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

TEXAS MEDICAL ASSOCIATION, *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 6:21-cv-00425-JDK

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Regulations

Additional Materials

INTRODUCTION

This case concerns how arbitrators will resolve disputes between health care providers and group health plans or health insurance issuers over the appropriate payment amount for out-of-network services covered by the No Surprises Act. The Act prohibits an out-of-network provider, under certain circumstances, from balance billing a patient for medical services, and refers the provider instead to arbitration with the patient's insurer or health plan. The patient's cost-sharing responsibilities for the out-of-network service are limited to what the patient would have paid if the service were performed in-network instead, a calculation that is based on what the Act defines as the "qualifying payment amount," that is, the median of in-network contracted rates for that service. The Act thus treats the qualifying payment amount as the reasonable rate of payment for the typical medical service.

The qualifying payment amount also plays a central role in a second calculation, of the amount that the group health plan or health insurance issuer owes to the provider for the out-of-network service. In making that calculation, the Act first instructs the arbitrator to consider the qualifying payment amount—again, the statutory proxy for what the payment rate for the service would have been, if it had been performed in-network. The Act then instructs the arbitrator to consider additional circumstances or additional information offered by the provider or by the group health plan or health insurance issuer, to arrive at the out-of-network payment amount for the service. This case involves the Plaintiffs' challenge to a rulemaking issued by the Defendants—the Departments of the Treasury, Labor, and Health and Human Services (the "Departments"), together with the Office of Personnel Management—to implement the Act's arbitration process.

There is far less to this case than might first meet the eye. The Plaintiffs challenge a caricature of the Departments' arbitration rule, which in their telling requires arbitrators to award the qualifying payment amount and forbids arbitrators from considering other information. The rule that the Departments actually issued, however, is nothing like that. The rule instructs the arbitrator to consider any relevant circumstances or information, and directs the arbitrator, for example, to award a payment amount that is higher than the qualifying payment amount if relevant information shows that such an

award is proper. The rule simply instructs the arbitrator to consider whether any additional credible information shows whether the input number for this process—the qualifying payment amount—should be different from the output number—the out-of-network payment amount.

In issuing this rule, the Departments faithfully exercised their substantive rulemaking authority to establish the process under which the arbitrator determines the out-of-network payment amount, and they did so in accordance with their reasonable reading of the statute's treatment of the factors for the arbitrator's decision making. *Chevron* deference is owed to the rule, and the rule easily meets that deferential standard. Nor is there any merit to the Plaintiffs' claim of a procedural violation. The Departments issued the arbitration rule as an interim final rule in response to requests from numerous regulated parties—including the Plaintiffs here—for early rulemaking, which was needed to permit these parties to begin complex preparations for the No Surprises Act's new legal regime.

The Plaintiffs, in any event, lack standing to raise any of these challenges. Neither Dr. Corley nor any of the association members belatedly named by the Texas Medical Association ("TMA") holds a direct financial interest in the outcome of this case. They all practice medicine through corporations, and their interest in this case is only an indirect one by virtue of their status as corporate shareholders. A corporation is a separate legal entity from its shareholders, and it is a matter of black-letter law that a shareholder lacks standing to litigate the corporation's rights.

For all these reasons, the Defendants' cross-motion for summary judgment should be granted.

ARGUMENT

I. THE PLAINTIFFS HAVE NOT SHOWN THAT THEY HAVE STANDING TO CHALLENGE THE RULE'S ARBITRATION PROCEDURES.

To prove Article III standing, the Plaintiffs must show that 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). The declarations that the Plaintiffs submitted with their summary judgment motion fell well short of the required proof, as they merely alleged in a conclusory fashion that they would suffer harm from the Departments' rule. These unadorned allegations do not satisfy the requirements of Article III. *See id.*

The Plaintiffs seek to shore up their claim to standing through the late submission of new declarations with their reply brief. But the Federal Rules of Civil Procedure expressly provide that "[a]ny affidavit supporting a motion must be served with the motion." Fed. R. Civ. P. 6(c)(2); *see also* Local Rules CV-7(b) (all affidavits "shall be served and filed with the motion"), CV-56(a) (all evidence for a summary judgment motion should be provided with the motion). The late-filed affidavits should be stricken and disregarded. *See Baker v. Puckett*, No. 18-cv-599, 2020 WL 5745812, at *4 (E.D. Tex. Aug. 13, 2020), *report and recommendation adopted*, 2020 WL 5630402 (E.D. Tex. Sept. 21, 2020).

Even if the declarations were timely, they would not cure the standing defects in the Plaintiffs' summary judgment motion. Dr. Corley, for example, confirms that he practices medicine as an employee of one corporation, and as a shareholder of a second corporation. Suppl. Decl. of Adam Corley, ¶ 3, ECF No. 98-4. These corporations, not Dr. Corley, have the right to payment for medical services performed at their facilities, and it is these corporations, not Dr. Corley, that would participate in any arbitrations under the No Surprises Act. *See id.* ¶ 6. Dr. Corley fears only that he would suffer an indirect injury from the rule, either because his hourly wage with one corporation would decrease, or because the value of his shares in the second corporation would be diminished. *Id.* ¶ 10. The proper plaintiff to bring a challenge to the rule, then, would be the corporation, not a corporate employee or a corporate shareholder. *See Daily Income Fund, Inc. v. Fox*, 464 U.S. 523, 542 (1984). An individual shareholder has no right to "initiat[e] actions to enforce the rights of the corporation." *Franchise Tax Bd. v. Alcan Aluminium Ltd.*, 493 U.S. 331, 336 (1990); *see also Gregory v. Mitchell*, 634 F.2d 199, 202 (5th Cir. 1981). Dr. Corley thus lacks standing to challenge the Departments' rule.

The Plaintiffs resist this conclusion by asserting that Dr. Corley is "directly regulated" by the rule, or that he falls within the "zone of interests" of the No Surprises Act as a provider of out-of-network medical services. Pls.' Opp'n to Defs.' Mot. for Summ. J. and Reply in Supp. of Summ. J. at 6, ECF No. 98 ("Pls.' Reply"). This is not so. The "provider" that is regulated by the Act's arbitration provisions, or whose interests these provisions (arguably) protect, is the corporation, as that is the entity that will submit the reimbursement claim and that will receive payment in the amount determined by the arbitrator. *See* 42 U.S.C. § 300gg-111(c)(1). Dr. Corley is not "directly regulated"

by these provisions at all; he has only an indirect interest in the Act's arbitration procedures, to the extent those procedures affect the corporations of which he is an employee or shareholder. Because Dr. Corley lacks a direct and personal interest in the action, independent of his status as a shareholder, he lacks standing. *See Stevens v. Lowder*, 643 F.2d 1078, 1080 (5th Cir. Unit B Apr. 1981).

There are circumstances, of course, where a party may have standing because he or she is regulated in his or her capacity as a shareholder. The Plaintiffs' citation to *Meland v. Weber*, 2 F.4th 838 (9th Cir. 2021), presents a case in point. In that case, the plaintiff had standing to challenge a state law that regulated how he exercised one of his rights as a shareholder, namely, his choice of how to vote for members of the corporate board of directors. *See id.* at 845. But here, again, the No Surprises Act does not regulate Dr. Corley as a shareholder, and his interest in this case is only an indirect one. Under the shareholder-standing doctrine, he is not a proper plaintiff to challenge the rule. *See Collins v. Mnuchin*, 938 F.3d 553, 575 (5th Cir. 2019), *rev'd in part sub nom. Collins v. Yellen*, 141 S. Ct. 1761 (2021).

The Texas Medical Association's claims fail for the same reason. The Plaintiffs' late-filed declarations identify three members of the association. Each of these members, however, practices medicine through corporations, and they hold only indirect interests, as corporate shareholders, in the results of arbitrations under the Act. *See* Decl. of Christopher Ryan Cook, ¶ 3, ECF No. 98-1; Decl. of Tu X. Dao, ¶ 3, ECF No. 98-2; Decl. of Steven Ford, ¶ 3, ECF No. 98-3. They would lack standing for the same reasons that Dr. Corley lacks standing. And this is fatal to the association's claim of standing, as it is required to show that "its members would otherwise have standing to sue in their own right." *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 377 (5th Cir. 2021). This Court therefore lacks jurisdiction over the Plaintiffs' claims.

II. THE RULE'S ARBITRATION PROCEDURES ARE CONSISTENT WITH THE NO SURPRISES ACT.

A. The Departments Reasonably Exercised Their Statutory Authority to Guide the Discretion of Arbitrators.

The Plaintiffs persist in challenging a version of the arbitration rule that does not exist. They contend that the rule improperly gives "controlling weight" to the qualifying payment amount, Pls.'

Reply at 9, or that the rule "made the [qualifying payment amount] determinative," *id.* at 11. The Departments' rule does no such thing. The rule directs the arbitrator to "tak[e] into account" each of the considerations that are listed in the statute itself. *See* 45 C.F.R. § 149.510(c)(4)(ii), (iii). The arbitrator is also instructed to consider any "[a]dditional information submitted by a party," so long as the information is credible, relates to either party's offer, and does not include information on the factors that the arbitrator is prohibited from considering under the statute. *Id.* § 149.510(c)(4)(iii)(D).

The rule further instructs the arbitrator, in choosing between the offer presented by the provider and the offer presented by the health insurance issuer or group health plan, to "select the offer closest to the qualifying payment amount" unless the arbitrator "determines that credible information submitted by either party … clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate." *Id.* § 149.510(c)(4)(ii)(A). This is the portion of the rule that the Plaintiffs object to, but the rule does not stop there. Critically, the rule defines several of the terms in this clause. Information is defined to be "credible" if "upon critical analysis [it] is worthy of belief and is trustworthy," *id.* § 149.510(a)(2)(v), and information is defined to show a "material difference" if there is "a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate," *id.* § 149.510(a)(2)(viii).

The rule thus directs the arbitrator to: (1) begin with the qualifying payment amount; (2) consider all of the additional factors or "any additional information" that may be credible and relevant; (3) assess whether there is a "substantial likelihood" that the information is "significant" in showing that the qualifying payment amount is not the appropriate out-of-network rate; and, after completing that analysis, then (4) select one of the offers as the payment rate, with the offer that is closest to the qualifying payment amount being the offer selected, unless the arbitrator finds that the additional statutory factors point in favor of a different decision.

The Departments explained the interplay between Section 149.510(c)(4) and the regulatory definitions in their opening brief, but the Plaintiffs ignore these definitions completely in their reply brief. Unlike the caricature of the arbitration rule that the Plaintiffs attack in their briefing, the rule that the Defendants actually issued leaves wide room for the arbitrator to apply his or her expertise to find that any additional information is relevant in setting the out-of-network payment rate.

The Departments tracked the statute when they structured the arbitrator's analysis to begin with the qualifying payment amount. The statute lists the qualifying payment amount as the first factor for the arbitrator's consideration, and it is the only factor that the statute requires the arbitrator to consider without the parties specifically bringing the issue to his or her attention. The statute describes the other factors listed for the arbitrator to consider as "additional information" or "additional circumstances," 42 U.S.C. § 300gg-111(c)(5)(C)(i)(II), (ii), thereby demonstrating that the statute directs the arbitrator to begin the analysis with the qualifying payment amount before moving on to address "supplemental" information. *See In re Border Infrastructure Env't Litig.*, 915 F.3d 1213, 1223 (9th Cir. 2019) ("In simple terms, 'additional' means 'supplemental.'"); *Springer v. Fairfax Cnty. Sch. Bd.*, 134 F.3d 659, 667 (4th Cir. 1998) ("We construe 'additional' in the ordinary sense of the word to mean supplemental.") (internal quotation and alterations omitted).

The Plaintiffs apparently now concede that the statute requires the arbitrator to proceed in this way, but they object that "the word 'additional' does not mean 'less important.'" Pls.' Reply at 13. The Defendants don't contend otherwise; under the rule, additional information could prove to be very important for the arbitrator's decision. *See* 45 C.F.R. § 149.510(c)(4)(iv)(B) (example in which arbitrator is required to find in the provider's favor, if additional information shows that the qualifying payment amount is not the appropriate out-of-network payment rate). One way or the other, however, to qualify as "additional" information under Section 300gg-111(c), that information "reasonably should bear some relation" to what came before it in the statute. *Peretz v. United States*, 501 U.S. 923, 930 (1991); *see also United States v. Underwood*, 597 F.3d 661, 666 (5th Cir. 2010).

Any additional information that the parties may provide to the arbitrator would "reasonably … bear some relation" to the first statutory factor—the qualifying payment amount—if that

information tends to show that that amount is different from the appropriate out-of-network payment amount. The No Surprises Act, after all, begins with the assumption that the qualifying payment amount is the reasonable amount of payment for a given medical service in the typical case. *See* 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(B); *see also id.* § 300gg-111(a)(3)(H). The Plaintiffs dispute this point, noting that the qualifying payment amount is defined as the median of *in-network* prices for a given service, but that some providers have commanded higher prices when they have chosen to remain *out of network*. *See* Pls.' Reply at 15. This precisely describes the problem that Congress sought to solve when it enacted the No Surprises Act. *See* Cong. Budget Office, *H.R. 5826, the Consumer Protections Against Surprise Medical Bills Act of 2020, as Introduced on February 10, 2020: Estimated Budgetary Effects* at 1 (Feb. 11, 2020), Administrative Record ("AR") 1757, ECF No. 66-8 (arbitrators "would be instructed to look to the health plan's median payment rate for in-network rate care," and as a result "average payment rates for both in- and out-of-network care would move toward the median in-network rate," thereby lowering health insurance premiums and budget deficits); *see also* H.R. Rep. No. 116-615, pt. I, at 57-58 (2020), AR 334-335, ECF No. 66-3.

The statute instructs the arbitrator to begin his or her analysis with one number—the qualifying payment amount, or the typical contracted rate for a given medical service—and further requires the arbitrator to conclude his or her analysis with a second number—the appropriate out-of-network payment amount. What comes in between is a series of "additional" circumstances or "additional" information for the arbitrator to consider. The Departments, accordingly, have reasonably read the statute to require the arbitrator to address whether any of this supplemental information reasonably bears on the question whether the second number should be different from the first number.

The arbitration rule is therefore nothing like the Clean Air Act rule that was at issue in *American Corn Growers Association v. EPA*, 291 F.3d 1 (D.C. Cir. 2002). In that case, the court invalidated an EPA rule that "extract[ed] one of the five statutory factors listed in [the Clean Air Act] and treat[ed] it differently than the other four." *Id.* at 6. The statute at issue listed five statutory factors together in a single clause, without any indication that any one factor should be treated differently. *See* 42 U.S.C.

§ 7491(g)(2). The No Surprises Act is quite different. Far from setting forth an "unadorned list of factors," Pls.' Reply at 10, the Act directs the arbitrator first to the qualifying payment amount, and then instructs the arbitrator to consider "additional information" or "additional circumstances" that may warrant an award of a different amount. 42 U.S.C. § 300gg-111(c)(5)(C)(i)(II), (ii). As the Plaintiffs acknowledge, Pls.' Reply at 10, Congress may prescribe a structure for an agency to address a set of statutory factors, and one way Congress can do so is by setting forth a sequence in which the agency is to address various factors. *See Ramirez v. ICE*, 471 F. Supp. 3d 88, 176-77 (D.D.C. 2020). Congress did just that in the "wording and apparent logic" of the No Surprises Act, *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1045 (D.C. Cir. 1978), by giving the qualifying payment amount "a level of greater attention and rigor," *id.* at 1045-46, than it did for the other statutory factors. At the very least, the Departments reasonably read the Act in this way, and deference is owed to their reading.

The Plaintiffs protest that the arbitration rule interferes with arbitrators' "sound discretion," Pls.' Reply at 10, to apply the statutory factors in any way that they wish. But the No Surprises Act assigns to the Departments, not to individual private arbitrators, the responsibility to "establish by regulation *one* independent dispute resolution process" to resolve payment disputes. 42 U.S.C. § 300gg-111(c)(2)(A) (emphasis added). The Act therefore gives the Departments, not arbitrators, the responsibility to resolve any ambiguities as to how the statutory factors are to be applied. Thus, the job of interpreting the various factors that go into setting out-of-network payment amounts is one that belongs to the Departments that are charged with administering the Act, not the arbitrators. *See Martin v. Occupational Safety & Health Rev. Comm'n*, 499 U.S. 144, 152 (1991) (according deference to the agency with rulemaking authority, rather than a separate adjudicative body); *see also Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 612 (1991) (recognizing agency authority to use rulemaking to "resolve certain issues of general applicability" for individualized adjudications, and to establish "general principles to guide the required case-by-case ... determinations").

It is not plausible that Congress intended to enact the Plaintiffs' alternative approach, in which private arbitrators would enjoy virtually complete discretion to weigh any of the statutory factors in any way they choose. The Plaintiffs protest that they do not seek to grant arbitrators "unfettered

discretion," Pls.' Reply at 10, but their reading of the statute would have just that result. As the Defendants explained in their opening brief, two of the factors for the arbitrator to consider are any "information as requested by the certified IDR entity relating to such offer," and "any information relating to such offer submitted by either party." 42 U.S.C. § 300gg-111(c)(5)(B), (C)(i)(II). These catch-all factors work logically under the Defendants' reading of the statute, as they afford the arbitrator leeway to find that some information not expressly listed in the statute might bear on whether the out-of-network payment amount should be higher or lower than the qualifying payment amount. But, under the Plaintiffs' reading, nothing would constrain the arbitrator from relying on any information he or she might choose—even information that is not "credible," or information that has no "substantial likelihood" of being considered "significant" by a reasonable arbitrator, 45 C.F.R. § 149.510(a)(2)(v), (viii)—according that information outsized weight, and then deciding as he or she wishes. This reading would render the Act's careful delineation of the qualifying payment amount, and its role in the arbitration process, meaningless. *See Fund for Animals, Inc. v. Kempthorne*, 472 F.3d 872, 878 (D.C. Cir. 2006) (Kavanaugh, J.) ("That plaintiffs interpret [certain statutory provisions] to be an empty gesture is yet another indication that their submission is erroneous.").

B. The Departments Are Entitled to *Chevron* Deference.

The Departments issued the arbitration rule to fulfill Congress's instructions that they "establish by regulation one independent dispute resolution process … under which" the arbitrator "determines … in accordance with the succeeding provisions of this subsection, the amount of payment" for a disputed out-of-network item or service. 42 U.S.C. § 300gg-111(c)(2)(A). The Departments' exercise of this rulemaking authority is entitled to deference under *Chevron*, and easily survives under this standard.[1]

The Plaintiffs renew their assertion that the Defendants lack rulemaking authority to address the factors for the determination of the out-of-network payment amount. Pls.' Reply at 18. But the

[1] The Plaintiffs hint in a footnote at a potential future challenge to the viability of the *Chevron* doctrine. Pls.' Reply at 17 n.7. 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.

plain language of the statute directs the Departments to "establish by regulation" the "process … under which" the arbitrator "determines … the amount of payment." 42 U.S.C. § 300gg-111(c)(2)(A). A directive to "establish by regulation" a process is, of course, a delegation of substantive rulemaking authority. *See In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 685 F.3d 353, 366 (3d Cir. 2012). The arbitration rule sets the process under which the amount of payment is determined by clarifying that the arbitrator should not rely on evidence that is not credible, or that a reasonable person would not consider to be significant in determining the out-of-network payment rate. 45 C.F.R. § 149.510(a)(2)(v), (viii). These procedural rules fall well within the grant of rulemaking authority to the Departments. *See City of Arlington v. FCC*, 569 U.S. 290, 296 (2013).

The Plaintiffs also contend, for the first time in their reply brief, that *Chevron* deference is not owed because the arbitration rule is "procedurally defective." Pls.' Reply at 18 (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016)). The rule is procedurally valid, as will be explained in more detail below. But, in any event, the Plaintiffs' procedural challenge to the rule has no bearing on the issue of *Chevron* deference. *Encino Motorcars* arose in the context of litigation between private parties; the Court remanded the case to the lower courts to resolve that private dispute without reference to a rule that had been promulgated without adequate consideration of certain reliance interests. *See Encino Motorcars*, 579 U.S. at 224. In contrast, this action arises under the Administrative Procedure Act. If the Plaintiffs were to succeed on their APA claim, the appropriate remedy would be for the Court to remand the matter to the Departments to correct the defect, not for the Court to resolve ambiguities in the statute on its own. *See Tex. Ass'n of Mfrs.*, 989 F.3d at 389-90; *see also Brackeen v. Haaland*, 994 F.3d 249, 269, 355 (5th Cir. 2021) (en banc), *petition for cert. filed*, No. 21-376 (U.S. Sept. 8, 2021).

The Plaintiffs have challenged the arbitration rule only at Step One of the *Chevron* analysis, asserting that the statute unambiguously forecloses the rule. *See* Pls.' Reply at 16-17. For the reasons explained above, this challenge fails. The best reading of the Act imposes a structure on the arbitrator's decision making, in which the arbitrator first addresses the qualifying payment amount, and then considers whether any additional circumstances or additional information would reasonably

bear on the decision of whether the out-of-network payment amount should be different from the qualifying payment amount. At the very least, this is a permissible reading of the statute.[2] And—although the Plaintiffs do not raise a Step Two challenge—the Defendants have reasonably explained their bases for the rule at this step of the *Chevron* inquiry. The rule "will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act," 86 Fed. Reg. 55,980, 56,061 (Oct. 7, 2021), and will protect patients "from excessive costs, either through reduced costs for items and services or through decreased premiums," thereby also "reduc[ing] government expenditures," *id.* The rule will also promote predictability in the arbitration process, limiting the transaction costs of arbitrations that patients would ultimately bear in the form of higher premiums. *See id.* at 55,996. And, perhaps most importantly, the rule will resolve the market failure that has given rise to surprise billing practices, by diminishing the discrepancy between out-of-network payments for medical services and the in-network payments for the same services that are negotiated at arm's length in a free market. *See id.*; *see also* Br. of *Amici Curiae* Health Policy Experts at 4-6, ECF No. 85.[3]

III. THE DEPARTMENTS WERE NOT REQUIRED TO ISSUE THE RULE THROUGH NOTICE-AND-COMMENT RULEMAKING.

In its September 7, 2021 letter to the Departments, TMA expressed its "great[] appreciat[ion for] the Departments' efforts to quickly publish Part 1 of the rules implementing the No Surprises Act." Letter from E. Linda Villarreal, President, Tex. Med. Ass'n, et al., to Xavier Becerra, Secretary,

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[2] Because the Plaintiffs have challenged the rule only at Step One, their invocation of *SEC v. Chenery Corp.*, 332 U.S. 194 (1947), Pls.' Reply at 9, is beside the point. Because "it is ultimately the function of the judiciary, not the administrative agency, to decide whether Congress spoke directly to the issue in question," *Bank of Am., N.A. v. FDIC*, 244 F.3d 1309, 1320 (11th Cir. 2001), the *Chenery* doctrine does not apply at Step One. In any event, the Departments' path certainly "may reasonably be discerned," *Tex. Ass'n of Mfrs.*, 989 F.3d at 389, from the preamble's discussion of the role that the qualifying payment amount plays in the structure of Section 300gg-111(c). *See* 86 Fed. Reg. at 55,996.

[3] The Plaintiffs briefly express, but do not explain, their concern that the arbitration rule will have the effect of limiting physicians' participation in health plan networks. The *amici* have ably explained why this concern is illusory. *See* Br. of America's Health Insurance Plans as *Amicus Curiae* at 13-15, ECF No. 75; Br. of *Amici Curiae* Health Policy Experts at 13-15, ECF No. 85; Br. of Leukemia & Lymphoma Society et al. as *Amici Curiae* at 13-15, ECF No. 92; Br. of *Amicus Curiae* Blue Cross Blue Shield Ass'n at 10-15, ECF No. 94.

U.S. Dep't of Health & Human Servs., et al. at 21 (Sept. 7, 2021), AR 2444, ECF No. 66-12 ("TMA Comment"). Nonetheless, TMA was "concerned that there are still two other parts of the rules that need to be published before the end of the year." *Id.* According to TMA, this would "be *a very short turnaround* for physicians and other providers to implement changes to their policies and procedures." *Id.* (emphasis added).[4] Put more clearly, TMA recognized then what it fails to recognize now: health care providers and other regulated parties needed adequate time to prepare for the No Surprises Act's new legal regime. *See* 86 Fed. Reg. at 56,044.

Despite having previously urged the Departments to act quickly to publish the arbitration rule, TMA now argues that the Departments committed legal error by honoring that request. TMA had it right the first time.

A. The Governing Statutes Authorize the Departments to Publish Interim Final Rules as They Deem to be Appropriate.

Under statutory authorities that were enacted as part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Departments exercised their power to "promulgate any interim final rules *as [each] Secretary determines are appropriate* to carry out this subchapter." 42 U.S.C. § 300gg-92 (emphasis added); *see also* 26 U.S.C. § 9833; 29 U.S.C. § 1191c. This grant of authority to issue interim final rules when the Departments find it "appropriate" to do so sets forth a different standard than what would ordinarily apply under the APA. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2448-49 (2019) (Kavanaugh, J., concurring) ("broad and open-ended terms like 'reasonable,' 'appropriate,' 'feasible,' or 'practicable' … afford agencies broad policy discretion"). This separate standard shows the "clear intent [of Congress] that APA notice and comment procedures need not be followed." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994).

[4] TMA proposed a one-year delay in the implementation of rules under the No Surprises Act. TMA Comment at 21, AR 2444. As the Defendants have explained, however, this was not a viable alternative to the issuance of an interim final rule. The Act's prohibitions on balance billing went into effect on January 1. Unless the Departments were also to delay enforcement of the Act's patient protections, the absence of a functional arbitration process would mean that providers would not be able to recover full payment for medical services from patients or from plans or insurers, resulting in "the possibility that [these providers] will be undercompensated for their services," 86 Fed. Reg. at 56,044.

Each of the Departments already possessed, and used, the authority to issue interim final rules prior to the enactment of HIPAA.[5] Under the Plaintiffs' reading, Section 300gg-92 would be entirely superfluous, as it would simply repeat an authority that the Departments already held. The Plaintiffs speculate that Section 300gg-92 simply exempts interim final rules "from [an] interagency consistency requirement that would otherwise apply." Pls.' Reply at 22. On this theory, Section 300gg-92 only permits one or more of the Departments to issue an emergency regulation on a temporary basis while issues of interagency conflicts are resolved. But Section 300gg-92 does not say that; it simply authorizes the Departments to issue interim final rules as they determine are appropriate, full stop. There is no reason to "favor [the Plaintiffs'] most unlikely reading over th[e Departments'] obvious one." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1813 (2019).

B. The Defendants Had Good Cause to Publish the Arbitration Rule.

In any event, the Departments properly invoked the APA's "good cause" exception to the requirement of notice and comment. The interim final rule was necessary to allow interested parties—including providers, group health plans and health insurance issuers, and prospective IDR entities—adequate time to prepare for the new regulatory regime. *See* 86 Fed. Reg. at 56,043-56,045; Defs.' Cross-Mot. for SJ at 31-35, ECF No. 62. Health care providers, in particular, needed assurances that the arbitration process would be functional for reimbursement of claims for medical services performed on or after January 1, 2022. As a coalition of providers warned the Departments, "if the IDR process [were] not ready on the backend by January 1 when the balance billing protections are implemented, then providers [would] be at the mercy of the insurer for reimbursement." Centers for Medicare & Medicaid Servs., *Report: No Surprises Act Listening Session with Providers* at 3 (Apr. 14, 2021), AR 2492, ECF No. 66-13. These circumstances "constitute[] the 'something specific' required to forgo notice and comment." *Biden v. Missouri*, 142 S. Ct. 647, 654 (2022).

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[5] *See, e.g.*, *Attestations by Employers for Off-Campus Work Authorization for Foreign Students (F-1 Nonimmigrants)*, 60 Fed. Reg. 61,209 (Nov. 29, 1995) (Department of Labor IFR); *Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments, and Indian Tribal Governments*, 59 Fed. Reg. 43,754 (Aug. 25, 1994) (HHS IFR); *Conversions From Mutual to Stock Form*, 59 Fed. Reg. 22,725 (May 3, 1994) (Treasury IFR).

The Plaintiffs apparently concede that the Departments had good cause to issue rules for certain aspects of the arbitration procedures, but they suggest that the Departments should have carved out the specific rules that address the arbitrator's consideration of the statutory factors. *See* Pls.' Reply at 23. This Swiss-cheese approach to rulemaking makes no sense. The Departments' rulemaking comprehensively addresses the arbitration process, setting forth rules on the content of open negotiation notices, 45 C.F.R. § 149.510(b)(1)(ii); the content of the notices for the initiation of arbitration, *id.* § 149.510(b)(1)(iii); the treatment of "batched" items for resolution on an aggregate basis by the arbitrator, *id.* § 149.510(c)(3); the content of the offers that the parties will submit to the arbitrator for decision, *id.* § 149.510(c)(4)(i); the content of the arbitrator's written decision, *id.* § 149.510(c)(4)(vi); and the legal effects of the arbitrator's decision, *id.* § 149.510(c)(4)(vii). It defies logic to suggest that the interim final rule could have addressed these subjects, while remaining silent as to any discussion of the statutory factors for the arbitrator's decision.

In addition to arguing that the Departments issued the arbitration rule too early, the Plaintiffs also accuse the Departments of acting too late. Pls.' Reply at 25. But Congress directed the Departments to proceed with their rulemaking in a particular order. The Departments were required to set the methodology for determining the qualifying payment amount by July 1, 2021, 42 U.S.C. § 300gg-111(a)(2)(B). Having completed that task, *see Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021), the Departments were then required to issue additional rules by December 27, 2021, to address the procedures for resolving payment disputes. 42 U.S.C. § 300gg-111(a)(2)(B), (c)(2)(A). The arbitration rule "work[s] in concert with the protections against surprise billing already instituted in the July 2021 interim final rules," 86 Fed. Reg. at 56,044, and "build[s] upon the protections in the July 2021 interim final rules," *id.* at 56,047-48. The Departments could not have addressed the role that the qualifying payment amount plays in the arbitration process in the second rule without first setting forth what the qualifying payment amount was in the first rule. And the Departments issued the arbitration rule within three months after the issuance of the first set of rules. This demonstrates that they acted with appropriate dispatch, not that they engaged in any delay. *See Biden v. Missouri*, 142 S. Ct. at 654.

Nor did the Departments issue the interim final rule simply "out of a desire to provide regulatory guidance." Pls.' Reply at 24. To the contrary, it was essential for the arbitration rule to be issued early enough in order to afford regulated parties the ability to prepare for the Act's new legal regime. *See* Br. of America's Health Insurance Plans as *Amicus Curiae* at 4-7, ECF No. 75. Group health plans and health insurance issuers needed the rules to be in place to set appropriate initial payment amounts for reimbursement claims beginning in January. *Id.* at 4. These entities also needed to set up their own internal systems for claims processing, to be able to make these initial payments on a timely basis. *Id.* at 4-5. These preparation efforts included both the creation of automated data systems and the hiring of new staff, as well as the negotiation of new contracts with vendors and employers. *Id.* at 5-6. None of these efforts would have been possible "without rules in place specifying how IDR decisions would be made," however. *Id.* at 5. In short, "[t]imely implementation of the Act would have been impossible if the rules had not been finalized until after the 60-day comment period." *Id.* at 7. This amply demonstrates the Departments' good cause to issue the interim final rule. *See Am. Transfer & Storage Co. v. ICC*, 719 F.2d 1283, 1293-94 (5th Cir. 1983); *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 20 (D.D.C. 2010) (upholding interim rule issued under Section 300gg-92 to implement new statutory requirements on a short timeline).

C. Any Error in Promulgating the Interim Final Rule Was Harmless.

"The APA demands that courts reviewing agency decisions under the Act '[take] due account … of the rule of prejudicial error.'" *United States v. Johnson*, 632 F.3d 912, 930 (5th Cir. 2011) (quoting 5 U.S.C. § 706). The Plaintiffs bear the burden to show that that they suffered prejudice from a purported APA violation. *See Shinseki v. Sanders*, 556 U.S. 396, 409–411 (2009). The Plaintiffs have not alleged, let alone proven, that they have suffered any prejudice. Far from suffering any prejudice, TMA submitted comments to the Departments presenting the same legal argument that it presents here, namely, that the Act requires the arbitrator "*not* to weigh the [qualifying payment amount] more than any other submitted information." TMA Comment at 16, AR 2439. The Departments considered TMA's views, and simply arrived at a different interpretation of the statute.

Each of the factors of the harmless error analysis points in the Departments' favor. *See City of Arlington v. FCC*, 668 F.3d 229, 243-44 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013); *see also* Defs.' Cross-Mot. for S.J. at 35-36. Given that the Plaintiffs have already presented their views during the rulemaking proceedings, they cannot show any "likelihood that the result would have been different," *City of Arlington*, 668 F.3d at 244, if they had submitted a second, repetitive letter in advance of the issuance of the arbitration rule. The parties simply disagree on a matter of statutory interpretation. This disagreement does not amount to prejudice, particularly given that the Departments will soon issue a final rule that incorporates the comments that they solicited from the public on the interim final rule.

IV. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED.

If the Court disagrees with the Departments' arguments, it should remand the matter to the Departments without vacating the challenged provisions. "Only in 'rare circumstances' is remand for agency reconsideration not the appropriate solution." *Tex. Ass'n of Mfrs.*, 989 F.3d at 389 (quoting *O'Reilly v. U.S. Army Corps of Eng'rs*, 477 F.3d 225, 238-39 (5th Cir. 2007)). "Remand, not vacatur, is generally appropriate when there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so." *Id.* (citing *Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000)).

This is not one of the rare circumstances in which vacatur would be required, as there is "at least a serious possibility" that the Departments would be able to address any error that the Court identifies in the arbitration rule. The Departments have already taken comments on the arbitration rule, and have begun preparing a final rule that will take those comments into account. The Departments anticipate that this final rule will be issued no later than May 2022. This would fully remedy any of the Plaintiffs' claimed procedural violations. *See id.* at 390. The Plaintiffs protest that, even though a final rule is imminent, vacatur is still required to ensure that the Departments are able to "consider the issue afresh." Pls.' Reply at 29. The APA does not permit the Plaintiffs or the courts to apply such an "open-mindedness test," however. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020). Under the APA's presumption of regularity, the

Departments should be understood to be capable of issuing a final rule even while an interim final rule is in place. *See id.*

Vacatur of the rule in the meantime, however, would be highly disruptive, upending the Act's efforts to control upward pressure on health care costs, just as arbitrations are set to begin this spring. Health insurance issuers and group health plans, in particular, have relied on the interim final rule; since the rule was published in September, they have devoted significant resources to build data management systems, hire staff, and negotiate contracts with vendors and employers in order to be ready to process claims under the Act's new legal regime. *See* Br. of America's Health Insurance Plans as *Amicus Curiae* at 4-6, ECF No. 75. These interests weigh heavily against vacatur. *See Cent. & S. W. Servs., Inc.*, 220 F.3d at 692.

If the Court were nonetheless to grant the request for vacatur, it should limit any relief to the specific, identified Plaintiffs with standing in this case. "Principles of judicial restraint control here," *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021), to preclude broader relief, particularly given that other courts are considering the same rule that the Plaintiffs have challenged.[6] 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); *see also 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.").

Contrary to the Plaintiffs' assertions, the APA does not require this Court to vacate the rule on a nationwide basis, or even permit it to do so under the circumstances of this case. *See* Pls.' Reply at 30. The APA authorizes a court to set aside agency action only "[t]o the extent necessary for decision," 5 U.S.C. § 706, and relief of no greater extent would be needed here beyond what would remedy the Plaintiffs' demonstrated injuries. *See also* 5 U.S.C. § 702 ("[n]othing herein affects … the power or duty of the court to … deny relief on any other appropriate legal or equitable ground"); *Va.*

[6] *See Ass'n of Air Ambulance Servs. v. U.S. Dep't of Health & Human Servs.*, No. 1:21-cv-03031-RJL (D.D.C.); *Am. Med. Ass'n v. U.S. Dep't of Health & Human Servs.*, No. 1:21-cv-03231-RJL (D.D.C.); *Am. Soc'y of Anesthesiologists v. U.S. Dep't of Health & Human Servs.*, No. 1:21-cv-06823 (N.D. Ill.); *Ga. Coll. of Emergency Physicians v. U.S. Dep't of Health & Human Servs.*, 1:21-cv-05267-MHC (N.D. Ga.).

Soc'y for Human Life, Inc. v. FEC, 263 F.3d 379, 394 (4th Cir. 2001) ("Nothing in the language of the APA, however, requires us to exercise such far-reaching power [of nationwide invalidation of a regulation]."), *overruled in part on other grounds by The Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544, 500 n.2 (4th Cir. 2012). Thus, whether the matter is viewed as one of the limits on the courts' equitable powers, or as a matter of the severability of applications of the arbitration rule that do not affect the Plaintiffs, *see K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988), the result is the same; this Court should not order relief broader than what is needed to address the claims of the Plaintiffs in this case.

CONCLUSION

For the foregoing reasons, the Defendants' cross-motion for summary judgment should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 2nd day of February, 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/ Joel McElvain
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