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. 6:23-cv-00059-JDK

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

The No Surprises Act (the "Act") created an independent dispute resolution process ("IDR process") to resolve payment disputes between out-of-network health care providers and facilities and group health plans and health insurance issuers, thus taking patients out of the middle of out-of-network billing disputes. Soon after the IDR process got off the ground in April 2022, however, the volume of disputes swelled beyond anything the Departments had anticipated. In the first nine months of its existence, the IDR program received over 164,000 disputes, a massive increase over the 22,000 disputes the Departments expected would be initiated annually.[1] As the volume of disputes grew, so did the backlog of disputes awaiting resolution, as overworked IDR entities (private arbitrators certified to participate in the IDR program) could not keep up with the ever-growing caseload. To make matters worse, the IDR entities were discovering, after time-consuming outreach and research, that many of those disputes were not even eligible for the Federal IDR process in the first place. And when a dispute is not eligible for the Federal IDR process, the IDR entity receives no compensation for the time-consuming and painstaking process of making that eligibility determination. That is because the fee that compensates IDR entities is submitted when parties submit their offers of payment, and ultimately paid by the prevailing party, which does not happen if a dispute is determined to be ineligible for the IDR process.

The Act tasks the Defendants here—the Departments of Health and Human Services, Labor, and the Treasury—with carrying out the IDR process, and it requires them to charge participants administrative fees sufficient to cover the estimated annual costs of administering the program. Faced with the daunting task of ensuring that the IDR process operates effectively, the Departments had to find a way to fix the untenable status quo. They decided to devote more resources to the IDR process, to assist IDR entities with eligibility determinations and to reduce the backlog of pending disputes,

[1] The Departments initially expected "17,000 disputes would be submitted in the IDR process each year," *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980, 56,056 (Oct. 7, 2021), and "4,899 air ambulance service claims submitted to the Federal IDR process each year," *id.* at 56,069-70, for a total of nearly 22,000 disputes. The Departments' opening brief inadvertently omitted estimated air ambulance disputes from the total figure. *See* Defs.' Cross-Mot. for Summ. J. and Mem. in Opp'n to Pls.' Mot. for Summ. J. 7, ECF No. 41 ("Defs.' Br.").

thus ensuring that providers get paid for their services sooner. As a result, the Departments increased the administrative fee to comply with the statutory mandate that the amount of fees be equal to the Departments' estimated expenditures. In December 2022, the Departments issued guidance setting the administrative fee at $350 for 2023.

Plaintiffs ignore this critical context. They fault the Departments for increasing the administrative fee without going through notice and comment and argue that the fee amount itself is arbitrary and capricious. But not only was the December 2022 guidance setting the administrative fee reasonable and reasonably explained, but it was entirely consistent with both the process announced in the Departments' own regulations and the Administrative Procedure Act ("APA"). The December 2022 Fee Guidance was an interpretive rule, and thus not required to go through notice and comment. And at any rate, the Departments had good cause for forgoing notice and comment given the time-sensitive nature of the growing problem and the need to update the fee annually based on actual costs. If there was any error in bypassing notice and comment, it was harmless.

Plaintiffs also challenge the "batching" regulation issued in September 2021 that determines which claims may be combined for resolution in a single IDR proceeding. This regulation is part of the same set of regulations that some of these Plaintiffs challenged a year and a half ago, and they are precluded from now raising additional claims that they could have, but chose not to, raise in that earlier litigation. In any event, Plaintiffs' assertion that the batching regulation is not adequately explained is baseless. The Departments explained that they designed the rule to permit combining claims involving the same medical procedures because doing so would be efficient and reduce redundancies, but not to permit combining multiple unrelated claims because doing so would render IDR proceedings unduly complex. And, as a rule of agency procedure, the batching regulation was not required to go through notice and comment, nor would that process have been practicable given the tight Congressional deadlines. Any procedural error was likewise harmless.

Plaintiffs challenge reasonable agency actions designed to ensure that payers and providers, like Plaintiffs, have available a functioning, efficient process for resolving payment disputes. Vacatur would be highly disruptive, as it would deprive the Departments of the resources needed to alleviate

the backlog of disputes and ensure the IDR process operates efficiently, and it could lead to chaos in the IDR process as providers may seek to batch a myriad of unrelated items and services, adding even more delays. If Plaintiffs succeed in this action, they will only make it more difficult for themselves to obtain compensation for their services in a timely manner.

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

ARGUMENT

I. The *TMA I* Plaintiffs' Claims Challenging The September 2021 IFR Are Barred By Claim Preclusion.

Claim preclusion bars the *TMA I* Plaintiffs' claims here—and Plaintiffs half-hearted explanations cannot save them. This is the fourth lawsuit that the Texas Medical Association and Dr. Adam Corley have brought challenging the Act's implementing regulations. *See Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* ("*TMA I*"), 587 F. Supp. 3d 528 (E.D. Tex. 2022); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* ("*TMA II*"), No. 6:22-cv-372, 2023 WL 1781801 (E.D. Tex. Feb. 6, 2023); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* ("*TMA III*"), No. 6:22-cv-450-JDK (E.D. Tex. Nov. 30, 2022). And this is the second lawsuit challenging the specific regulations, issued in September 2021, setting forth IDR procedures. *TMA I*, 587 F. Supp. 3d at 536. Plaintiffs do not dispute, as they must, that the Texas Medical Association and Dr. Adam Corley are the same exact parties as in the previous lawsuits, nor do they dispute that the previous litigation ended with a final judgment on the merits rendered by a court of competent jurisdiction. *See* Pls.' Opp'n to Defs.' Mot. for Summ. J. and Reply in Supp. of Summ. J. 2, ECF No. 44 ("Pls.' Reply Br."). Instead, they argue that because this lawsuit involves a different provision of the regulations setting forth the IDR process's procedures, this case involves different claims, and therefore should not be precluded.[2]

Parties simply cannot relitigate "claims that . . . could have been raised in a prior action." *Davis v. Dall. Area Rapid Transit*, 383 F.3d 209, 312-13 (5th Cir. 2004). Here, Plaintiffs certainly could have,

[2] Although Plaintiffs have joined additional parties to each one of their successive lawsuits, perhaps in an attempt to prevent the entire lawsuit from being dismissed on claim preclusion grounds, claim preclusion principles at a minimum bar the two plaintiffs to the original *TMA I* lawsuit from obtaining relief here.

but chose not to, litigate the same challenges to the September 2021 interim final rules ("September 2021 IFR") they now bring. Plaintiffs argue that the claims at issue in this case and the claims at issue in previous litigation "have nothing in common." Pls.' Reply Br. 2. But the "operative facts" reveal that the claims raised in *TMA I* and the claims challenging the regulations here both involve the procedures for the IDR process established in the September 2021 IFR and both arise out of the same transaction or connected transactions. The facts giving rise to both lawsuits "are related in time, space, origin, or motivation, [and they] form a convenient trial unit." *Davis*, 383 F.3d at 313 (quoting *Petro-Hunt LLC v. United States*, 365 F.3d 385, 395-96 (5th Cir. 2004)).

Plaintiffs argue that applying claim preclusion would encourage a "kitchen-sink approach" to litigation. Pls.' Reply Br. 3. Not so. To the contrary, it furthers the purposes of claim preclusion by "protect[ing] adversaries from the expense and vexation attending multiple lawsuits, conserv[ing] judicial resources, and foster[ing] reliance on judicial action by minimizing the possibility of inconsistent decisions." *Apotex, Inc. v. FDA*, 393 F.3d 210, 217 (D.C. Cir. 2004) (quoting *Montana v. United States*, 440 U.S. 147, 153-54 (1979)). Like the doctrine of claim splitting, which similarly bars Plaintiffs' claims, it furthers the reasonable goal of ensuring that "all claims arising out of a single wrong be presented in one action." *Ameritox, Ltd., v. Aegis Scis. Corp.*, No. 3:08-cv-1168-D, 2009 WL 305874, at *4 (N.D. Tex. Feb. 9, 2009) (citation omitted)). In short, it promotes efficient litigation. Plaintiffs could have asserted their challenges to the portions of the September 2021 IFR establishing batching rules and fee procedures for the IDR process when they brought their challenge to other portions of the September 2021 IFR relating to the IDR process. There must be some limits to Plaintiffs' iterative litigation strategy. Each re-reading of the same regulation cannot, upon further consideration, result in a new lawsuit when the alleged legal errors could have been equally discerned upon the first reading.

II. The December 2022 Fee Guidance Was Lawful.

The December 2022 Fee Guidance was lawfully issued. The IDR process has been inundated with claims, many of which are ineligible for the Federal IDR process, overwhelming arbitrators and

delaying payments to providers. The Departments acted reasonably to prioritize reducing the backlog and expediting payments to providers. However, doing so required the Departments to incur additional costs. Consistent with both their statutory and regulatory obligations, the Departments proceeded to adjust the administrative fee so that it would bring in enough funding to cover the Departments' estimated expenses in administering the IDR program. The administrative fee was set via guidance in a manner consistent with both prior practice, which Plaintiffs never previously challenged, and the Departments' regulations, which Plaintiffs do not substantively challenge.[3] At any rate, any procedural error was harmless.

A. Plaintiffs Have Failed To Show That The Fee Guidance Is Arbitrary And Capricious.

The administrative fee change was reasonable given the realities of administering the IDR program, and Plaintiffs' brief does not show otherwise. Plaintiffs point to different ideas the Departments could have considered or alternatives they could have weighed. To be sure, Plaintiffs are unhappy about the $300 fee increase. And, certainly, Plaintiffs have a different perspective on how to approach the IDR backlog problem. But whether an agency's decision was "ideal, or even necessary, is irrelevant to the question of whether it was arbitrary and capricious 'so long as the agency gave at least minimal consideration to the relevant facts as contained in the record.'" *City of Arlington v. FCC*, 668 F.3d 229, 261 (5th Cir. 2012) (quoting *Tex. Clinical Labs, Inc. v. Sebelius*, 612 F.3d 771, 775 (5th Cir. 2010)). Defendants more than met that standard here.

First, contrary to Plaintiffs' brief, the administrative record supports the fee change. The December 2022 Fee Guidance explains the reasoning for the change in plain terms. Specifically, it explains that the Departments previously lacked sufficient data to accurately aggregate costs and calculate the administrative fee. Once the Departments had the data necessary to estimate those costs,

[3] Although Plaintiffs contend that a single sentence in their summary judgment brief preserved a challenge to the substantive lawfulness of the regulation establishing the procedures for setting the administrative fee through guidance, any such claim should be considered waived or forfeited. *See Audler v. CBC Innovis Inc.*, 519 F.3d 239, 255 (5th Cir. 2008) ("A party 'waives an issue if he fails to adequately brief it.'") (citation omitted).

including the Departments' new expenditures to help IDR entities make eligibility determinations, they promptly updated the fee calculation. Ctrs. for Medicare & Medicaid Servs., Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee, at 1, 5 (Dec. 23, 2022) ("Dec. 2022 Fee Guidance") (AR 9888, AR 9892). The December 2022 Fee Guidance explained the Departments' reasoning in clear terms: "[T]here is a significant backlog of disputes pending eligibility determinations before certified IDR entities which has continued to grow since the publication of the prior 2023 guidance. To address this issue, the Departments have engaged a contractor and government staff to conduct pre-eligibility reviews, which include outreach and technical assistance in support of the certified IDR entities' eligibility determinations." *Id.* at 3. The Departments took on these additional costs to "allow certified IDR entities to focus on making payment determinations and expedite the resolution of initiated disputes." *Id.* at 5. This is consistent with the Act's requirement that the IDR process operate on a balanced budget with administrative fees sufficient to cover estimated costs. *See* 42 U.S.C. § 300gg-111(c)(8).

Plaintiffs claim that the Departments considered only the benefits of their decision, and not the disadvantages, contending that the Departments failed to consider the impact of the fee increase on providers. Pls.' Reply Br. 10. But, as explained earlier, *see* Defs.' Br. 15, the fee affects providers and payers equally, as both are required to pay the fee—a fact Plaintiffs' brief elides. Likewise, Plaintiffs make much of the fact that the Departments, in their view, did not sufficiently consider the "barrier" posed by the $350 fee. Pls.' Reply Br. 10. But again, that "barrier" is not exclusive to providers as both parties have to pay the fee. And, in any event, a higher fee might well make it more cost effective for a payer to accede to a provider's payment demands any time the claim is for less than $350—a point that Plaintiffs conspicuously ignore.[4]

The gravamen of Plaintiffs' argument is that the fee guidance was not sufficiently "reasoned."

[4] Plaintiffs also argue that the Departments "now concede they could have 'var[ied]' the fee 'based on the value of the dispute.'" Pls.' Reply Br. 11 (quoting Defs.' Br. 14). But that is a mischaracterization of Defendants' briefing, which simply addressed Plaintiffs' argument that the Departments were required to do so and explained why that was not the case. *See* Defs.' Br. 14.

Pls.' Reply Br. 9-10. For example, Plaintiffs contend that the Departments failed to adequately consider alternatives. *Id.* But the Departments did in fact consider alternatives to the fee increase, such as whether it is possible to change the process for collection and payment of the administrative fee. *See, e.g.*, AR 9927-33. Likewise, Plaintiffs complain that the Departments' explanation that enforcing current regulations is impossible is both inadequate and a post-hoc rationalization. Pls.' Reply Br. 12. But the difficulty of collecting fees on the timelines set by the regulation was specifically discussed in the Fee Guidance, at 5 & n.22, and administrative record (AR 9927-36), and the briefing in this litigation has merely elaborated on and further developed those points, *see Nat'l Elec. Mfrs. Ass'n v. Dep't of Energy*, 654 F.3d 496, 515 (4th Cir. 2011) (holding that counsel may make "more sophisticated legal arguments" to explain the agency's decision). And courts rarely second-guess an agency's enforcement decisions, determinations that "often involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). At bottom, while Plaintiffs point to various solutions they claim are "obvious" alternatives to a fee increase, Pls.' Reply Br. 11; *see also id. passim* (using the word "obvious" no fewer than eight times), they make no effort to show how those alternatives are realistic—a new agency rulemaking, for example, cannot be summoned instantaneously. *See 10 Ring Precision, Inc. v. Jones*, 722 F.3d 711, 724 (5th Cir. 2013) (explaining that agencies must consider only "significant and viable" alternatives).

Plaintiffs go on to argue that Congress's rejection of a minimum claim threshold showed it wanted to include low-value claims, not exclude them—but nothing in the regulations or fee guidance excludes low-value claims or otherwise prohibits parties from accessing the IDR process with low-value claims. *Cf.* Pls.' Reply Br. 12-13. Congress mandated only that the administrative fee for patient-provider dispute resolution be set "in such a manner as to not create a barrier to *an uninsured individual's* access to such process," 42 U.S.C. § 300gg-137(c) (emphasis added); it imposed no similar requirement to lower barriers to access for sophisticated business entities like providers and facilities. More broadly, Congress did not include any minimum threshold to enter the arbitration process yet required the payment of an administrative fee, necessarily understanding that there would be claims that cost more to arbitrate than they are worth, at least in monetary terms. A party may have other reasons to arbitrate

a claim even if its value is less than the fee: to obtain a favorable determination to use as a reference in future negotiations, for example. *See also* 42 U.SC. § 300gg-111(c)(5)(E)(ii) (mandating a 90-day waiting period before filing a sufficiently similar dispute). This is not unlike litigating a federal question case in federal court, which still requires set filing fees regardless of the underlying "value" of the claim. *See* Defs.' Br. 15. These sorts of economic judgments are inherent at the start of any sort of dispute resolution process. It is no different here. There is no statutory requirement that it be economically sensible for a party to arbitrate every disputed claim under the Act—but there is a Congressional mandate that the IDR process operate on a balanced budget, 42 U.S.C. § 300gg-111(c)(8), which the Departments properly effectuated through the guidance at issue here.

B. The December 2022 Fee Guidance Is An Interpretive Rule Not Subject To Notice And Comment.

Even if the December 2022 Fee Guidance amounts to a rule, not all rules must go through notice and comment. *Perez v. Mortg. Bankers' Ass'n*, 575 U.S. 92, 96 (2015). The December 2022 Fee Guidance does not create the obligation to pay an administrative fee, nor does it announce the process for setting the fee annually. Those requirements flow from the statute and from the regulation. Because it merely "explain[s] something the statute or regulation already required," *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014), the December 2022 Fee Guidance is an interpretive rule, and thus not subject to notice and comment. *See Flight Training Int'l, Inc. v. FAA*, 58 F.4th 234, 242 (5th Cir. 2023) ("rejecting the proposition that a rule cannot be interpretative if it . . . uses binding language").

Plaintiffs argue first that the December 2022 Fee Guidance cannot be an interpretive rule because it used the label "Guidance" and did not declare itself to be an "interpretive rule." Pls.' Reply Br. 3-4. But there is no such magic-words requirement, and courts have not hesitated to find that a document labeled "Guidance" can be an interpretive rule. *See, e.g., POET Biorefining, LLC v. EPA*, 970 F.3d 392, 407 (D.C. Cir. 2020) (holding that a document labeled "Guidance" was an interpretive rule). Indeed, the Departments' decision to label the document as "Guidance" demonstrates that they did not view it as a new legislative rule, and the agency's view on this point is a relevant factor. *Gen. Motors*

Corp. v. Ruckelshaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc).

The December 2022 Fee Guidance does not "create new law, rights or duties," but merely "reminds affected parties of existing duties." *Warshauer v. Solis*, 577 F.3d 1330, 1337 (11th Cir. 2009) (quoting *Gen. Motors Corp.*, 742 F.2d at 1565). It does not, as Plaintiffs suggest, obligate the parties to pay the administrative fee in the first place, nor does it establish the legally binding requirement for parties to pay a fee sufficient to cover the expenses of administering the IDR process. Pls.' Reply Br. 4. Those obligations flow from the statute, which requires the Departments to set an administrative fee sufficient to cover the estimated costs of the IDR program, 42 U.S.C. § 300gg-111(c)(8), and the regulation, which explains how the fee is paid and explains that the Departments will update the specific fee amount annually through guidance, 45 C.F.R. § 149.510(d)(2). The December 2022 Fee Guidance simply supplies the specific dollar amount, as dictated by the statute and the regulations. Because the December 2022 Fee Guidance "clarifies, rather than creates, law," it is an interpretive rule and is not subject to notice and comment. *Flight Training Int'l*, 58 F.4th at 240 (citation omitted). Absent the December 2022 Fee Guidance, providers would still be obligated to pay an administrative fee to access the IDR process, *cf.* Pls.' Reply Br. 4, the Guidance simply identifies the specific amount.

Plaintiffs also argue that the December 2022 Fee Guidance cannot be an interpretive rule because the Departments cannot point to a particular part of the statute that requires the annual fee be $350, as opposed to some other amount, and thus the specific amount of $350 cannot be an interpretation of the text of the statute. *Id.* at 5. But the interpretation need not be as literal as Plaintiffs suggest to qualify as an interpretive rule. In *Warshauer v. Solis*, for example, the Eleventh Circuit found a rule to be interpretive when the agency announced a $250 threshold for reporting gifts. 577 F.3d at 1340. The specific amount of $250 was listed nowhere in the statute, which only required reporting gifts above an "insubstantial" amount. *Id.* The rule imposed mandatory reporting duties for any gift above a $250 threshold. *Id.* Nevertheless, because the statute imposed a reporting requirement for gifts above an "insubstantial" amount generally, the court held that the rule was interpretive, because it informs the public about the Secretary's "current view" of the specific amount. *Id.* So too here, the December 2022 Fee Guidance clarifies the Departments' "current view" of the amount of

administrative fee required by the statute. *Id.*

Furthermore, the Departments explained in the preamble to the September 2021 IFR that they intended to evaluate the costs of administering the IDR process when determining the amount of administrative fee sufficient to cover those costs. And the preamble also explained that, as more accurate data about costs became available, the Departments would base their cost estimates, to the extent possible, on that actual cost data. *See* 86 Fed. Reg. at 56,001-03. The Departments therefore explained their methodology for how they would reach an administrative fee amount, and they followed that methodology in setting the December 2022 Fee Guidance. *See* Ctrs. for Medicare & Medicaid Servs., Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act, at 1 (Oct. 31, 2022) ("Oct. 2022 Fee Guidance") (AR 9869) (stating intention to update fee guidance when more data becomes available); Dec. 2022 Fee Guidance 5 (updating fee guidance in light of new aggregation of data); *see also City of Idaho Falls v. FERC*, 629 F.3d 222, 227 (D.C. Cir. 2011) (requiring notice and comment only when update to annual fee was done using a new methodology). Because the Departments followed the same procedures outlined in the September 2021 IFR, the December 2022 Fee Guidance was not required to go through notice and comment simply to update the amount of fee that resulted from following those procedures. *Id.*

C. Plaintiffs Fail To Show That The Departments Insufficiently Invoked The Good Cause Exception And That Rulemaking In Perpetuity Is Feasible.

Plaintiffs ignore what the plain text of the APA makes clear: that notice-and-comment rulemaking may be excused where "impracticable." 5 U.S.C. § 553(b)(3)(B). That is the case here.

First, Plaintiffs do not contest that the Departments invoked the good faith exception, but now argue that the Departments did not sufficiently explain their reasons. Pls.' Reply Br. 7. But the very Fourth Circuit case on which Plaintiffs base their argument makes clear that there is not even a "rigid requirement that an agency must explicitly invoke the good cause exception" so long as the agency record shows "the agency's *reliance* on the exception." *N.C. Growers' Ass'n, v. United Farm Workers,* 702 F.3d 755, 768 (4th Cir. 2012) (emphasis added). Here, there can be no doubt the agency

relied on the exception. The Departments clearly invoked the exception, *see* 86 Fed. Reg. at 56,004, and, as they explained in the December 2022 Fee Guidance, the Departments were updating the fee "due to supplemental data analysis," which they only obtained after October 2022, leaving them with only a matter of weeks to update the guidance for 2023. Dec. 2022 Fee Guidance 1.

Second, Plaintiffs' description of rulemaking in *perpetuity* as "a little extra work" is a considerable understatement. Pls.' Reply Br. 8. While they analogize this to annual Medicare rulemakings, *id.* at 7, those proceedings are conducted under a very different set of statutory and regulatory constraints, with a much more robust and established dataset to anticipate costs. Here, the Departments are charged with standing up and funding an entirely new program, with a specific statutory directive to maintain a balanced budget. The practical reality was that, by the time they received the data necessary to update the fee by the adequate amount, there would not have been sufficient time to engage in the notice and comment even if it had been required.

D. Plaintiffs Fail To Show That They Suffered Any Prejudice From The Issuance Of The Fee Guidance Without Notice And Comment

Even if notice and comment was required, Plaintiffs have failed to show that they were harmed by its absence. *City of Arlington*, 668 F.3d at 243 (holding that parties must show prejudice from the alleged error). Plaintiffs had an opportunity to comment on the Department's regulation announcing its decision to set the administrative fee through annual guidance, and they did not do so. And Plaintiffs do not meaningfully take issue with the previous guidance documents setting the annual fee at $50—indeed, they even ask for those previous guidance documents, issued in accordance with the procedures outlined in the regulation, just like the December 2022 Fee Guidance they challenge here, to be reinstated. Pls.' Reply Br. 20.

As the Departments explained, the statute requires the Departments to set the administrative fee at a level sufficient to cover the estimated costs of administering the IDR process. Even if Plaintiffs had submitted a comment requesting that the Departments set the administrative fee at an amount insufficient to cover the costs, the Departments could not have done so consistent with the statutory command. Therefore, Plaintiffs cannot show a "likelihood that the result would have been different."

City of Arlington, 668 F.3d at 244 (quoting *Shinseki v. Sanders*, 556 U.S. 396, 411-12 (2009)). Plaintiffs likewise assert that they were prejudiced because the Departments did not consider various alternative proposals for ensuring that administrative fees are sufficient to cover the estimated costs of administering the IDR process. But an agency "need not consider every alternative proposed," *10 Ring Precision*, 722 F.3d at 724 (citation omitted), and, at any rate, the administrative record demonstrates that the Departments did consider some of the unworkable "proposals" Plaintiffs put forward, such as attempts to increase fee collection by the IDR entities. *See* AR 9927-36. The Administrative Record and the December 2022 Fee Guidance both explain that the Departments considered the pros and cons of keeping the status quo and letting the backlog of unresolved claims grow or expending more resources to address the backlog in order to ensure providers get paid for their services sooner. Having considered both options, the Departments reasonably explained their decision. Thus, even if there were procedural error, Plaintiffs fail to show they suffered any prejudice.

III. The Batching Rule, And Its "Same Or Similar Items And Services" Criteria, Is Lawful.

The Departments also issued a reasonable regulation permitting certain claims to be submitted jointly for a single IDR determination, otherwise known as "batching." The rule permits batching only in certain circumstances to avoid unnecessarily complicated and inefficient payment determinations that combine multiple unrelated claims and require IDR entities to consider a multitude of factors. The Departments exercised their statutory authority to draft a regulation for the batching of claims, the regulation reflects a reasonable determination of what criteria should apply to batched claims, and the Departments provided a reasonable explanation for that decision. *See FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

A. The Batching Criteria Are Not Arbitrary Or Capricious.

The Act directs the Secretary to "specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination." 42 U.S.C. § 300gg-111(c)(3)(A). Acting pursuant to that statutory authority, the Departments reasonably explained the criteria under which multiple items or services may be "batched" into a single IDR

dispute in the September 2021 IFR. *See* 86 Fed. Reg. at 55,994. The IFR provides that batched items and services can be combined when they are billed by the same provider or group of providers, facility, or provider of air ambulance services; the payment would be made by the same plan or issuer; the items are the same items and services, meaning each is billed under the same or similar service code; and the items were furnished within a 30-day period. 45 C.F.R. § 149.510(c)(3)(i)(A)-(D).

First, Plaintiffs assert that this regulation is invalid because the Departments did not define every term in the statute. Pls.' Reply Br. 16. But that argument holds agencies to the wrong standard; the Departments were not required to define every term in the statute in issuing the regulations, and their not doing so does not render the batching regulation arbitrary or capricious. *See e.g., Nat'l R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407, 420 (1992) (rejecting a similar notion, deferring to agency's interpretation even though the agency "did not in so many words articulate its interpretation of the word 'required'"); *see also Nat'l Elec. Mfrs. Ass'n*, 654 F.3d at 514 (upholding regulation even though agency "did not state its interpretation in exacting detail in the rulemaking").

The Departments explained they adopted these rules to "avoid combinations of unrelated claims, providers, facilities, providers of air ambulance services and plans and issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies in the Federal IDR process." 86 Fed. Reg. at 55,994. The preamble further explains the decision to limit batching to only the same or similar items and services, because, under that rule, batched items and services will "involve the same or similar medical procedure, [and] batching is likely to reduce redundant IDR proceedings as well as streamline the certified IDR entity's decision-making, as some of the considerations relate to factors not specific to the individual encounter." *Id.* For context, during the IDR process the IDR entity considers information relating to certain statutory factors, some of which, like the experience and training of the provider or the patient's acuity, may be unique to each individual encounter, while others, like the item or service at issue, the market share of the plan or issuer, or previous years' contracted rates, are consistent among multiple batched encounters. 42 U.S.C. § 300gg-111(c)(5)(C)(ii). For example, if a single radiology practice group employs 15 radiologists who performed 15 chest x-rays with the same service code on 15 different patients

covered by the same health insurance issuer within a 30-day period, under the current regulation all 15 of those chest x-rays could be batched together. *See* 45 C.F.R. § 149.510(c)(3)(i)(C). The IDR entity in that dispute would be required to consider information submitted by the disputing parties including, for example, the training and experience of each of the 15 physicians, the acuity of each of the 15 patients, and the different QPAs for the service code under each of the of the issuer's various plans in the applicable insurance markets that cover those patients. 42 U.S.C. § 300gg-111(c)(5)(C)(ii). Therefore, contrary to Plaintiffs' feigned confusion at how IDR proceedings could possibly become complex, Pls.' Reply Br. 19, even with a batching rule that limits batching to claims billed under the same service code, IDR entities must still consider vast amounts of information, including some pieces of information that are necessarily unique to each individual claim. If multiple unrelated claims involving disparate and wide-ranging medical procedures could be batched together, the number of factors that an IDR entity would have to consider would grow exponentially, leading to "unnecessarily complicate[d]" and unmanageable IDR proceedings. 86 Fed. Reg. at 55,994. The Departments' explanation for the batching rule therefore reasonably supports their decision to limit batching to claims involving the same or similar item or service.

Plaintiffs' suggestion that this explanation leaves this Court guessing at the Departments' rationale, Pls.' Reply Br. 17, is not only belied by the clear explanation in the preamble to the September 2021 IFR, but also misapplies the arbitrary and capricious standard. An agency's explanation need not be encyclopedically thorough, and courts should uphold a "decision [of] less than ideal clarity . . . if the agency's path may reasonably be discerned," *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 497 (2004) (citation omitted)—a test that is readily satisfied here.

Plaintiffs also argue that the Departments' decision to use language in the batching regulation that appears elsewhere in the regulations is "misdirection." Pls.' Reply Br. 17. But it is hardly arbitrary or capricious to give a single phrase the same definition it carries elsewhere in the regulations. *See, e.g.*, *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1512 (2019) (explaining that a phrase should generally have a fixed meaning). And there are benefits to using standard, defined terms throughout the regulation. Parties to the IDR process submit offers of payment for each "item or

service" and the IDR entity considers the QPA for each "item or service." 42 U.S.C. § 300gg-111(c)(5)(B)(i)(I), (C)(i)(I). Limiting batching to claims involving the same or similar item or service is consistent with this statutory and regulatory structure, and not arbitrary or capricious.[5]

Finally, Plaintiffs' assertion that the batching rule restricts providers' *ability* to pursue IDR for low-value claims is inaccurate. Pls. Reply Br. 17-18. As discussed above, providers such as Plaintiffs have the option to pursue arbitration for claims worth as little as $1 and the batching regulation does not prohibit providers from initiating the IDR process for low-value claims.

B. The Batching Rule Is A Rule of Agency Procedure Not Required To Go Through Notice And Comment.

The batching rule was not required to go through notice and comment because it is a rule of agency procedure. *See U.S. Dep't of Lab. v. Kast Metals Corp.*, 744 F.2d 1145, 1152 (5th Cir. 1984). Plaintiffs argue that the batching regulation cannot be a procedural rule because the Departments did not expressly label it as such. Pls.' Reply Br. 13. But there is no such magic-words requirement that an agency "find" that a rule is procedural. *See* 5 U.S.C. § 553(b); *see also Kast Metals Corp.*, 744 F.2d at 1153 (explaining that "courts have been less concerned with the formal appellation of a rule" when deciding whether it is procedural). The batching regulation is a procedural rule because it embodies a judgment about "what mechanics and processes are most efficient," *Pub. Citizen v. Dep't of State*, 276 F.3d 634, 640 (D.C. Cir. 2002) (citation omitted), and it does not "modif[y] substantive rights and interests." *Kast Metals Corp.*, 744 F.2d at 1153. The batching regulation does not impact the substantive rights or interests of the parties—it impacts neither the right to compensation for out-of-network services or the amount of compensation for those services. And the preamble to the IFR explains that one of the goals of the batching regulation was to "reduce redundan[cies]" and "streamline" the process. 86 Fed. Reg. at 55,994; *see also* 42 U.S.C. § 300gg-111(c)(3)(A) (directing Secretary to specify criteria for

[5] In addition to the batching rule, providers also have the option of combining multiple claims under a bundled payment arrangement, which likewise gives providers an option of combining multiple services that a patient received during a single episode of care, rather than arbitrating each service separately. 86 Fed. Reg. at 55,994. Like the batching rule, the bundling rule is designed to "reduce redundant IDR proceedings" and "streamline the certified IDR entity's decision-making," while avoiding "combinations of unrelated claims" that could "unnecessarily complicate" the IDR process. *Id.*

batching "for purposes of encouraging the efficiency . . . of the IDR process").

Plaintiffs further argue that the batching regulation cannot be a rule of agency procedure because an independent arbitrator makes the ultimate payment determination during the IDR process. Pls.' Reply Br. 14. But the overall IDR process is established and carried out by the Departments and the Departments administer the procedures for presenting disputes to an IDR entity. *See* 42 U.S.C. § 300gg-111(c)(8)(B) (describing the Departments' role as "carrying out the IDR process"). The batching regulations relate to how disputes are organized and presented to the IDR entities—a process that involves initiating a dispute through the Departments' IDR portal and identifying the claims at issue and whether items or services are designated as batched items or services, 45 C.F.R. § 149.510(b)(2)(iii)(A), and that takes place before an IDR entity is even assigned to the dispute. 86 Fed. Reg. at 55,991. The process of initiating IDR disputes and organizing the claims at issue in the dispute is administered by the Departments and is an internal process designed for "improving the efficient and effective operations of [the] agency" in consolidating claims for resolution. *AFL-CIO v. Nat'l Lab. Rels. Bd.*, 57 F.4th 1023, 1034 (D.C. Cir. 2023) (citation omitted).

Plaintiff's cited cases only illustrate why the batching regulation is properly considered a rule of agency procedure. "[T]he critical feature of a rule that satisfies the so-called procedural exception is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." *AFL-CIO*, 57 F.4th at 1034 (quoting *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000)). In *AFL-CIO*, the court held that, while not all aspects of the challenged rules were properly considered rules of agency procedure, "some of the [challenged] provisions do regulate how the parties present disputes to the Board" and thus were properly considered procedural rules. 57 F.4th at 1034. Just like the procedural rules in *AFL-CIO*, the batching regulation "regulate[s] how the parties present disputes" in the IDR process but does not bear on the outcome of those disputes. *Id.*; *see also James V. Hurson Assocs., Inc.*, 229 F.3d at 281 ("[A]n otherwise-procedural rule does not become a substantive one, for notice-and-comment purposes, simply because it imposes a burden on regulated parties."); *Pub. Citizen*, 276 F.3d at 640 (holding that rules can be "procedural despite their sometimes harsh

effects").

C. Plaintiffs Fail To Show That The Departments Lacked Good Cause To Forgo Notice And Comment Given The Tight Deadlines And Need For Preparation For The New Legal Regime.

Even if the September 2021 IFR was subject to notice and comment, there was "good cause" to forgo it here. In the Act, Congress called for the Departments to draft a large volume of regulations, including the regulations needed to establish the entire process for resolving payment disputes for out-of-network claims—a process that had never before existed at the federal level and that the Departments would need to design and build based on the statutory scaffolding. In cases such as this one, where "congressional deadlines are very tight and . . . the statute is particularly complicated[,]" courts have found good cause to forgo notice and comment. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994); *see also United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009) (noting that "Congress can implicitly set aside the APA when it specifically requires rapid action"). And the Departments explained that notice and comment would be impracticable and contrary to the public interest. 86 Fed. Reg. at 56,043. The Departments recognized that providers, facilities, plans, issuers, and potential IDR entities would need months of lead time to prepare for the new legal regime. *Id.* at 56,043-44.

Plaintiffs respond that the Departments' explanation that industry stakeholders needed time to prepare for the new legal system is "meritless." Pls.' Reply Br. 15. But it was Plaintiffs themselves who went so far as to request an extension of the statutory deadlines in order to allow more time for them to prepare, noting that "there will be a very short turnaround for physicians and other providers to implement changes to their policies and procedures." Letter from E. Linda Villarreal, President, Tex. Med. Ass'n, et al., to Xavier Becerra, Secretary, U.S. Dep't of Health & Hum Servs., et al., at 21 (Sept. 7, 2021) (AR 2444). Plaintiffs appear to concede that parties needed time to prepare for at least some of the regulations adopted in the September 2021 IFR, but argue that the batching regulation is simply not among them. Pls.' Reply Br. 15-16. But, given that the Act's ban on balance billing went into effect January 1, 2022, the regulations relating to the IDR process were among the most important

regulations to prioritize because without a clear understanding of the policies and procedures for submitting claims to the IDR process, out-of-network providers faced the risk that their services could go uncompensated. 86 Fed. Reg. at 56,044. And potential parties weren't the only ones who needed time to familiarize themselves with the batching regulations—arbitrators themselves needed time to "acquire the necessary expertise and evidence of qualification" before they could begin adjudicating payment disputes. *Id.* It generally takes federal agencies more than a year to complete the notice and comment rulemaking process—the Departments did not have the luxury of time here, given the need for advance planning shared by payers, providers, and arbitrators alike. *See* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 N.W.U. L. Rev. 471, 513-19 (2011).

D. Plaintiffs Fail To Show That They Suffered Any Prejudice From The Lack Of Notice And Comment.

Any procedural error was in any event harmless. Plaintiffs assert that, if they had been given an opportunity, providers could have submitted comments about why they disagree with the batching regulation. Pls.' Reply Br. 16. But there is no need to hypothesize here. Plaintiffs had an opportunity to comment on the interim final rules, and they submitted comments on other aspects of the Departments' regulations, but they chose not to comment on the batching regulation. Having failed to take advantage of the opportunity to comment on the regulation, any claim that Plaintiffs were prejudiced rings hollow. *See Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999). Nonetheless, each of the relevant factors points towards a finding that any error was harmless here. *See City of Arlington*, 668 F.3d at 244 (listing four factors). The preamble to the September 2021 IFR demonstrates that the Departments considered the same concerns Plaintiffs now raise, and ultimately concluded that the batching permitted by this regulation balances the goals of "reduc[ing] redundant IDR proceedings" and "streamlin[ing] the certified IDR entity's decision-making," while avoiding the sorts of "combinations of unrelated claims" that could "unnecessarily complicate" the IDR process if even broader and more permissive batching rules, like those Plaintiffs prefer, were adopted. 86 Fed. Reg. at 55,994.

IV. Plaintiffs' Requested Remedies Are Unnecessary And Improper.

Plaintiffs do not challenge the Departments' statutory authority to undertake the challenged actions; they instead argue that the Departments failed to adequately explain their reasoning, failed to consider Plaintiffs' preferred alternatives, or did not follow proper procedures. In such cases, "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *see also Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1135 & n.4 (D.C. Cir. 1995) (remanding to the agency so that it may "provide the requisite opportunity for meaningful comment and explanation").

Vacatur would be highly disruptive here, as it would leave the Departments without adequate funding to effectively administer the IDR process and would exacerbate the backlog of pending disputes. And vacatur of the batching regulation would be very disruptive—without clear standards defining what items or services can be batched together, the system could devolve into chaos, with providers submitting dozens of unrelated claims, pertaining to a wide variety of medical services provided to many different patients, in IDR proceedings that quickly become unmanageable. Plaintiffs' proffered solution of allowing IDR entities to decide for themselves what claims meet the vague statutory criteria of being related to a similar condition is wholly unworkable. Different IDR entities may reach vastly different conclusions about what conditions are sufficiently similar, leading to the prospect that some disputes will be closed as ineligible and others allowed to proceed based on each IDR entity's idiosyncratic views. Congress plainly did not intend for such a result when it specifically directed the "Secretary" to "specify criteria" for batching. 42 U.S.C. § 300gg-111(c)(3)(A).

Plaintiffs are not entitled to monetary relief in the form of their requested "refund" of administrative fees either. Plaintiffs now assert, for the first time, that their refund should be in the amount of $300 out of every $350 paid, but any belated attempt to rectify the defects in their vague request that the Departments pointed out, Defs.' Br. 30, should be considered waived or forfeited. The refund request is substitute relief and is thus barred by sovereign immunity. *Dep't of the Army v. Blue Fox, Inc.*, 525 U.S. 255, 261-62 (1999). As the Departments explained, Defs.' Br. 29, the funds from the administrative fees already paid have likely been comingled with other funds and expended

in carrying out the IDR process. *Cf.* Pls.' Reply Br. 20. Finally, this Court should not order that the statutory deadlines be altered, as this is "an extraordinary remedy not to be imposed as a matter of course." *Nat. Res. Def. Council, Inc. v. EPA*, 22 F.3d 1125, 1135 (D.C. Cir. 1994). Unlike in the cases Plaintiffs cite, no providers have been prevented from accessing the IDR process due to the December 2022 Fee Guidance or the batching rule and providers have not been required to miss deadlines. *C.f., e.g., id.* (extending statutory deadline where agency's delay limited parties' time to act on agency guidance); Pls.' Reply 20 (citing cases). Here, by contrast, Plaintiffs seek an extension of statutory deadlines based on their suspicions that some providers may have chosen not to pursue IDR based on a qualitative evaluation of the financial pros and cons. And there is no way to discern which providers opted not to proceed to the IDR process over concerns with the administrative fee amount and which may have simply accepted what they thought was a reasonable offer of payment for their services.

CONCLUSION

For the foregoing reasons, the Defendants' 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 7th day of April, 2023, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ Anna Deffebach

ANNA DEFFEBACH