

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION OF AIR MEDICAL SERVICES,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Civ. No. 1:21-cv-3031 (RJL)

Consolidated with
No. 1:21-cv-3231 (RJL)

PLAINTIFF’S NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiff Association of Air Medical Services (AAMS) respectfully submits this Notice to inform the Court of the February 23 memorandum opinion and order in *Texas Medical Association v. U.S. Department of Health and Human Services*, No. 6:21-cv-00425 (*TMA*) (attached as Exhibit A). Like AAMS, the *TMA* plaintiffs challenged the provisions of *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (IFR Part II) creating a presumption that the qualified payment amount (QPA) is the appropriate out-of-network rate.

The *TMA* opinion supports the entry of a similar order by this Court that the provisions of IFR Part II challenged by AAMS are unlawful.

First, the *TMA* court held that the No Surprises Act “plainly requires” arbitrators to consider “all” the Subparagraph C Factors and *not* “weigh any one factor or circumstance more heavily than the others.” Op. 17. Because “the Act is unambiguous,” the Departments were not entitled to *Chevron* deference. Op. 16.

Second, the *TMA* court held that the proper remedy was vacatur of the provisions challenged there. Given IFR Part II’s “serious[]” deficiencies, “there is nothing the Departments can do on remand to rehabilitate or justify the challenged portions of the Rule.” Op. 32. And vacatur

would not be unduly disruptive because the Act and the remaining provisions of IFR Part II provide a sufficient framework to resolve payment disputes through arbitration. Op. 33.

Third, the provisions vacated in *TMA* overlap substantially with those challenged here. The *TMA* court vacated the second sentence of 45 C.F.R. § 149.510(c)(4)(ii)(A), and the final sentence of 45 C.F.R. § 149.510(c)(4)(iii)(C). AAMS asks this Court to set aside 45 C.F.R. §§ 149.510(c)(4)(ii)(A) and 149.520(b)(2) in full. Sections 149.520(b)(2) and 149.510(c)(4)(iii)(C) are interrelated. *See* 45 C.F.R. § 149.520(b)(1) (“[R]eferences in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2)”).

For the same reasons, this Court should promptly enter an order holding unlawful and vacating the provisions of IFR Part II challenged by AAMS. In addition, this Court should promptly enter an order holding unlawful and vacating the provisions of *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021) challenged by AAMS. Unlike in the *TMA* case, AAMS’ standing is undisputed and the nationwide membership of AAMS obviates any question regarding the geographic scope of relief.

Alternatively, this Court should promptly schedule a hearing on AAMS’ motion for summary judgment and the Defendants’ cross-motion for summary judgment given the ongoing disruptions to AAMS members and the short time remaining before independent dispute resolution (IDR) entities begin issuing decisions.

Dated: February 24, 2022

Respectfully submitted,

/s/ Brian Stimson

Brian R. Stimson (D.C. Bar No. 1657563)

Sarah P. Hogarth (D.C. Bar. No. 1033884)

MCDERMOTT WILL & EMERY LLP

500 North Capitol Street NW

Washington, DC 20001

(202) 756-8000

bstimson@mwe.com

shogarth@mwe.com

Attorneys for Plaintiff

Association of Air Medical Services

Exhibit A

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

TEXAS MEDICAL ASSOCIATION and
ADAM CORLEY,

Plaintiffs,

V.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
et al.,

Defendants.

Case No. 6:21-cv-425-JDK

MEMORANDUM OPINION AND ORDER

Plaintiff healthcare providers challenge an interim final rule issued pursuant to the No Surprises Act (“Act”). The Rule governs the arbitration process for resolving payment disputes between certain out-of-network providers and group health plans and health insurance issuers. As explained below, the Court concludes that the Rule conflicts with the Act and must be set aside under the Administrative Procedure Act (“APA”). Defendants also improperly bypassed notice and comment required by the APA, and thus the Rule must be set aside for this additional reason. Accordingly, the Court **GRANTS** Plaintiffs’ motion for summary judgment (Docket No. 25) and **DENIES** Defendants’ cross-motion for summary judgment (Docket No. 62).

I.

A.

The No Surprises Act was enacted on December 27, 2020, as part of the Consolidated Appropriations Act of 2021 to address “surprise medical bills.” Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758–2890 (2020). Generally, the Act limits the amount an insured patient will pay for emergency services furnished by an out-of-network provider and for certain non-emergency services furnished by an out-of-network provider at an in-network facility. 42 U.S.C. §§ 300gg-111, 300gg-131, 300gg-132.¹

The Act also addresses the payment of these out-of-network providers by group health plans or health insurance issuers (collectively, “insurers”). In particular, the Act requires insurers to reimburse out-of-network providers at a statutorily calculated “out-of-network rate.” § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D). In states with an All-Payer Model Agreement or specified state law, the out-of-network rate is the rate provided by the Model Agreement or state law. § 300gg-111(a)(3)(K). In states without a Model Agreement or specified state law, the out-of-network rate is either the amount agreed to by the insurer and the out-of-network provider or an amount determined through an independent dispute resolution (“IDR”) process. *Id.*

¹ The Act amended three statutes: the Public Health Service Act (“PHSA”) (administered by the Department of Health and Human Services), the Employee Retirement Income Security Act (“ERISA”) (administered by the Department of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). For ease of reference, this Opinion cites to the PHSA.

When there is no Model Agreement or state law, the Act establishes the procedure to determine payment. Insurers must issue an initial payment or notice of denial of payment to a provider within thirty days after the provider submits a bill for an out-of-network service. § 300gg-111(a)(1)(C)(iv), (b)(1)(C). If the provider disagrees with the insurer's determination, the provider may initiate a thirty-day period of open negotiation with the insurer over the claim. § 300gg-111(c)(1)(A). If the parties cannot resolve the dispute through negotiation, the parties may then proceed to IDR arbitration. § 300gg-111(c)(1)(B).

The IDR process—which is the subject of this lawsuit—is a “baseball-style” arbitration. The provider and insurer each submits a proposed payment amount and explanation to the arbitrator. § 300gg-111(c)(5)(B). The arbitrator must select one of the two proposed payment amounts “taking into account the considerations specified in subparagraph (C).” § 300gg-111(c)(5)(A). Subparagraph C states as follows:

(C) Considerations in determination

(i) In general

In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider-

(I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and

(II) subject to subparagraph (D), information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

(ii) Additional circumstances

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

(I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).

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

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

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

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

§ 300gg-111(c)(5)(C).

The Act also prohibits the arbitrator from considering the provider's usual and customary charges for an item or service, the amount the provider would have billed for the item or service in the absence of the Act, or the reimbursement rates for the item or service under the Medicare, Medicaid, Children's Health Insurance, or Tricare programs. § 300gg-111(c)(5)(D). The arbitrator's selection of a payment amount is binding on the parties, and is not subject to judicial review, except under the circumstances described in the Federal Arbitration Act. § 300gg-111(c)(5)(E).

Important to the challenge here is “the qualifying payment amount” (“QPA”), referenced in § 300gg-111(c)(5)(C)(i)(I). The QPA is generally “the median of the contracted rates recognized by the plan or issuer . . . under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item[s] or service is furnished,” with annual increases based on the consumer price index. § 300gg-111(a)(3)(E)(i)(I)-(II). In other words, the QPA is typically the median rate the insurer would have paid for the service if provided by an in-network provider or facility. And because insurers had ultimate say on what in-network rates they accepted in 2019, insurers now hold ultimate power—and are charged by regulation—to calculate the QPA. § 300gg-111(a)(3)(E)(i)(I); *e.g.*, 86 Fed. Reg. 36,872, 36,891 (explaining that certain definitions of the July interim final rule “will make it easier for plans and issuers to calculate the QPA, and for providers and facilities to understand the QPA”); 86 Fed. Reg. at 55,996 (“[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the plan or issuer correctly.”).

Finally, the Act requires the Secretaries of Health and Human Services, Labor, and the Treasury, to “establish by regulation one independent dispute resolution process (referred to in this subsection as the ‘IDR 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.” § 300gg-111(c)(2)(A). The deadline for the regulation was December 27, 2021. *Id.*

B.

On September 30, 2021, the Departments issued an interim final rule implementing the IDR process (herein, the “Rule”). Requirements Related to Surprise Billing: Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021). Under the Rule, the arbitrator must select the proposed payment amount closest to the QPA unless certain conditions are satisfied, as set forth below:

Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must: (A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the [QPA] unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the [QPA] but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

45 C.F.R. § 149.510(c)(4)(ii).² The Rule defines “material difference” as “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

² As with the Act, identical rules appear in three separate sections of the C.F.R., specifically Title 45 – Public Health, Title 26 – Internal Revenue, and Title 29 – Labor. For ease of reference, this Opinion cites to Title 45.

information as showing that the [QPA] is not the appropriate out-of-network rate.”
§ 149.510(a)(2)(viii).

As the Departments explained when issuing the Rule, the Rule effectively creates a “rebuttable presumption” that the amount closest to the QPA is the proper payment amount. *See* 86 Fed. Reg. at 56,056–61.

C.

Plaintiffs are the Texas Medical Association (“TMA”), a trade association representing more than 55,000 physicians, and Dr. Adam Corley, a Tyler, Texas physician. Plaintiffs challenge the Rule under the APA, arguing that it improperly requires arbitrators to “give outsized weight” to a single statutory factor, the QPA, in conflict with the Act. Docket No. 1 at 4–5, 28–31; Docket No. 25 at 2, 13–23. Plaintiffs also argue that the Rule was issued without the required notice and comment. Docket No. 1 at 5–7, 31–32; Docket No. 25 at 2–3, 23–30. Accordingly, Plaintiffs request that the Court vacate certain provisions of the Rule—namely, 45 C.F.R. § 149.510(a)(2)(viii), the second sentence of 45 C.F.R. § 149.510(c)(4)(ii)(A), the final sentence of 45 C.F.R. § 149.510(c)(4)(iii)(C), 45 C.F.R. § 149.510(c)(4)(iv), 45 C.F.R. § 149.510(c)(4)(vi)(B), as well as the identical provisions found in Titles 26 and 29 of the Code of Federal Regulations. Docket No. 1 at 32–33; Docket No. 25-3 at 1–2.

Defendants are the Departments responsible for promulgating the Rule—the Departments of Health and Human Services, Labor, and the Treasury, along with the Office of Personnel Management and the current heads of those agencies in their official capacities (collectively, the “Departments”). Docket No. 1. The Departments

contend that the Rule is consistent with the Act and that no notice and comment was required here. Docket No. 62.

Both sides now move for summary judgment under Federal Rule of Civil Procedure 56. Docket Nos. 25, 62. Summary judgment is proper when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986); *Ragas v. Tenn. Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998).

Here, both sides agree that the Court can determine Plaintiffs’ APA challenge as a matter of law.

II.

The Departments first argue that neither Plaintiff has standing to challenge the Rule because their alleged injuries are speculative. The Departments also argue that Dr. Corley and the identified members of the TMA practice medicine through corporations and thus are not personally harmed by the Rule. Docket No. 62 at 16–18. As explained below, the Court concludes that Plaintiffs have demonstrated two cognizable injuries resulting from the Rule and that Plaintiffs are not challenging the Rule on behalf of the corporations they own or work for.

A.

“The irreducible minimum constitutional standing requirement to invoke a federal court’s article III jurisdiction is (1) injury-in-fact (2) fairly traceable to the defendant’s actions and (3) likely to be redressed by a favorable decision.” *Ensley v.*

Cody Res., Inc., 171 F.3d 315, 319 (5th Cir. 1999) (citing *Raines v. Byrd*, 521 U.S. 811, 818 (1997); *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982)).

Here, Plaintiffs have established two injuries fairly traceable to the Rule.

First, Plaintiffs assert that the Rule deprives them of the arbitration process established by the Act. Docket No. 98 at 4. Rather than having an arbitrator consider all statutory factors as provided by the Act, Plaintiffs argue, the Rule puts a substantial thumb on the scale in favor of the QPA. *See id.*; Docket No. 25-1 at 3; Docket No. 25-2 at 2; Docket No. 98-1 at 3–5; Docket No. 98-2 at 3–4; Docket No. 98-3 at 4–6; Docket No. 98-4 at 2–3. Further, Plaintiffs contend that the Rule “will pressure healthcare providers to lower their offers toward the QPA to increase the likelihood they will be selected.” Docket No. 98 at 5 (citing 86 Fed. Reg. at 56,061). This claimed procedural injury is sufficient to confer Article III standing. *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (“A plaintiff can show a cognizable injury if [he] has been deprived of a ‘procedural right to protect [his] concrete interests.’”) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009)); *see also Lujan*, 504 U.S. at 573 n.8.

Plaintiffs, moreover, need not prove that following proper procedure will necessarily create different outcomes. They must merely show a “reasonable claim of minimal impact.” *Kinetica Partners, LLC v. United States Dep’t of the Interior*, 505 F. Supp. 3d 653, 671 (S.D. Tex. 2020), appeal dismissed sub nom. *Kinetica Partners, L.L.C. v. United States Dep’t of Interior*, 2021 WL 3377978 (5th Cir. Mar. 22, 2021)

“A procedural injury can suffice for standing even where the plaintiff does not prove that adherence to the proper procedure would have produced a different outcome because the likelihood and extent of impact are properly addressed in connection with the merits in a harmless error analysis.” (quoting *United States v. Johnson*, 632 F.3d 912, 921 (2011)); *Johnson*, 632 F.3d at 921 n.45 (citation omitted).

Second, Plaintiffs have established that they will likely suffer financial harm because—as the Departments acknowledge—the Rule’s presumption in favor of the offer closest to the QPA “will systematically reduce out-of-network reimbursement compared to an IDR process without such a presumption.” Docket No. 95 at 5 (citing Docket No. 62 at 10–11, 22, 32, 37). Plaintiffs contend that the offers they will submit to the arbitrator will nearly always be higher and farther from the QPA than the offers submitted by the insurers. Docket No. 98-1 at 3; Docket No. 98-2 at 3; Docket No. 98-3; Docket No. 98-4 at 2. This is because the QPA will not “accurately reflect [the providers’] cost of providing services” in most cases. Docket No. 98-1 at 3–4. Plaintiffs provide multiple reasons why the QPA could significantly differ from actual costs or market rates, including geographic disparity (Docket No. 98-1 ¶ 9), differences in provider training (Docket No. 98-2 ¶ 10), and differences in patient and case complexity (Docket No. 98-2 ¶¶ 10–11; Docket No. 98-3 ¶ 10; Docket No. 98-4 ¶ 8). Such “economic injury is a quintessential injury upon which to base standing.” *El Paso Cnty., Texas v. Trump*, 982 F.3d 332, 338 (5th Cir. 2020) (quoting *Tex. Democratic Party v. Benkiser*, 459 F.3d 582, 586 (5th Cir. 2006)).

The Departments contend that Plaintiffs offer “only speculation and conclusory assertions that they will suffer” injury. Docket No. 62 at 16. But Plaintiffs submit detailed affidavits with specific facts establishing that their injuries are not only likely and imminent, but inevitable. *See, e.g.*, Docket No. 25-2 ¶ 9 (“Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will result in lower reimbursement rates and, correspondingly, will cause my hourly compensation for out-of-network services to decrease.”); Docket No. 98-1 (“[T]he rebuttable presumption in favor of the QPA will drive out-of-network reimbursement rates to the QPA as a de facto benchmark, resulting in financial harm to physicians.”); Docket No. 98-2 ¶ 13 (“Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will thus result in lower reimbursement rates for my services and, correspondingly, will cause my compensation to decrease.”). This evidence is sufficient to establish Article III injury in fact. *See, e.g., Sabre, Inc. v. Dep’t of Transp.*, 429 F.3d 1113, 1118 (D.C. Cir. 2005) (finding a “a sufficiently distinct and palpable injury” from agency action that had “immediate, unavoidable implications for [the plaintiff’s] business choices”); *see also Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008) (“[S]tanding is usually self-evident when the plaintiff is a regulated party or an organization representing regulated parties.”).

The Departments argue that Plaintiffs’ affidavits were “late” and should be “stricken and disregarded” because Plaintiffs failed to submit the affidavits with their opening summary judgment motion. Docket No. 104 at 3. This argument is

meritless. The Departments moved for summary judgment for lack of standing *after* Plaintiffs filed their summary judgment motion. Docket No. 64. Plaintiffs then submitted the affidavits with their “Opposition to Defendants’ Motion for Summary Judgment and Reply in Support of Summary Judgment.” Docket No. 98. Plaintiffs’ evidence was neither late nor improper. *See Celotex*, 477 U.S. at 324.

Finally, the Departments argue that the TMA lacks standing as an association. An association has standing on behalf of its members when: “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Hunt v. Wash. State Apple Advertising Comm’n*, 432 U.S. 333, 343 (1977). Here, TMA provided affidavits from three members establishing that each has suffered and will suffer harm. Docket No. 98-1 ¶¶ 6–13; Docket No. 98-2 ¶¶ 7–14; Docket No. 98-3 ¶¶ 7–14. Thus, these three members have individual standing. Further, TMA is a medical trade association seeking to protect the interests of its members as healthcare providers, an interest germane to TMA’s purpose. Docket No. 1 at 7–8. And neither TMA’s claim nor the requested relief (vacatur of the Rule) requires the participation of TMA’s individual members in this suit. The Court is satisfied that TMA has standing to bring this action on behalf of its members. *S. Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882, 895–96 (D.C. Cir. 2006) (finding organizational standing where it was “inconceivable” that the challenged agency action would fail to affect at least one organization member).

B.

The Departments also argue that Dr. Corley and the TMA members lack prudential standing because they are improperly seeking relief on behalf of corporations they are employed by or own shares in. In general, the prudential shareholder-standing doctrine prohibits a shareholder from suing to enforce the rights of the corporation. *Collins v. Mnuchin*, 938 F.3d 553, 575 (5th Cir. 2019) (en banc), *rev'd in part on other grounds sub nom. Collins v. Yellen*, 141 S. Ct. 1761 (2021). But the shareholder-standing rule does not apply here.

Plaintiffs contend—and the Court agrees—that they are not challenging the Rule on behalf of the companies they work for or own. Docket No. 98 at 6. Rather, it is the providers themselves—Dr. Corley and the individual TMA-members—who suffer a redressable injury from the Rule. The Act defines “nonparticipating provider” as “a physician or other health care provider . . . who does not have a contractual relationship with the plan or issuer, respectively, for furnishing such item or service under the plan or coverage, respectively.” 42 U.S.C. § 300gg-111(a)(3)(G)(i). According to their affidavits, Dr. Corley and the TMA members are “nonparticipating providers” for certain medical services. *See* Docket Nos. 98-1, 98-2, 98-3, 98-4.

Further, the providers—not the corporations—furnish services to patients, negotiate with insurers, invoke the arbitration process, and submit offers and other information to the arbitrator. § 300gg-111(c)(1). *See also, e.g.*, Docket No. 98-1 ¶ 7 (TMA member explaining that when negotiations with an insurer fail, “I will work with my administrative staff to submit claims to the NSA’s IDR process . . . [a]

certified IDR entity will then determine the reimbursement rate *I* receive, as set forth in the NSA and the Departments’ regulations”) (emphasis added); Docket No. 98-2 ¶ 10 (same). And it is the providers—not the corporations—whose training, experience, and quality and outcome measurements are to be considered by the arbitrator. § 300gg-111(c)(5).

Even if the Departments were correct about injury to corporations, the providers would nevertheless have prudential standing here. “For a plaintiff to have prudential standing under the APA, ‘the interest sought to be protected by the complainant [must be] arguably within the zone of interests to be protected or regulated by the statute . . . in question.’” *Collins*, 938 F.3d at 575 (quoting *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). Because, as explained above, the Act and Rule plainly regulate “providers,” the providers are unquestionably within the zone of interests and may challenge the Rule under the APA. *See, e.g., Match-E-Be-Nash-She-Wish Band of Pottawatomí Indians v. Patchak*, 567 U.S. 209, 224–25 (2012) (holding that plaintiff satisfied zone-of-interest test by asserting “economic, environmental, and aesthetic harm as a nearby property owner”); *Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin.*, 656 F.3d 580, 585–86 (7th Cir. 2011) (truckers had standing as “objects” of the challenged rule).

* * *

Accordingly, Plaintiffs have satisfied the requirements of both constitutional standing under Article III and prudential standing.

III.

Plaintiffs argue that the Rule conflicts with the Act by imposing a rebuttable presumption in favor of the offer closest to the QPA. Docket No. 25 at 14. They ask the Court to set aside the Rule under the APA on this basis alone. The Departments counter that the “overall statutory scheme” supports the Rule and that they are entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Docket No. 62 at 20, 26.

The APA requires a reviewing court to “hold unlawful and set aside” agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). The Court reviews an agency’s statutory interpretation under the two-step *Chevron* framework. *See generally Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1014 (5th Cir. 2019) (discussing *Chevron*); *see also City of Arlington v. FCC*, 569 U.S. 290, 306–07 (2013). The first step determines “whether Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Chevron*, 467 U.S. at 843. However, if the statute is ambiguous, the Court proceeds to step two: “asking whether the agency’s construction is ‘permissible.’” *Sw. Elec. Power Co.*, 920 F.3d at 1014 (quoting *Chevron*, 467 U.S. at 843).

As explained below, the Court determines that the Act unambiguously establishes the framework for deciding payment disputes and concludes that the Rule conflicts with the statutory text.

A.

In determining whether Congress has unambiguously spoken through a statute, the Court applies all the “traditional tools of construction,” including “text, structure, history, and purpose.” *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quoting *Chevron*, 467 U.S. at 843 n.9; *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 707 (1991) (Scalia, J., dissenting)); *Gulf Fishermens Ass’n v. Nat’l Marine Fisheries Serv.*, 968 F.3d 454, 460 (5th Cir. 2020). “[W]here a statute’s text is clear, courts should not resort to legislative history” and “should not introduce ambiguity through the use of legislative history.” *Adkins v. Silverman*, 899 F.3d 395, 403 (5th Cir. 2018) (citing *BedRoc Ltd. v. United States*, 541 U.S. 176, 183 (2004) (plurality opinion)).³

Here, the Act is unambiguous. The Act provides that arbitrators deciding which offer to select “shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii).” 42 U.S.C. § 300gg-111(c)(5)(C)(i). Clause (ii) in turn lists five “circumstances” to consider, including (1) “the level of training, experience, and quality and outcomes measurements of the provider or facility”; (2) the “market share held by the nonparticipating provider or facility”; (3) the “acuity of the individual receiving such item or service”; (4) the “teaching status, case mix, and scope of services of the nonparticipating facility”; and (5) “[d]emonstrations of good faith efforts (or lack of good faith efforts)” made by the

³ Although the parties and various amici discuss the Act’s legislative history, *see, e.g.*, Docket Nos. 34, 57, and 83, statements of intent do not override the plain text. *Hammack v. Baroid Corp.*, 142 F.3d 266, 271 (5th Cir. 1998) (“[T]heories of underlying intent or purpose cannot trump statutory language.”). Nor can a statement from two members of Congress who helped draft the statute, *see* Docket No. 83, overcome the plain text. *Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc.*, 447 U.S. 102, 118 (1980) (“[O]rdinarily even the contemporaneous remarks of a single legislator who sponsors a bill are not controlling in analyzing legislative history.”).

provider and insurer to enter into a network agreement. § 300gg-111(c)(5)(C)(ii). Arbitrators must also consider any relevant information submitted by either party. § 300gg-111(c)(5)(B). Because “the word ‘shall’ usually connotes a requirement,” the Act plainly requires arbitrators to consider all the specified information in determining which offer to select. *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016).

Nothing in the Act, moreover, instructs arbitrators to weigh any one factor or circumstance more heavily than the others. A statute’s “lack of text” is sometimes “more telling” than the text itself. *Gulf Fishermens Ass’n*, 968 F.3d at 460. And here, the Act nowhere states that the QPA is the “primary” or “most important” factor. *See Am. Corn Growers Ass’n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002) (holding that where “no weights were assigned” to statutory factors, “treat[ing] one of the five statutory factors in such a dramatically different fashion distorts the judgment Congress directed”). Nor does the Act impose a “rebuttable presumption” that the offer closest to the QPA should be chosen—or suggest anywhere that the other factors or information is less important than the QPA. *Compare* § 300gg-111(c)(5)(A)(i)–(ii) (making no mention of rebuttable presumption), *with* 8 U.S.C. § 1158(b)(1)(B)(iii) (creating a “rebuttable presumption” of credibility), *and* 15 U.S.C. § 3608(b) (creating a “rebuttable presumption” of unconscionability), *and* 42 U.S.C. § 15942(a) (creating a “rebuttable presumption” of exemption from environmental review). Rather, the Act instructs arbitrators to select one of the two offers submitted by the parties after

“taking into account the considerations specified in subparagraph (C).” 42 U.S.C. § 300gg-111(c)(5)(A)(i).

Because Congress spoke clearly on the issue relevant here, the Departments’ interpretation of the statute is owed no *Chevron* deference. *See Chevron*, 467 U.S. at 843; *Gulf Fishermens Ass’n*, 968 F.3d at 459 (“[C]ourts will not defer to agency interpretation of an unambiguous statute.”).

B.

It is a “core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate.” *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014). But here, the Departments impermissibly altered the Act’s requirements.

Rather than instructing arbitrators to consider all the factors pursuant to the Act, the Rule requires arbitrators to “select the offer closest to the [QPA]” *unless* “credible” information, including information supporting the “additional factors,” “clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate” (or if the offers are equally distant from the QPA in opposing directions). 45 C.F.R. § 149.510(c)(4)(ii)(A). The Departments in fact characterize the non-QPA factors as “*permissible* additional factors” that may be considered only “when appropriate.” 86 Fed. Reg. at 56,080. The Rule thus places its thumb on the scale for the QPA, requiring arbitrators to presume the correctness of the QPA and then imposing a heightened burden on the remaining statutory factors to overcome that presumption.

The Departments’ arguments for the Rule are unpersuasive. They first claim that the “overall statutory scheme” supports the Rule. Docket No. 62 at 20. The Act “lists the [QPA] as the first factor,” and the subchapter heading describes the other factors as “additional circumstances” to consider. *Id.* But the Departments cite no authority holding that a statutory factor is entitled to more weight simply because it is the first in a list. *See* Docket No. 62 at 20; Docket No. 104 at 6. And “subchapter heading[s] cannot substitute for the operative text of the statute.” *United States v. Lawrence*, 727 F.3d 386, 393 (5th Cir. 2013). The term “additional,” moreover, does not justify weighing the other factors less than the QPA. *See* BLACK’S LAW DICTIONARY (6th ed. 1990) (“This term embraces the idea of joining or uniting one thing to another, so as thereby to form one aggregate.”).

Rather, the Act “clearly sets forth a list of considerations and does not dictate a procedure” or a “procedural order for the [agency’s] considerations.” *Missouri-Kansas-Texas R.R. Co. v. United States*, 632 F.2d 392, 412 (5th Cir. 1980) (interpreting a statute’s plain command that an agency “shall consider” certain factors). If Congress had wanted to restrict arbitrators’ discretion and limit how they could consider the other factors, it would have said so—especially here, where Congress described the arbitration process in meticulous detail. 42 U.S.C. § 300gg-111(c)(2)–(9); *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) (“Congress could have limited [the agency’s] discretion in any number of ways, but it chose not to do so . . . [b]y introducing a limitation not found in the statute, respondents ask us to alter, rather than to interpret, the [statute].”).

Next, the Departments claim that the Plaintiffs misread the Rule. The Rule merely directs arbitrators to “begin[] with a review of the [QPA],” the Departments contend, and then depart up or down based on the “additional” factors. Docket No. 62 at 22–23. But the Rule adds several key words not in the statute. The Act instructs arbitrators to “consider” the QPA and the five other factors in deciding which offer to accept. § 300gg-111(c)(5)(C). That’s it. The Rule, in contrast, requires arbitrators to “select the offer closest to the [QPA]” and deviate from that number only if “credible information” “clearly demonstrates” that the QPA is “materially different from the appropriate out-of-network rate.” 45 CFR § 149.510(c)(4)(ii). The Rule thus impermissibly “rewrite[s] statutory language by ascribing additional, material terms.” *Texaco Inc. v. Duhe*, 274 F.3d 911, 920 (5th Cir. 2001); *Rotkiske v. Klemm*, 140 S. Ct. 355, 360–61 (2019) (“It is a fundamental principle of statutory interpretation that ‘absent provision[s] cannot be supplied by the courts.’” (citation omitted)); *In re Benjamin*, 932 F.3d 293, 300 (5th Cir. 2019) (“[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate.” (citation omitted)).

The Departments suggest that the additional terms do not really do anything—that the Plaintiffs “attack[] a straw man of their own devising.” Docket No. 62 at 22. But the Rule treats the QPA—an insurer-determined number—as the default payment amount and imposes on any provider attempting to show otherwise a heightened burden of proof that appears nowhere in the statute.⁴ This is why the

⁴ Defendants argue that Congress intended the QPA to be a “proxy for the in-network price” and that the QPA is therefore the “reasonable amount of payment” for out-of-network services. Docket No.

Departments themselves repeatedly touted the Rule as establishing a “rebuttable presumption” in favor of the QPA when they presented the Rule for public viewing. 86 Fed. Reg. at 56,056–61. And it is undoubtedly why the Departments argued to the Court that vacating the Rule would result in higher reimbursement payments to providers, “would be highly disruptive” to insurance companies, and would “upend[] . . . efforts to control upward pressure on health care costs.” Docket No. 104 at 17; see also Docket No. 62 at 10–11, 28; 86 Fed. Reg. at 56,061.

Because the Rule “rewrites clear statutory terms,” it must be “h[e]ld unlawful and set aside” on this basis alone. *Util. Air Regul. Grp.*, 573 U.S. at 328; 5 U.S.C. § 706(2)(A).

IV.

Plaintiffs alternatively argue that the Rule should be vacated because the Departments failed to provide notice and comment as required by the APA. Docket No. 25 at 23–30. The Departments claim that they were exempted or excused from notice and comment, and that any error was harmless. Docket No. 62 at 29–36.

The APA requires that agencies publish a “notice of proposed rule making” and “give interested persons an opportunity to participate . . . through submission of written data, views, or arguments.” 5 U.S.C. § 553(b), (c). The purpose of the “notice-and-comment” requirement is to “assure fairness and mature consideration of rules having a substantial impact on those regulated” and for the agency to “disclose its

62 at 20. But nothing in the Act treats the QPA as a proxy for the in-network price. And for all the reasons stated above, the Act does not treat the QPA as a proxy for the out-of-network price—which is why the Act requires arbitrators to consider several factors in addition to the QPA in determining the proper reimbursement amount.

thinking on matters that will affect regulated parties.” *Johnson*, 632 F.3d at 931. Unless an agency can show an exception to the APA’s notice-and-comment requirement, the regulation is “contrary to law” and must be “set aside.” 5 U.S.C. § 706(2)(A); *see also Dialysis Patient Citizens v. Burwell*, No. 4:17-cv-16, 2017 WL 365271, at *4–6 (E.D. Tex. Jan. 25, 2017).

For the following reasons, the Court concludes that the Departments were not excused from providing notice and comment and that the error was not harmless.

A.

The Departments first argue that Congress “expressly” authorized them to bypass notice and comment because each of their governing statutes “authorizes the Secretary of each of the Departments to ‘promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter.’” Docket No. 62 at 29 (quoting 42 U.S.C. § 300gg-92; 26 U.S.C. § 9833; 29 U.S.C. § 1191c).

The APA allows a statute to modify or supersede its procedural requirements “to the extent [the statute] does so expressly.” 5 U.S.C. § 559. But the language cited by the Departments neither expressly nor implicitly exempts them from the APA’s notice-and-comment requirement here. In fact, every court that has addressed the Departments’ argument has rejected it. *See, e.g., Pennsylvania v. President of United States*, 930 F.3d 543, 566 (3d Cir. 2019), *rev’d on other grounds*, 140 S. Ct. 2367 (2020) (“[T]he Regulation Provision does not expressly excuse the Agencies from complying with APA procedures and therefore does not provide a basis for issuing the IFRs without notice and comment.”); *California v. Azar*, 911 F.3d 558, 578–79 (9th Cir. 2018) (same). *See, also, e.g., Chamber of Com. of United States v. IRS*, 2017 WL

4682050, at *6 (W.D. Tex. Oct. 6, 2017) (statute requiring “[a]ny temporary regulation issued by the Secretary [to] be issued as a proposed regulation” does not “expressly exempt” temporary regulations from APA requirements); *cf. Dir., Off. of Workmen’s Comp. Program, U. S. Dep’t of Lab. v. Alabama By-Prod. Corp.*, 560 F.2d 710, 719 (5th Cir. 1977).⁵

The cases cited by the Departments, moreover, do not support their position. Docket No. 62 at 29. In *Methodist Hospital of Sacramento v. Shalala* and *Asiana Airlines v. FAA*, the courts found express waivers because the statutes explicitly directed the agencies to issue interim final rules first, *then* provide a comment period, and *then* issue final rules. *See* 38 F.3d 1225, 1237 (D.C. Cir. 1994); 134 F.3d 393, 397–98 (D.C. Cir. 1998). Nothing like that exists here. And in *National Women, Infants, & Children Grocers Ass’n v. Food & Nutrition Services*, the court held that it was unnecessary for Congress to expressly exempt the agency from notice and comment because the APA did not require it in the first place for the provisions at issue there. 416 F. Supp. 2d 92, 105 n.5 (D.D.C. 2006).

Defendants argue that the statutes authorizing them to issue “interim final rules as the Secretary determines” must be read to exempt them from notice and comment because the APA already gave the Departments authority to issue

⁵ Defendants also initially argued—but abandoned in their reply brief—that “the meaning of the term ‘interim final rule’ . . . is . . . a rule issued without notice and comment.” Docket No. 62 at 30; *see also* Docket No 104 at 11–13. Courts have correctly rejected this argument. *See, e.g., Mack Trucks, Inc. v. EPA.*, 682 F.3d 87, 94 (D.C. Cir. 2012) (“[I]f a rule’s interim nature were enough to satisfy the element of good cause, then ‘agencies could issue interim rules of limited effect for any plausible reason, irrespective of the degree of urgency’ and ‘the good cause exception would soon swallow the notice and comment rule.’”) (quoting *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1145 (D.C. Cir. 1992)).

temporary rules. Docket No. 62 at 30 (arguing that 42 U.S.C. § 300gg-92 would be “surplusage” if not interpreted as an express authorization to depart from APA notice-and-comment requirement); Docket No. 104 at 13 & n.5. But the authorizing statutes provided express authority to issue such rules, which is lacking in the APA. *Compare* 5 U.S.C. § 553, *with* 42 U.S.C. § 300gg-92. As one court explained in rejecting a similar surplusage argument, “we need not give the second sentence [of § 300gg-92] the agencies’ expansive interpretation in order for the second sentence to retain independent effect.” *Azar*, 911 F.3d at 579.

Accordingly, the Court holds that the Departments were not exempted from the APA’s notice-and-comment requirement.

B.

Next, the Departments invoke the good cause exception to notice and comment. Docket No. 62 at 31.

The APA excuses agencies from notice and comment “when the agency for good cause finds . . . that [the] notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B). The good cause exception, however, “should be read narrowly in order to avoid providing agencies with an escape clause from the requirements Congress prescribed.” *Johnson*, 632 F.3d at 928. It applies only in situations where “delay would do real harm.” *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979). The Court finds that the exception does not apply here.

The Departments claim notice and comment was “impracticable” and “contrary to the public interest” because the Act went into effect “barely twelve months” after

it was enacted and because “regulated entities would need months of lead time to prepare for the new legal regime.” Docket No. 62 at 32; 88 Fed. Reg. at 56,043–44. But “the mere existence of deadlines for agency action, whether set by statute or court order, does not in itself constitute good cause for a § 553(b)(B) exception.” *U.S. Steel Corp.*, 595 F.2d at 213; *see also City of Waco v. EPA*, 620 F.2d 84, 86 (5th Cir. 1980). In fact, in *U.S. Steel*, an agency failed to show the “impracticability of affording notice and comment” where it could have accepted comments during the 60-day period Congress gave the agency to review and publish a list. *U.S. Steel Corp.*, 595 F.2d at 213; *see also, e.g., Johnson*, 632 F.3d at 929 (“Full notice-and-comment procedures could have been run in the [seven months] time taken to issue the interim rules.”); *Nat’l Ass’n of Farmworkers Organizations v. Marshall*, 628 F.2d 604, 622 (D.C. Cir. 1980) (finding no good cause in part because agency had “nearly seven months” during which it could have provided notice and comment for a rule modification); *Louisiana v. Becerra*, 2022 WL 16571, at *13 (W.D. La. Jan. 1, 2022) (finding no good cause where agency defendants “could have completed notice and comment TWICE” during a three-month period).

The Departments, moreover, fail to justify why they could not have provided notice and comment in the time they had—a full year. They claim that the Rule “work[s] in concert with” the July rule defining the QPA, and that the QPA needed to be defined before they could issue the Rule at issue here. Docket No. 104 at 14; 86 Fed. Reg. at 56,044. But the Departments nowhere explain why they could not have worked on both rules in tandem. Nor do they explain why they could not have issued

the substance of the Rule as a proposed rule instead of an interim final rule, provided notice and comment, and integrated feedback into the eventual final rule. *See U.S. Steel Corp.*, 595 F.2d at 214 (holding that the “same guidance that was accomplished by the [agency’s] procedures could have been accomplished by issuing a proposed [rule] . . . followed by final promulgation after notice and comment”).

Although the Departments maintain that providing notice and comment would not have allowed “sufficient time for regulated entities to implement the requirements [of the Rule],” they acknowledge that the effective date of the Act (January 1, 2022) “may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date.” 86 Fed. Reg. at 56,043–44. In any event, as the Fifth Circuit held in a similar context, “Congress could have expressly waived the APA procedural requirements . . . if it feared those requirements would produce significant harm or excessive delay.” *Johnson*, 632 F.3d at 928 (finding no good cause despite agency claims of public endangerment from delaying a sex offender registration regulation).

The Departments cite *Methodist Hospital*, a case finding good cause where the deadline was 135 days, and *Petry v. Block*, which involved a 60-day deadline. 38 F.3d at 1237; 737 F.2d 1193, 1200–02 (D.C. Cir. 1984). Neither is apposite here, where the Departments had a year before the Act became effective. The statute in *Methodist Hospital*, moreover, explicitly instructed the agency to issue an interim rule *without* notice and comment. 38 F.3d at 1237. The Departments also cite *American Transfer & Storage Co. v. ICC*, but that case too is inapposite. 719 F.2d 1283 (5th Cir. 1983).

In *American Transfer*, the Fifth Circuit found good cause because the agency was: (1) responsible for handling a high volume of applications; (2) “bogged down with an intolerable backlog”; (3) required by a new statute to completely replace its application process while having “no transition period”; and (4) expected to receive “more, not [fewer] applications” because of the statute. *Id.* at 1293–94. The Departments have presented no such evidence here.

The Departments claim that insurers, providers, and arbitrators needed sufficient “lead time” to avoid “uncertainty” and to adapt to the Rule’s guidance. Docket No. 62 at 32. But the “desire to provide immediate guidance, without more, does not suffice for good cause.” *Johnson*, 632 F.3d at 929. Moreover, “the goal of reducing uncertainty is undercut by the request for post-promulgation comments, which could have resulted in a [final] rule change.” *Id.* (cleaned up). And here, the Departments have “invited comments from the public” and will “consider these comments prior to the promulgation of final rules.” Docket No. 62 at 36 (citing 86 Fed. Reg. at 55,980). As in *Johnson*, the Court finds that engaging in this post-promulgation process undercuts the claimed need for certainty since there is a chance the Rule could still change.

Further, even if the Departments had good cause “to allow time for arbitrators to ‘acquire the necessary expertise and evidence of qualification to apply for certification,’” as the Departments claim, Docket No. 62 at 33, good cause does not exist to rush the provisions of the Rule at issue here. *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985) (holding that the court “will not allow a regulation

otherwise subject to section 553 procedures to piggyback” on properly-issued regulations).

Accordingly, the Court finds that the Departments lacked good cause to bypass notice and comment.

C.

When an agency lacks good cause to depart from APA requirements, courts must consider whether that error was harmless, a burden borne by the party asserting error. *Johnson*, 632 F.3d at 930; *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). “[T]he touchstone is ‘whether it is clear that the lack of notice and comment did not prejudice the petitioner.’” *City of Arlington*, 668 F.3d at 244 (citing *Johnson*, 632 F.3d at 931). Plaintiffs argue that the error was not harmless because “it deprived [them] of notice of and an opportunity to comment on both the Departments’ proposed rules and the asserted justifications for them.” Docket No. 98 at 26. The Court agrees.

Courts should “rare[ly]” find harmless error for failure to provide notice and comment because the “vast majority of agency rulemaking, which produces nuanced and detailed regulations[,] greatly benefit[s] from expert and regulated entity participation.” *Johnson*, 632 F.3d at 932. Even when the public is generally aware that an agency is considering an issue, “[t]he agency’s rationale must be made clear and subjected to public comment.” *Tex. Ass’n of Mfrs. v. U.S. Consumer Prod. Safety Comm’n*, 989 F.3d 368, 382 (5th Cir. 2021) (remanding because agency failed to provide notice and comment regarding its changed justification for a rule).

Here, if the Departments had provided notice and comment, Plaintiffs could have submitted the specific reasons and authorities for why they believed the Rule is inconsistent with the Act, how the Rule would impact them as providers, and how the Rule could be drafted to track the statutory text more closely. On the record before the Court, the Departments cannot demonstrate that they considered and fully addressed these issues. *Cf. City of Arlington*, 668 F.3d at 245 (failure to provide notice and comment was harmless because court was “not aware of a single argument the [plaintiffs] now present to this court that was not considered by the FCC in the agency proceedings below”); *Johnson*, 632 F.3d at 932 (failure to provide notice and comment was harmless in part because agency “nevertheless considered the arguments Johnson has asserted and responded to those arguments during the interim rulemaking”).

The Departments argue that “there is no indication that [their] conclusions would have been materially different had they first engaged in notice and comment.” Docket No. 62 at 36. But agencies cannot bypass notice and comment by claiming after the fact that they would not have changed anything. *See Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir. 1992) (“[I]f the harmless error rule were to look solely to result, an agency could always claim that it would have adopted the same rule even if it had complied with the APA procedures. . . . [H]armless error analysis . . . must therefore focus on the process as well as the result.”); *see also Paulsen v. Daniels*, 413 F.3d 999, 1006 (9th Cir. 2005) (“[A]n agency could always claim that it would have adopted the same rule even if it had complied with the APA’s

procedures.”); *United States v. Reynolds*, 710 F.3d 498, 517 (3d Cir. 2013) (same). The Rule here, moreover, does not involve a simple binary decision, but rather establishes an exhaustive and complex arbitration process that would have almost certainly changed—even if in small part—had the Departments properly considered Plaintiffs’ objections. *See Johnson*, 623 F.3d at 933 (holding that “harmless error is more fitting” for failure to provide notice and comment regarding a “binary decision” than for “nuanced and detailed regulations”).

The Departments also argue that Plaintiff TMA “addressed the arbitration standards in a comment it submitted in response to the first interim final rule, which raised the same legal argument that it now relies on.” Docket No. 62 at 36. But the first interim final rule established how to determine the QPA, not the arbitration process at issue here. TMA thus had no notice of the Rule or its establishment of a QPA presumption when it submitted that comment—and did not and could not have provided the extensive arguments and authorities raised here. *See Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002) (holding that the notice-and-comment requirement “would be eviscerated” if agency could bypass it without good cause simply because plaintiffs “cannot identify any additional arguments they would have made in a notice-and-comment procedure that they did not make” informally).

Finally, the Departments claim that there is no harm because they “will soon issue a final rule” incorporating Plaintiffs’ comments. Docket No. 104 at 16. The Fifth Circuit, however, has twice rejected the argument that a “post-promulgation

comment period cure[s] whatever procedural error may have been committed,” concluding that such a position would “allow any agency to dispense with pre-promulgation notice and comment whenever it so desired.” *City of Waco v. EPA*, 620 F.2d at 86; *see U.S. Steel Corp.*, 598 F.2d at 213–215; *see also Texas v. Lyng*, 868 F.2d 795, 799 (5th Cir. 1989) (holding that *U.S. Steel Corp.* “preclude[s] a finding of harmless error where the agency fails to allow any public comment before reaching a decision, thus circumventing the entire purposes of the APA notice and comment provisions”).

Accordingly, the Court concludes it is not “clear that the lack of notice and comment did not prejudice [Plaintiffs].” *Johnson*, 632 F.3d at 931.

* * *

The Departments’ failure to comply with the notice-and-comment requirement provides a second and independent basis to hold unlawful and set aside the Rule under the APA.

V.

Having determined that the Rule violates the APA, the Court considers the proper remedy.

Plaintiffs ask the Court to vacate five portions of the Rule. Docket No. 1 at 32–33; Docket No. 25-3 at 1–2. Plaintiffs argue that vacatur, rather than remand without vacatur, is the appropriate remedy because the errors in the Rule are serious and because vacatur will not cause significant disruption. Docket No. 98 at 29–30.

The Departments argue that remand without vacatur is the appropriate remedy because they will be able to adequately address any error identified by the Court. Docket No. 104 at 16–17. The Departments further request that any vacatur be limited to the identified Plaintiffs with standing in the case. *Id.* at 17.

The Court finds that vacatur of the challenged portions of the Rule is the appropriate remedy here. “[B]y default, remand *with* vacatur is the appropriate remedy” in a case challenging agency action under the APA. *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021) (citing *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019)). This accords with the APA itself, which requires a reviewing court to “hold unlawful and set aside agency action” found to be unlawful. 5 U.S.C. § 706(2). Courts consider two factors to determine whether vacatur is appropriate: “(1) the seriousness of the deficiencies of the action, that is, how likely it is the agency will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur.” *Texas*, 20 F.4th at 1000 (quoting *United Steel*, 925 F.3d at 1287).

Here, the seriousness of the deficiency weighs heavily in favor of vacatur. As explained above, the Rule conflicts with the unambiguous terms of the Act in several key respects. This means that there is nothing the Departments can do on remand to rehabilitate or justify the challenged portions of the Rule as written. *Sw. Elec. Power Co.*, 920 F.3d at 1022 (vacating and remanding part of final rule that was contrary to statute).

Also, vacatur will not be unduly disruptive here. The Departments argue that insurers “have relied on the interim final rule” and “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.” Docket No. 104 at 17. But the Departments do not explain why vacating only the challenged portions of the Rule will upend the insurers’ plans. The remaining provisions of the Rule and the Act itself provide a sufficient framework for providers and insurers to resolve payment disputes, including specifying what criteria an arbitrator “shall” consider and those the arbitrator “shall not.” 42 U.S.C. § 300gg-111(c)(5)(C), (D). As Plaintiffs assert, “the only consequence of vacatur will be that [arbitrators] will decide cases under the statute as written without having their hands tied by the Departments’ QPA presumption.” Docket No. 98 at 30.

The Departments also request that any vacatur apply only to the named Plaintiffs in this case. But “[w]hen a court holds unlawful and sets aside agency rules that are ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,’ ‘the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.’” *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 944–45 (N.D. Tex. 2019) (quoting *Nat’l Mining Ass’n v. U.S. Army Corps of Eng’rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)) (cleaned up); see also *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 913 (1990) (Blackmun, J. dissenting) (“In some cases the ‘agency action’ will consist of a rule of broad applicability; and if the plaintiff prevails,

the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual.”).

The Court therefore finds that vacatur and remand is the proper remedy here.

VI.

In sum, the Court holds that (1) Plaintiffs have standing to challenge the Departments' September 2021 interim final rule implementing the No Surprises Act, (2) the Rule conflicts with the unambiguous terms of the Act, (3) the Departments improperly bypassed notice and comment in implementing the challenged portions of the Rule, and (4) vacatur and remand is the proper remedy.

Accordingly, the Court **GRANTS** Plaintiffs' motion for summary judgment (Docket No. 25), **DENIES** Defendants' cross-motion for summary judgment (Docket No. 62), and **ORDERS** that the following provisions of the Rule are **VACATED**:

- (1) 45 C.F.R. § 149.510(a)(2)(viii); the second sentence of 45 C.F.R. § 149.510(c)(4)(ii)(A); the final sentence of 45 C.F.R. § 149.510(c)(4)(iii)(C); 45 C.F.R. § 149.510(c)(4)(iv); and 45 C.F.R. § 149.510(c)(4)(vi)(B);
- (2) 26 C.F.R. § 54.9816-8T(a)(2)(viii); the second sentence of 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A); the final sentence of 26 C.F.R. § 54.9816-8T(c)(4)(iii)(C); 26 C.F.R. § 54.9816-8T(c)(4)(iv); and 26 C.F.R. § 54.9816-8T(c)(4)(vi)(B); and
- (3) 29 C.F.R. § 2590.716-8(a)(2)(viii); the second sentence of 29 C.F.R. § 2590.716-8(c)(4)(ii)(A); the final sentence of 29 C.F.R. § 2590.716-

