mountain Ranch of Tex., Inc. v. Chesapeake Energy Corp.*, 810 F.3d 335, 339 n.4 (5th Cir. 2016). *Chevron*, of course, remains precedent that is binding on this Court.

value of the item or service under dispute”) *with* Fed. R. Evid. 401 (“Evidence is relevant if it has a tendency to make a fact more or less probable . . . and the fact is of consequence in determining the action).

An agency may establish procedural, methodological, and evidentiary rules to govern individual adjudications. *See, e.g., Chem. Mfrs. Ass’n v. Dep’t of Transp.*, 105 F.3d 702, 705 (D.C. Cir. 1997); *Am. Hosp. Ass’n v. NLRB*, 499 U.S. 606, 612 (1991) (recognizing agency authority to use rulemaking to establish “general principles to guide the required case-by-case . . . determinations”); *Martin v. Occupational Safety and Health Review Comm’n*, 499 U.S. 144, 152 (1991) (accord[ing] deference to the agency with rulemaking authority, rather than a separate adjudicative body). Those rules are entitled to deference. *See Martin*, 499 U.S. at 152; *Nat’l Min. Ass’n v. Dep’t of Labor*, 292 F.3d 849, 868 (D.C. Cir. 2002). Plaintiffs complain (TMA Reply at 9) that the cases cited by Defendants deal with adjudications that are not only overseen by agencies, but also conducted by agency staff. *See Martin*, 499 U.S. at 152; *see also New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992); *Cent. Vt. Ry., Inc. v. Interstate Commerce Comm’n*, 711 F.2d 331, 336 (D.C. Cir. 1983); *Ramirez v. ICE*, 471 F. Supp. 3d 88, 175 (D.D.C. 2020). That is true. But it does not logically follow that agencies that oversee adjudications may promulgate reasonable procedural and evidentiary rules only when their own employees conduct those adjudications, and Plaintiffs cite no caselaw to suggest that the same rule would not govern here. The Act provides for the Departments to supervise the IDR entities through certification, decertification, and audits of the IDR entities’ decisions—a degree of control comparable to that exercised by many agencies over their own adjudicators. *See* 42 U.S.C. § 300gg-111(a)(2)(A), (c)(4), (c)(7)(C). As the Supreme Court has explained, this authority to promulgate reasonable procedural rules is to stem the “discretionary chaos” that would result if each individual adjudicator made up their own rules. *Am. Hosp. Ass’n*, 499 U.S. at 612 (quoting K. Davis, *Administrative Law Text* § 6.04, p. 145 (3d ed. 1972)). And the need to stem that chaos is no less great when the adjudicators are independent arbitrators rather than agency employees. Each participant in the IDR process should have an expectation that their dispute will be decided under similar procedures no matter which individual IDR entity happens to be conducting the adjudications. Therefore, the caselaw that Defendants rely

on applies with equal force to the circumstances here. And Plaintiffs have no other rebuttal to the well-established proposition that agencies can establish reasonable procedural, methodological, and evidentiary rules to ensure consistency and predictability among individual adjudications. *See Chem. Mfrs. Ass'n*, 105 F.3d at 705; *Nat'l Min. Ass'n*, 292 F.3d at 868; *Am. Hosp. Ass'n*, 499 U.S. at 612.

All of the reasonable procedural and methodological provisions that Plaintiffs challenge here are consistent with the Act. The final rule requires the arbitrator to consider all the permissible information before her. 45 C.F.R. § 149.510(c)(4)(iii)(B)-(D). After considering all that information, however, the final rule explains that the arbitrator, in reaching her decision, should not give weight to information that is noncredible, irrelevant to the task at hand, or duplicative. *Id.* § 149.510(c)(4)(iii)(E). Although Plaintiffs fault the rules for establishing a decision-making process, *see* TMA Reply at 23 (describing Plaintiffs' characterization of a three-step process), it is just that—a process under which arbitrators make their determinations—that Congress directed the Departments to establish by regulation. These rules are important to ensure that arbitrators approach payment disputes with a similar methodology and procedure. *See* 87 Fed. Reg. at 52,627. By promoting consistency and predictability in the IDR process, the final rule also furthers the Act's goal of lowering administrative costs and encouraging the parties to resolve disputes through negotiation. *See* H.R. Rep. No. 116-615, at 58 (AR 335); 42 U.S.C. § 300gg-111(c)(5)(E)(ii). As explained below, each challenged provision reflects a reasonable interpretation of the Act and is therefore entitled to deference.<sup>4</sup> Likewise, none of the challenged provisions are arbitrary or capricious, and those provisions do not meet the high bar that courts set for setting aside agency action under that “highly deferential” standard. *Knapp v. Dep't*

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<sup>4</sup> Plaintiff LifeNet attempted to submit with its reply brief what appears to be a letter from two members of Congress claiming that some portions of the final rule do not reflect legislative intent. But post-enactment views of a couple of members of Congress cannot be presumed to reflect the intent of Congress as a whole and are of little value in determining legislative intent. *See SE Cmty. Coll. v. Davis*, 442 U.S. 397, 411 n.11 (1979) (“isolated statements made by individual Members of Congress or its committees, all made after the enactment of the statute under consideration, cannot substitute for a clear expression of legislative intent at the time of enactment”). Additionally, the exhibit was untimely evidence and should not be considered. *See* Local Rule CV-56(a) (all evidence for a summary judgment motion should be provided with the motion). Even if this Court were to review the letter, the members of Congress only appear to take issue with the double-counting rule and accompanying written decision requirements and are not critical of the credibility or relevancy provisions in the final rule. *See* LifeNet Reply Ex. 1, ECF No. 83-3.

*of Agric.*, 796 F.3d 445, 453 (5th Cir. 2015).

**A. The Credibility Provision Is A Reasonable Procedural Rule Entitled To Deference And Is Not Arbitrary Or Capricious.**

The final rule carries over a provision from the interim final rule that instructs arbitrators to give weight only to information that is credible—that is, “worthy of belief” and “trustworthy.” 45 C.F.R. § 149.510(a)(2)(v).<sup>5</sup> The arbitrator should determine whether information submitted by the parties—either because the information relates to the statutory factors, was requested by the arbitrator, or was submitted by the parties because it relates to the offer of payment—is credible before the arbitrator gives that information weight in making her final determination. The rules promulgated under the Act, including the July 2021 interim final rules relating to the QPA and the August 2022 final rule, provides that the arbitrator should give weight only to information that bears some indicia of credibility. For the QPA, that credibility is ensured through detailed regulations governing how that amount is calculated, *see* 45 C.F.R. § 149.140, and through an auditing and reporting system that imposes penalties for violations of those regulations, 42 U.S.C. § 300gg-111(a)(2)(A) (establishing an audit process), (a)(2)(B)(iv) (establishing a process for receiving complaints of violations); *id.* § 300gg-22; 45 C.F.R. § 150.301 (authorizing civil money penalties). For all other information before the arbitrator, which may often be subjective and qualitative in nature, the arbitrator should evaluate the credibility of the information before her. And the final rule does not circumscribe in any way the arbitrator’s discretion to weigh all of the pieces of credible information in reaching her final decision. The final rule thus promotes Congress’s goals of a uniform IDR process that will provide an efficient and consistent decision-making process for all the parties involved and helps ensure that arbitrators will not base their decisions on untrustworthy or noncredible information, while leaving the ultimate

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<sup>5</sup> Plaintiffs have waived any challenge to the credibility requirement, which was carried over from the interim final rule, and which Plaintiffs did not challenge in their prior litigation. Although Plaintiffs point to comments that raised complaints with how the QPA is calculated, Plaintiffs have no explanation for why they decided not to comment on or challenge the requirement that arbitrators consider only credible information, that is, information that is “worthy of belief and is trustworthy,” 45 C.F.R. § 149.510(a)(2)(v), and they point to no other commenters who took issue with the credibility requirement in the interim final rule either. It is “well established that issues not raised in comments before the agency are waived.” *Nat’l Wildlife Fed’n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002).

weighing of credible information to the discretion of the arbitrator.

Even though the final rule instructs arbitrators not to give weight to noncredible information in making their ultimate determination, the arbitrators are still required to consider all the permissible information before them. *See* 45 C.F.R. § 149.510(c)(4)(iii)(B)-(D). This is not a distinction without a difference, as Plaintiffs argue, TMA Reply at 10, but a procedural rule to aid arbitrators in wading through potentially voluminous and complex information. *See* 87 Fed. Reg. at 52,627. The arbitrator, faced with two offers, must select between them. The arbitrator will also be given a potentially vast amount of information pertaining to many aspects of the item or service at issue—the provider’s training and experience, the acuity of the patient, the case mix of the facility, to name just a few. After considering all this information, the arbitrator must decide which pieces of information tip the selection in favor of one offer over the other. The final rule thus instructs arbitrators not to rely on—or give weight to—noncredible information in making their ultimate selection of an offer.

Plaintiffs say that they take no issue with a general, across-the-board credibility requirement, TMA Reply at 13, but object that it is the Departments, not the arbitrators, who are tasked with policing the accuracy of the QPA. But it was Congress, not the Departments, who chose to place the obligation on monitoring and policing the accuracy of the QPA with the Departments, rather than the arbitrators. *See* 42 U.S.C. § 300gg-111(a)(2)(A) (tasking the Departments with establishing an audit process), (a)(2)(B)(iv) (tasking the Departments with establishing a process for receiving complaints of violations); 87 Fed. Reg. at 52,626 (noting “that the statute places the responsibility for monitoring the accuracy of plans’ and issuers’ QPA calculation methodologies with the Departments”). The final rule is consistent with this statutory delegation of responsibility.

Plaintiffs hypothesize about a situation where an insurer, contrary to the Departments’ guidance, uses \$0 “ghost rates” to calculate the QPA, and the provider believes that this renders the QPA noncredible. TMA Reply at 19. But the proper course of action in that scenario would not be to ask the arbitrator to re-examine or re-calculate the QPA—to the contrary, the provider in that scenario should follow the procedures created by Congress and implemented by the Departments for just such a situation. *See* 42 U.S.C.A. § 300gg-111(a)(2)(B)(iv) (requiring Departments to establish “a process to

receive complaints of violations of the requirements described in subclauses (I) and (II) of subparagraph (A)(i) [calculating the QPA] by group health plans and health insurance issuers offering group or individual health insurance coverage.”). Drafted against the background of the comprehensive regulatory framework for calculating, auditing, and reporting violations of the QPA, the final rule recognizes that, so long as the QPA is calculated in compliance with these regulatory requirements, it will have some indicia of credibility. And payers are deterred by the threat of monetary penalties if they do not calculate the QPA in accordance with the regulations. 45 C.F.R. § 150.301 (authorizing civil money penalties). It is not unreasonable, or arbitrary and capricious, to rely on the threat of civil money penalties to deter payers from violating the law in calculating the QPA. *Dep’t of Revenue of Mont. v. Kurth Ranch*, 511 U.S. 767, 778 (1994) (“civil penalties . . . deter certain behavior”).

Plaintiffs at times seem to conflate questioning the “credibility” of the QPA with questioning whether the QPA is representative of the value of the qualified IDR item or service. While arbitrators are not the ones that Congress tasked with evaluating whether the QPA was calculated correctly and accurately, and thus not the ones tasked with determining whether the QPA is “credible,” arbitrators can always evaluate whether the QPA represents the value of the qualified IDR item or service. Parties are free to argue that the QPA does not reflect the value of an item or service because, for example, the medical procedure at issue was particularly complex or required special skills that only providers with a particular level of training and experience can provide; because the payer has such a high market share in the region that it has monopolized compensation below fair value; or because the cost of providing the item or service exceeds the QPA, and they may make any other arguments not based on impermissible information. *See* 87 Fed. Reg. at 52,627. All these arguments go towards convincing the arbitrator that the QPA does not reflect the value of the item or service, but do not require the arbitrator to investigate the credibility or accuracy of the QPA.<sup>6</sup>

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<sup>6</sup> Plaintiffs, particularly LifeNet, fault the Departments for stating that their goal is to reduce health care costs overall, but this was Congress’s own goal. *See* LifeNet Reply at 6-9. The IDR process would not help lower health care costs if it served as a one-way ratchet, driving prices higher and higher. And, as Congress was well aware, prices for certain health care providers and services have skyrocketed in recent years, reflecting a market failure and calling out for a course correction to protect consumers from rising costs. *See* H.R. Rep. No. 116-615 at 53 (AR 330) (noting that “surprise billing

The Departments reasonably determined, consistent with the obligations imposed by Congress, that it was the duty of the Departments to monitor the accuracy of the QPA, and, because the Departments also wanted to ensure that arbitrations under the Act do not become long, drawn-out affairs, the arbitrators are not tasked with examining or re-calculating the accuracy of the QPA. As the Departments explained in the final rule, the regulations aimed to strike a balance between promoting an efficient arbitration process and providing some transparency into how the QPA was calculated. 87 Fed. Reg. at 52,625. “The Departments sought to balance those competing interests by, on the one hand, requiring plans and issuers to make certain disclosures with each initial payment or notice of denial of payment and to provide certain additional information upon request . . . and, on the other hand, avoiding more wide-reaching disclosure requirements that could add to the costs and burdens of adjudicating claims.” *Id.* And this is consistent with the statutory language evincing Congress’s intent for the IDR process to be low-cost and efficient. *See* 42 U.S.C. § 300gg-111(c)(3)(A) (Congress sought to “encourag[e] the efficiency” and “minimiz[e the] costs” of the arbitration process).

Congress, and the Departments, chose not to burden arbitrators with policing the accuracy of the QPA in order to ensure that the arbitration process is an efficient and cost-effective dispute resolution process. And because a single QPA may be used in multiple arbitrations at once (in multiple disputes before multiple IDR entities involving a single payer and the same kind of item or service), allowing one arbitrator to re-calculate or re-examine the QPA could have a ripple effect, disrupting

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represents a market failure” that has “enable[d] some providers to charge amounts for their services that exceed the marginal cost of producing those services and resulting in compensation far above what is needed to sustain their practice.”). Congress understood that “[t]he presence of this market failure in certain provider specialties is strongly supported by evidence reflecting the highly inflated payment rates for these services.” *Id.* Because Congress intended for the Act to rein in the “highly inflated payment rates” it is not surprising that some of the biggest offenders of price increases, such as Air Methods, saw their stock decline after the Act went into effect. *See* Loren Adler et al., *High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers*, USC-Brookings Schaeffer on Health Policy (Oct. 13, 2020) (AR 4769) (noting that Air Methods Corporation, in particular, took advantage of this market distortion by increasing its prices for medical transports by 283 percent from 2007 to 2016.) That the stock decline can be pegged to when the Act went into effect, and not when the final rule was issued, further supports that it was the Act itself, not the final rule, that aims to tamp down on excessive payments. LifeNet Reply at 8.

other ongoing arbitrations. The final rule thus furthers the Congressional purpose for the Act's independent dispute resolution mechanism to "reduce premiums and the deficit," H.R. Rep. No. 116-615, at 58 (AR 335), a goal that could only be accomplished if that mechanism were structured to facilitate a streamlined and efficient arbitration process, *see id.* at 57 (AR 334). While there will always be some administrative costs incurred in the arbitration process, "[i]f those administrative costs are high enough, they could undermine the effectiveness of the [Act.]" Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions, 116th Cong. 8 (2019) (statement of Christen Linke Young, Brookings Inst.) (AR 460). The volume of arbitrations initiated under the Act has already far exceeded the Departments' initial expectations, burdening arbitrators with high caseloads and administrative costs. Ctrs. for Medicare & Medicaid Servs., *Calendar Year 2023 Fee Guidance for the Federal [IDR] Process under the No Surprises Act*, at 5 (Oct. 31, 2022). Adding additional responsibilities and tasks to the arbitrations could make the burden on IDR entities unworkable and could threaten a mass exodus of certified IDR entities from the program.

Plaintiffs' other arguments for why the final rule is arbitrary and capricious for allegedly failing to take into account supposed "problems" with how the QPA is calculated are misdirected, incorrect, or both.<sup>7</sup> Most of Plaintiffs' arguments about flaws in the QPA calculation and disclosure requirements are really arguments against the statute itself: Congress required the arbitrators to consider the QPA in every single dispute, and the supposed "flaws" that Plaintiffs identify would, under Plaintiffs' theory,

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<sup>7</sup> Plaintiffs and their *amici*, for example, fault the Departments for not allowing arbitrators to consider the impact that single case agreements would have had if included in the QPA. But this is not a "flaw" in the calculation of the QPA or the final rule, but a deliberate action taken by the Departments to ensure that the QPA calculation methodology reflects Congressional intent. By limiting the calculation to contracts that have been negotiated in advance, the Departments decided to exclude "single case agreements" that may be negotiated between a provider and a health plan or issuer, either at the time that a service is performed, or after the fact. *See Requirements Related to Surprise Billing: Part I*, 86 Fed. Reg. 36,872, 36,889 (July 13, 2021). The Departments excluded these agreements from the calculation of the median because they understood the statutory term "contracted rate" to refer "only to the rate negotiated with providers and facilities that are contracted to participate in any of the networks of the plan or issuer under generally applicable terms of the plan or coverage [to exclude] rates negotiated with other providers and facilities." *Id.* The Departments found that "this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." *Id.*

infect any arbitration that considers the QPA. Plaintiffs chose not to challenge the regulations governing the calculation of the qualifying payment amount in this lawsuit, instead attempting to attack those regulations in a separate suit.<sup>8</sup> Meanwhile, “[t]he Departments are continuing to consider comments on the July 2021 interim final rules about whether additional disclosures related to the QPA calculation methodology should be required to be provided with an initial payment or notice of denial of payment, or upon request.” 87 Fed. Reg. 52,626.<sup>9</sup> If Plaintiffs wish to challenge the QPA calculation methodology and disclosure requirements, the comment process for the July 2021 interim final rule was the place to do so.

**B. The Relevance Provision Is A Reasonable Procedural Rule Entitled To Deference And Is Not Arbitrary Or Capricious.**

The final rule reasonably instructs arbitrators to give weight only to relevant information, meaning information that bears on which “offer best represents the value of the item or service under dispute.” 87 Fed. Reg. at 52,628; See 45 C.F.R. § 149.510(c)(4)(iii)(E). This rule is not only consistent with the statutory language allowing parties to submit information that “relates to” the offers but it also does not impose a heightened evidentiary burden on non-QPA information. It does not, contrary to Plaintiffs’ puzzling contention, “prevent[] arbitrators from giving weight to the other statutory

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<sup>8</sup> Perhaps recognizing the futility of the relief they seek here, Plaintiffs have filed new lawsuits challenging the regulations governing the calculation of the QPA. *Tex. Med. Ass’n v. U.S. Dep’t of Health & Hum. Servs.*, No. 6:22-cv-450-JDK (E.D. Tex. Nov. 30, 2022); *LifeNet, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, No. 6:22-cv-00453-JDK (E.D. Tex. Dec. 1, 2022).

<sup>9</sup> LifeNet again devotes substantial space in its brief to taking issue with how the QPA is calculated, including that the QPA calculation does not depend on how many times a particular item or service was provided under a contract. LifeNet Reply at 2-3. Defendants have not, as LifeNet claims, “waived” a response to LifeNet’s arguments that the QPA calculation methodology is flawed. Defendants pointed out that in this lawsuit challenging the IDR process the regulations governing the calculation of the QPA are not at issue and LifeNet does not challenge them here. Defs.’ Mot. at 37 n.9. A decision from this court vacating the final rule would not address LifeNet’s complaints with how the QPA is calculated, nor would it eliminate the statutory requirement that arbitrators consider the QPA in the IDR process. At any rate, the Departments did issue guidance addressing the issue of what Plaintiffs call “ghost rates” and clarified that, if a plan’s or issuer’s contracted rates for a service code vary based on provider specialty, plans and issuers are required to calculate a median contracted rate separately for each provider specialty, which will ensure the median rate calculation includes only providers who actually provide the item or service. *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* at 16-17 (Aug. 19, 2022) available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-55.pdf>.

factors,” TMA Reply at 3, but instead instructs that arbitrators should give weight only to information, including information relating to the statutory factors, that is relevant to the task at hand: deciding which offer best represents the value of the item or service. The final rule does not restrict arbitrators’ discretion in deciding what information is relevant. It reflects a reasonable evidentiary rule that the Departments promulgated consistent with their obligation to establish one IDR process under which arbitrators make payment determinations.

The statute requires that any information submitted must, as a precondition, “relat[e] to such offer” and then goes on to explain that information that relates to an offer may include information relating to the statutory factors listed in subparagraph (C)(ii). 42 U.S.C. § 300gg-111(c)(5)(B)(ii). (parties “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” the statutory factors) (emphasis added); *id.* § 300gg-112(b)(5)(A)(ii) (governing air ambulances). The most natural reading of the statute is that the statutory factors listed are examples of types of information that may “relat[e] to such offer” but not a mandate that those categories of information will always relate to every offer. As even Plaintiffs admit, the word “including” can sometimes introduce examples that are “broader than the general category[.]” *Massachusetts v. EPA*, 549 U.S. 497, 557 (2007) (Scalia, J., dissenting). Such is the case here—any information that the parties submit should relate to the offer, or else there would be no need for that information to be presented to the arbitrator in the first place. And it is not difficult to conceive of examples where information under the statutory factors might have no bearing on which offer best represents the value of the qualified IDR item or service at issue. For example, the fact that an item or service was performed in a Level One trauma center capable of handling complex services may not have any bearing on the value of the item or service if the item or service at issue was extremely simple or routine and could have been performed in a facility of any level.

At any rate, the relevance rule does not eliminate the requirement that the arbitrator must consider all the information before her, including all of the information that relates to the statutory factors. *See* 45 C.F.R. § 149.510(c)(4)(iii)(B). But, as discussed above, the arbitrator must, at the end of

the day, select one offer over another, and in doing so must consider which pieces of information tip the scales in favor of the selected offer. Thus, the relevance rule requires the arbitrator to consider all the information and then, in making her decision of which offer to select, to give weight only to information that is relevant, which the Departments have defined as information that “tends to show that the offer best represents the value of the item or service under dispute.” 87 Fed. Reg. 52, 628. Basing a decision on information that “tends to show that the offer best represents the value of the item or service under dispute” is hardly arbitrary or capricious. *Id.*

The relevance rule likewise does not impose a heightened evidentiary burden on any non-QPA information that the QPA is not itself required to meet, because the QPA will always be relevant to the parties’ offers. Because the QPA—which, as the median of the contracted rates for the same or similar item or service, is designed to be a rough proxy for the market value of the item or service—will always be relevant to determining the value of the item or service, it will always pass any relevancy test imposed on it. In other words, even if a different final rule required arbitrators to separately evaluate the relevance of the QPA, the difference would be immaterial, because the QPA will always be relevant. The final rule does not subject non-QPA information to any relevance requirement that the QPA does not itself meet.

**C. The Rule to Avoid Double Counting Information Is A Reasonable Procedural Rule Entitled To Deference And Is Not Arbitrary Or Capricious.**

The rule against double counting information is likewise a reasonable procedural rule that is intended to prevent arbitrators from giving any single piece of information undue weight, driving the arbitrator’s selection away from the offer that best represents the value of the item or service at issue. In setting the process for selecting the offer that best represents the value of the qualified IDR item or service, the final rule explains “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.” 45 C.F.R. § 149.510(c)(4)(iii)(E). As the Departments explained, the purpose of this provision is “to avoid weighting the same information twice.” 87 Fed. Reg. at 52,628.

The double counting rule does not give preference to the QPA. As Plaintiffs recognize, the

admonition against double counting applies to any information submitted by the parties, not just the QPA. *See id.* (“the certified IDR entity should evaluate the information and should not give weight to that information if it is already accounted for by any of the other information submitted by the parties”). And it is consistent with the statutory requirement to consider all the information relating to an offer submitted by either party, including information pertaining to the statutory factors described in 42 U.S.C. § 300gg-111(c)(5)(C)(ii) or, in the case of air ambulances 42 U.S.C. § 300gg-112(b)(5)(C)(ii), and within the Departments’ regulatory authority to prescribe order to the decisionmaking process, *see Am. Hosp. Ass’n*, 499 U.S. at 612. The double counting rule is a reasonable procedural rule that instructs the arbitrators, when faced with a voluminous record of information that contains the same piece of information multiple times, not to give double or triple weight to any piece of information when deciding which information counsels in favor of selecting which offer. By discouraging arbitrators from giving outsized weight to a single piece of information that is already accounted for—whether accounted for in the QPA or in other information submitted by the parties, the final rule is designed to ensure that arbitrators will select the offer that best represents the true value of the item or service.

The double counting rule likewise does not require arbitrators to ignore any piece of information just because the information is accounted for multiple times. The arbitrator is, as always, required to consider all of the information before her, but when deciding which information tips the scale in favor of one offer or the other, should evaluate whether some information is already accounted for multiple times. An arbitrator may conclude that a facility’s case mix and scope of services, for example, is already reflected in the contracted rates between the payer and the facility during the previous four years. The final rule instructs the arbitrator to consider that information, but not to give it outsized weight.

Plaintiffs’ claim that Defendants ignored their contention that the rule against double counting information is also arbitrary and capricious because it is “unworkable,” TMA Reply at 27, is mistaken. As Defendants explained, with accompanying examples, in their opening brief, Defs.’ Mot. at 34-35, the rule instructs arbitrators not to give weight to the same information repeatedly, even though it

may come up in several contexts. By explaining how this rule would work in practice, Defendants demonstrated that it is not “unworkable” and therefore not arbitrary and capricious. Instead, it reflects a reasonable procedural and methodological rule that is well within the Departments’ discretion to establish.

Plaintiffs’ claimed confusion over the double-counting rule is, at any rate, belied by statements in their brief demonstrating their clear understanding of how the rule would operate. They claim confusion over how arbitrators could determine “whether additional case-specific information is ‘accounted for’ or ‘reflected’ in the QPA—a median number based on contracts from 2019.” TMA Reply at 28. But in doing so, they demonstrate a very clear understanding of when exactly the double-counting rule would come into play and what sort of information would not be captured in the QPA (even though the double-counting rule applies to all information, not just information accounted for in the QPA). Generally, the QPA is based on median contracted rates, and so necessarily cannot reflect case-specific information or circumstances. *See, e.g., id.* at 17 (observing that, because the QPA is “indicative of the *median* in-network provider’s level of training, the characteristics of the *individual* provider that performed the service” may not be fully captured). In many cases, the QPA may already take into account non-case-specific information, i.e., information that will be true of the qualified IDR item or service in every case involving that item or service. For example, if a particular billing service code applies only to patients whose condition is high acuity, the QPA may already reflect that the patient was high acuity. But the QPA cannot, and indeed will not, reflect case-specific or individual circumstances, such as a patient who is unusually high acuity. The QPA is a median, a rough proxy for a typical market rate price for a given item or service. It does not necessarily account for case-specific circumstances that parties may bring to the arbitrator’s attention to influence the selection of the offer. Plaintiffs’ understanding that the QPA might not account for individual, unique, or case-specific circumstances underscores that they are capable of understanding how the double-counting rule would apply to information already accounted for in the QPA. The rule is not unworkable, and therefore is not arbitrary and capricious.

Plaintiffs also challenge an analogous provision of the final rule that instructs arbitrators to

explain in their written decisions, if the arbitrator relied on any of the categories of additional information, why the arbitrator concluded that the information was not already reflected in the QPA. 45 C.F.R. § 149.510(c)(4)(iv)(B). Arbitrators are also required to explain in their written decision what information they determined demonstrated that the offer selected best represented the value of the item or service and to explain the weight given to the QPA and any additional credible information. *Id.* This provision is not arbitrary and capricious, but instead represents a reasonable procedural rule to guide the Departments in their study and evaluation of the new IDR process. As the Departments explained, they “are continuing to consider comments on the July 2021 interim final rules about whether additional disclosures related to the QPA calculation methodology should be required.” 87 Fed. Reg. at 52,626. Additional explanation from arbitrators about why they determined that relevant information was not accounted for by the QPA can help the Departments continue to evaluate whether additional QPA disclosure requirements are necessary. And the requirement that arbitrators provide a written explanation for their decision applies in every circumstance—regardless of which offer the arbitrator has selected. 45 C.F.R. § 149.510(c)(4)(iv)(B). Given that arbitrators are already required to explain in writing how they reached their decision, Plaintiffs’ speculation that requiring arbitrators to also explain how useful they found the QPA would cause arbitrators to “throw up their hands” at having to write even one additional sentence is baseless. TMA Reply at 25.

**D. Guiding Arbitrators to Begin with the QPA Is Not Arbitrary And Capricious.**

The Act requires the arbitrator to consider the QPA in every single arbitration, and it is the only piece of information that will always be submitted to the arbitrator. 42 U.S.C. § 300gg-111(c)(5)(C)(i); *id.* § 300gg-112(b)(5)(C)(i). It was thus reasonable for the final rule to guide the arbitrator to begin with this one guaranteed piece of information and then consider the other information, found under the statutory heading “additional circumstances” in those instances where the parties choose to submit additional information. 45 C.F.R. § 149.510(c)(4)(iii)(B). The statutory heading “additional circumstances” underscores why the final rule is reasonable, and not arbitrary and capricious, here. These circumstances could only be “additional,” if there were some other

circumstances already in place that they could be added to—here, the QPA. The statute thus demonstrates that the analysis can begin with the QPA, and then should move on to take into account the other, “additional,” statutory factors, if they are present. *See In re Border Infrastructure Envtl. Litig.*, 915 F.3d 1213, 1223 (9th Cir. 2019) (“In simple terms, ‘additional’ means ‘supplemental.’”).

Plaintiffs likewise minimize the fact that the arbitrator is not instructed to give extra weight to the QPA or defer to it in any way. 87 Fed. Reg. at 52,628 (“these final rules do not require certified IDR entities to default to the offer closest to the QPA or to apply a presumption in favor of that offer”). Thus, unless an arbitrator blatantly disregards the Departments’ clear guidance, considering the QPA first should not lead arbitrators to place any greater weight on that factor. The arbitrator’s task remains to select the offer that best represents the value of the item or service, regardless of whether the arbitrator considers the QPA as the first factor or the last, or the only factor, in instances where the parties have chosen to submit no additional information.

#### **IV. Plaintiffs’ Requested Remedies Are Improper And Unnecessary.**

If the Court disagrees with the Departments’ arguments, it should remand the matter without vacating the challenged provisions. Contrary to Plaintiffs’ argument that vacatur should be ordered as a matter of course, TMA Reply at 29, “[o]nly in ‘rare circumstances’ is remand for agency reconsideration not the appropriate solution.” *Tex. Ass’n of Mfrs. v. U.S. Consumer Prod. Safety Comm’n*, 989 F.3d 368, 389 (5th Cir. 2021) (quoting *O’Reilly v. U.S. Army Corps of Eng’rs*, 477 F.3d 225, 238-39 (5th Cir. 2007)). Any argument that vacatur would not be highly disruptive, TMA Reply at 29, is easily disproven by the evidence of arbitrations initiated thus far under the Act: over 90,000 disputes have been initiated, far exceeding the Departments’ initial estimates, yet only about 3,500 payment determinations had been issued as of October. Ctrs. For Medicare & Medicaid Servs., *Calendar Year 2023 Fee Guidance for the Federal IDR Process under the No Surprises Act* at 5 (Oct. 31, 2022). The high number of disputes that cannot be resolved through negotiation may be the result of a less predictable IDR process, which undermines parties’ abilities to accurately estimate the risks and benefits of negotiating a settlement. And the lack of clear guidance to the arbitrators may also be contributing to

delays in reaching payment determinations. Vacatur of the final rule would further exacerbate the unmanageable and backlogged IDR process. *Id.*

And remanding with specific instructions is both unnecessary and beyond the scope of judicial review. When reviewing actions of administrative agencies, a court may not “substitute its judgment for that of the agency,” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (internal quotation marks omitted), but instead assess only whether the decision was “based on a consideration of the relevant factors and whether there has been a clear error of judgment,” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). When a “court reviewing agency action determines that an agency made an error of law, the court’s inquiry is at an end.” *Palisades Gen. Hosp. Inc., v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). Remand with instructions is also unnecessary. The Departments have demonstrated a good-faith commitment to adhering to the reasoning in this Court’s opinions and would do so again in the future. *See* 87 Fed. Reg. at 52,624-25 (providing detailed discussion of changes made in response to this Court’s opinions). The Departments took this Court’s prior opinions seriously and considered them carefully in the final rule, as the preamble repeatedly shows. They have in no way demonstrated a “stubborn refusal” to follow this Court’s guidance. TMA Reply at 29 (quoting *Loc. Joint Exec. Bd. of Las Vegas v. NLRB*, 657 F.3d 865, 873 (9th Cir. 2011)).

The Court should likewise limit the relief to the specific parties in this lawsuit. The Court’s Article III judicial power extends only to “vindicat[ing] the individual rights of the people appearing before it.” *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018). Setting aside the challenged portions of the final rule only with respect to these Plaintiffs would remedy the injuries sustained by Plaintiffs here. *Dep’t of Homeland Sec. v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring) (“Equitable remedies, like remedies in general, are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit.”).

## CONCLUSION

For the foregoing reasons, the Defendants’ motion for summary judgment should be granted, and the Plaintiffs’ motion for summary judgment should be denied.

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Respectfully submitted,

BRIAN M. BOYNTON  
Acting Assistant Attorney General

BRIT FEATHERSTON  
United States Attorney

JAMES GILLINGHAM  
Assistant U.S. Attorney  
Eastern District of Texas  
110 N. College Street; Suite 700  
Tyler, Texas 75702  
E-mail: James.Gillingham@usdoj.gov  
Phone: (903) 590-1400  
Fax: (903) 590-1436  
Texas State Bar # 24065295

SEAN C. DAY  
Special Assistant United States Attorney  
Eastern District of Texas  
101 E. Park Blvd., Suite 500  
Plano, Texas 75074  
Phone: (202) 934-4060  
Fax: (972) 590-1209  
D.C. Bar No. 502363

ERIC B. BECKENHAUER  
Assistant Branch Director

*/s/ Anna Deffebach*  
ANNA DEFFEBACH  
Trial Attorney  
United States Department of Justice  
Civil Division, Federal Programs Branch  
1100 L Street, NW  
Washington, DC 20005  
Phone: (202) 305-8356  
Fax: (202) 993-5182  
E-mail: Anna.L.Deffebach@usdoj.gov  
D.C. Bar No. 341246

*Counsel for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify on this 7th day of December, 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

*/s/ Anna Deffebach* \_\_\_\_\_

ANNA DEFFEBACH