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

TEXAS MEDICAL ASSOCIATION, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civil Action No. 6:23-cv-00059-JDK

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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For the reasons stated below, Defendants respectfully move for summary judgment.

INTRODUCTION

In the No Surprises Act (the "NSA" or the "Act"), Congress sought to protect Americans from the practice of "surprise" medical billing, whereby health care providers and facilities balance bill patients for out-of-network items or services they may have never agreed to at sometimes shocking sticker prices. The Act spares patients from an estimated one million surprise medical bills every month. In this case, Plaintiffs principally take issue with an increase in the administrative fee for participating in the NSA's the independent dispute resolution ("IDR") process—a cornerstone of the Act that Congress intended to be self-sustaining through the collection of such fees.

The Act prohibits health care providers and facilities, in certain circumstances, from balance billing patients for out-of-network items or services. Instead of recovering reimbursement for those services directly from patients, if the provider and the health insurance plan or issuer cannot agree on a payment amount through negotiation, the Act creates an IDR process through which an arbitrator selects among offers of payment submitted by each party. Congress required this IDR process to be self-sustaining and ordered the Departments of Health and Human Services, Labor, and the Treasury (the "Departments")—Defendants in this suit—to assess an administrative fee for participating in the IDR process, estimated to be sufficient to cover projected costs. Congress also authorized the IDR entities (private arbitration businesses who have chosen to become certified to participate in the IDR program) to assess fees on the losing party to compensate them for their services.

The number of payment disputes submitted to the IDR process has far exceeded estimates: the Departments anticipated 17,000 claims annually, and instead received 164,000 claims in just nine months last year. Yet 70% of disputes closed during that period were closed because they were found ineligible for the IDR process to begin with. Eligibility determinations are a time-consuming and complex process. When a dispute is found ineligible, the IDR entity ultimately collects no fee—the time and effort it expends in making the eligibility determination goes entirely uncompensated. As the volume of disputes grew last year, so did the backlog of disputes awaiting resolution. That dynamic threatened the IDR program's viability: if serving as an IDR entity becomes financially unviable, IDR

entities may exit the program, and the backlog of claims awaiting resolution will grow even larger. This backlog also harms providers, whose compensation may be delayed while disputed claims languish.

To address these challenges, the Departments decided to devote additional resources to the IDR process in 2023, with a focus on assisting the IDR entities with eligibility disputes and alleviating the backlog of claims that delay payments to providers. These new efforts, however, imposed additional costs on the Departments, which Congress understood would be passed along to IDR participants as part of the administrative fee, such that the program would be self-sustaining. With new data regarding costs in hand, the Departments issued a guidance document increasing the administrative fee to $350 for 2023—a process consistent with their regulations, which explained the administrative fee would "established in guidance published annually." 45 C.F.R. § 149.510(d)(2)(ii). This figure reflects the Departments' calculation that this is the amount necessary to ensure that the "total amount of fees paid" for 2023 is "equal to the amount of expenditures estimated to be made by the Secretary for [2023] in carrying out the IDR process," 42 U.S.C. § 300gg-111(c)(8)(B), including the additional costs to assist with eligibility determinations and reduce the backlog.

Here, Plaintiffs principally argue the fee change should have undergone notice-and-comment rulemaking and that the $350 amount is arbitrary and capricious. They also challenge the "batching" regulations permitting multiple claims to be combined in a single IDR proceeding, contending the combined effect of the fee and those regulations make it cost prohibitive to arbitrate small-value claims. Each of these arguments should be rejected. The Departments were statutorily obligated to set a fee estimated to be sufficient to cover costs, the amount selected was reasonably explained and is amply justified by the record, and its announcement via guidance was not only entirely consistent with the Departments' regulations and the APA's procedural requirements, but the very same process that the Departments had used twice before to announce the administrative fee, with no complaint from Plaintiffs. The batching regulation likewise was reasonable and reasonably explained, and consistent with the APA's procedural requirements. At any rate, many of Plaintiffs' regulatory challenges are precluded. Having already brought a separate challenge to the September 2021 interim

final rules setting forth the IDR procedures, the Texas Medical Association and Dr. Adam Corley are barred from raising additional claims they could have, but did not, raise in that prior lawsuit.

STATEMENT OF ISSUES

1. Whether the December 2022 Fee Guidance was lawful, and not arbitrary and capricious or procedurally defective.
2. Whether the September 2021 Interim Final Rule provisions regarding "batching" of items and services was lawful, and not arbitrary and capricious or procedurally defective.

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. Congress Enacts the No Surprises Act to Protect Patients from Surprise Medical Bills.

Congress passed the No Surprises Act in December 2020 to combat the growing crisis of surprise medical billing. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182, 2758-2890 (2020). Most health plans and health insurance issuers "have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services." *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872, 36,874 (July 13, 2021) (AR 166). When an individual receives care from a provider or facility outside of their plan or issuer's network, however, the plan or issuer could decline to pay for the services, or could pay an amount lower than the provider's billed charges, leaving the patient responsible for the balance of the bill. *Id.* This practice, where the provider bills the patient for the difference between the charges the provider billed and the amount paid by the patient's health plan, is known as balance billing or (where the patient did not select the provider) surprise billing. This out-of-network billing phenomenon had been rapidly growing before Congress acted, indeed, "becoming more common and potentially more costly in both the emergency department and inpatient settings." Eric C. Sun et al., *Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals*, 179 JAMA INTERN. MED. 1543, 1544 (2019) (AR 4574) (finding mean potential liability to patients from balance bills increased from $804 to $2040 between 2010 and 2016).

The Act protects insured patients from unexpected liabilities arising from the most common forms of balance billing. If an insured patient receives emergency care, or if he or she receives scheduled care at certain types of in-network facilities, health care providers and facilities are generally prohibited (absent, in certain circumstances, the patient's consent) from balance billing the patient for any part of his or her care that is furnished by an out-of-network provider or facility. *See* 42 U.S.C. §§ 300gg-131, 300gg-132, 300gg-135.[1] In lieu of recovering payment from patients, the Act allows out-of-network providers and facilities to obtain payments from payers directly, taking patients out of the middle of payment disputes. The Act specifies that a plan or issuer will issue an initial payment, or notice of a denial of payment, to a provider or facility within 30 calendar days after the provider or facility submits a bill to the plan or issuer for an out-of-network service. *Id.* § 300gg-111(a)(1)(C)(iv), (b)(1)(C). If the provider or facility is not satisfied with this determination, either party may initiate a 30-day period of open negotiation over the claim. *Id.* § 300gg-111(c)(1)(A). If those negotiations do not resolve the dispute, the parties may then proceed to the IDR process. *Id.* § 300gg-111(c)(1)(B). In the IDR process, private arbitrators, certified by the Departments, resolve payment disputes. The Act employs a system of "baseball-style" arbitration under which both the provider or facility and the group health plan or issuer will each submit an offer for a proposed payment amount and the arbitrator will select one or the other offer as the amount of payment for the item or service that is in dispute, taking into account the considerations specified in the statute and additional information submitted by the parties. *Id.* § 300gg-111(c)(5)(A)(i), (c)(5)(B)(i)(II). The arbitrator's decision is binding on the parties and is not subject to judicial review except under certain circumstances described in the Federal Arbitration Act. *Id.* § 300gg-111(c)(5)(E).

The Act contemplates that multiple IDR items and services may, under certain circumstances, be considered jointly as part of a single determination. The statute authorizes the Secretary to "specify

[1] The Act makes parallel amendments to the Public Health Service Act ("PHSA"), the Employee Retirement Income Security Act ("ERISA"), and the Internal Revenue Code. In addition, the Act requires the Office of Personnel Management to ensure that that its contracts with Federal Employees Health Benefits Program carriers require compliance with applicable provisions in the same manner as group health plans and health insurance issuers. 5 U.S.C. § 8902(p). For ease of reference, except where otherwise noted, this brief cites only the Act's amendments to the PHSA.

criteria" under which multiple items and services may be considered jointly, but also requires that such items and services may be considered jointly only if certain conditions are met, including that the items or services were furnished by the same provider or facility, the payment is to be made to the same plan or issuer, the items and services are related to the treatment of a similar condition, and the items and services were furnished during a certain time period. *Id.* § 300gg-111(c)(3)(A).

For private arbitrators, choosing to participate in the IDR program is a business decision, and private arbitrators presumably will participate in the IDR program only if it proves to be an economically viable line of work. The Act therefore permits the arbitrators to charge fees for their services, ultimately paid by the party whose offer is not selected. *See id.* § 300gg-111(c)(5)(F).

Congress also recognized that running and overseeing the IDR process would impose costs on the Departments. However, Congress mandated that the IDR process be funded by the private parties who choose to utilize the IDR process and required parties to pay fees to the Departments sufficient to cover the costs of the program. Congress vested discretion with the Secretary to determine the time and manner of paying the fees but required that "the total amount of fees paid" for a year "be equal to the amount of expenditures estimated to be made by the Secretary for such year in carrying out the IDR process." *Id.* § 300gg-111(c)(8). In other words, Congress mandated that the IDR process operate on a balanced budget and be self-funded each year.

The Act went into effect on January 1, 2022, and the first IDR proceedings under the Act began three months later.

II. The Departments Issued Rules to Implement the Act's Framework.

Congress instructed the Departments to issue one set of rules no later than July 1, 2021, addressing the Act's patient protections, and to issue a second set of rules no later than December 27, 2021, addressing the procedures for resolving payment disputes. 42 U.S.C. § 300gg-111(a)(2)(B), (c)(2)(A). The Departments released the rules governing the IDR process in September 2021, allowing providers, facilities, payers, and arbitrators three months to familiarize themselves with the rules before the provisions of the Act went into effect. *Requirements Related to Surprise Billing; Part II*, 86 Fed.

Reg. 55,980 (Oct. 7, 2021) ("Sept. 2021 IFR"). The September 2021 IFR set forth procedures for arbitrators to be certified, and for providers, facilities, group health plans, and issuers to invoke the Act's IDR system, pay the statutorily required fees, and submit claims for payment determinations, among other things. *See id.* at 55,985.

As relevant here, the September IFR established the methodology for assessing both the IDR entity fees and the administrative fees. Under the IFR, each party shall pay the IDR entity fee to the IDR entity at the time the parties submit their offers. 45 C.F.R. § 149.510(d)(1)(i).[2] The IDR entity fee of the prevailing party is returned to the prevailing party within 30 business days of the IDR entity's determination. *Id.* § 149.510(d)(1)(ii). The Departments issue guidance annually setting the IDR entity fee range. 86 Fed. Reg. at 56,001.

The interim final rule further requires each party to submit the administrative fee to the IDR entity at the time the IDR entity is selected; that fee is then remitted to the Departments. 45 C.F.R. § 149.510(d)(2)(i). The regulation explains that the administrative fee will be established annually through guidance but reiterates the statutory command that the fee will be assessed "in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the [Departments]." *Id.* § 149.510(d)(2)(ii). The preamble to the IFR explained that, "[i]n setting the administrative fee, the Departments will consider the estimated costs for the Departments to administer the Federal IDR process for the following calendar year, including the staffing and contracting costs related to certifying and providing oversight to certified IDR entities; the costs of developing and publishing reports as required under [the Act]; the costs of collecting the administrative fees from certified IDR entities; and the cost of maintaining the Federal IDR portal." 86 Fed. Reg. at 56,001-02. The Departments also explained that, in "future years, such projected costs will be informed by the actual costs incurred by the Departments to date to administer the Federal IDR process." *Id.* at 56,002.

[2] The rules set forth parallel regulations implemented by the Departments. For ease of reference, except where otherwise noted, this brief cites only the HHS regulations.

The September 2021 IFR also established regulations governing the batching of multiple items or services into a single dispute to be resolved by an IDR entity. The regulations permit items or services to be submitted and considered jointly as part of one payment determination only if the items or services are billed by the same provider or facility, the payment would be made to the same plan or issuer, the disputed items or services are the same or similar items and services, and the disputed items or services were furnished during a 30-day period. 45 C.F.R. § 149.510(c)(3)(i)(A)-(D). The term "same or similar items or services" is used throughout the regulations, and items or services are the "same or similar" if billed under the same service code or a comparable code under a different procedural code system. *Id.* § 149.510(c)(3)(i)(C). The regulations also permit the resolution of "bundled" services (*i.e.*, multiple services an individual received during a single episode of care which are billed or paid as part of a bundled payment arrangement) into a single IDR proceeding. 86 Fed. Reg. at 55,994.

The Departments have accepted comments on the September interim final rules and are in the process of issuing a proposed rule that, when finalized, would supersede the IFR.

III. The IDR Process Experiences Unexpected Volume and Logistical Difficulties.

The Departments estimated 17,000 disputes would be submitted in the IDR process each year. 86 Fed. Reg. at 56,056. However, between April 15, 2022 and December 5, 2022 parties initiated over 164,000 disputes. 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 4 (Dec. 23, 2022) ("Dec. 2022 Fee Guidance") (AR 9888). This represents a *nearly ten-fold increase* over the number of disputes that the IDR entities were expecting to resolve. Indeed, during a one-week period in November, over 13,000 disputes were submitted—a number approaching the total number of disputes originally expected during an entire year. *Id.* at 5.[3]

Not only did the sheer volume of disputes initiated in the IDR process vastly exceed the Departments' expectations, but the reason for this volume was also largely unforeseen by the

[3] Additionally, the Departments anticipated certifying 50 IDR entities, 86 Fed. Reg. at 56,002 n.42, but currently only 13 IDR entities are certified, Ctrs. for Medicare & Medicaid Servs., *List of Certified Independent Dispute Resolution Entities*, https://www.cms.gov/nosurprises/help-resolve-payment-disputes/certified-idre-list.

Departments. The majority of disputes initiated in the IDR process appear to have been ineligible for that process. Over 69% of the disputes that were closed from April 15 to September 30, 2022 were closed because the dispute was found to be ineligible for the IDR process to begin with, *see* Ctrs. for Medicare & Medicaid Servs., Initial Report on the Independent Dispute Resolution (IDR) Process April 15-September 30, 2022, at 8 (AR 9997)—for example, because a state jurisdiction applied to the dispute, *see id.* at 10, because disputed claims were improperly batched together, *id.* at 11, or because the parties submitted incomplete information., *id.* at 9. When a dispute is found ineligible for the IDR process, the IDR entity does not accept or review offers of payment from the disputing parties. Therefore, because the IDR entity fee is submitted at the time parties submit their offers—and ineligible disputes do not result in submission of offers—IDR entities are required to perform vast amounts of work entirely uncompensated. The time-consuming and often fact-intensive process of making eligibility determinations in the massive number of IDR disputes has led to a considerable backlog, delaying payment determinations and the issuance of payments to providers and facilities.

In September 2021 and October 2022, the Departments issued guidance setting the administrative fee at $50 for 2022 and keeping it at $50 for 2023 due to the lack of reliable data to support a change in the fee. *See* Ctrs. for Medicare & Medicaid Servs., Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee (Sept. 30, 2021) ("Sept. 2021 Fee Guidance") (AR 9733); Ctrs. for Medicare & Medicaid Servs., Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act (Oct. 31, 2022) ("Oct. 2022 Fee Guidance") (AR 9869). However, in light of the backlog of disputes, the Departments decided to devote more resources to the IDR process in 2023 to conduct pre-eligibility reviews of disputes to assist IDR entities with eligibility determinations. Dec. 2022 Fee Guidance 3. The Departments also obtained newly available data on the costs of the IDR process. *Id.* And, because the statute requires that the administrative fee be sufficient to cover the Departments' costs in administering the IDR process, the Departments were required to raise the administrative fee to cover the increased costs. *Id.* The Departments conducted detailed analyses of the costs of administering the IDR process as well as the

estimated collection of fees that would be necessary to cover those costs. *See* Updated Admin Fee Spend Plan Cash Flow (Dec. 19, 2022) (AR 9895). After a careful calculation, the Departments issued an amended 2023 Fee Guidance in December of 2022, raising the administrative fee to $350 for calendar year 2023. *Id.*

In short, the Departments were stuck between a rock and a hard place: they could allow the backlog to continue to grow, which would not only further delay payments to providers but also require IDR entities to perform vast amounts of uncompensated work, potentially threatening the viability of the entire IDR program but keeping the costs and the administrative fee low. Or they could take steps to reduce the backlog and ensure that disputes were resolved sooner by assisting IDR entities with eligibility determinations but incurring additional costs and thus requiring an increase of the administrative fee. The Departments quite reasonably chose to prioritize reducing the backlog and ensuring providers get paid for their services, incurring costs that would necessarily increase the administrative fee. The fee increase went into effect on January 1, 2023.

IV. This Litigation.

In several prior cases, this Court has addressed the Act and reviewed the interim final rules issued by the Departments governing the arbitration process. Three of those cases, *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*"), 6:22-cv-372-JDK, 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), were brought by two of the Plaintiffs here, represented by the same counsel. *TMA I*, filed in October 2021, challenged portions of the same September 2021 IFR that Plaintiffs again challenge here. In that case, Plaintiffs chose not to challenge the batching regulations or the regulations setting the process for determining the administrative fee through annual guidance. Instead, Plaintiffs chose to challenge only the regulations providing guidance to arbitrators in making payment determinations. Plaintiffs have since filed two other lawsuits challenging various regulations

relating to the No Surprises Act, *TMA II* and *TMA III*, but neither of those cases took any issue with the batching or fee regulations either.

STANDARD OF REVIEW

When reviewing agency action under the Administrative Procedure Act ("APA"), a court may set aside agency action when it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)). This standard is "narrow and highly deferential." *Sierra Club v. U.S. Dep't of Interior*, 990 F.3d 909, 913 (5th Cir. 2021). "[T]he court is not to substitute its judgment for that of the agency." *Id.* (citation omitted). Rather, the court "consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation omitted). In short, the arbitrary-and-capricious standard simply "requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

ARGUMENT

I. Texas Medical Association and Dr. Adam Corley's Claims Challenging the September 2021 IFR Are Barred by the Doctrines of Claim Preclusion and Claim Splitting.

Nearly eighteen months after Plaintiffs Texas Medical Association and Dr. Adam Corley filed *TMA I*, they filed this case challenging provisions of the same September 2021 IFR promulgating regulations relating to the Act's IDR proceedings. This case raises many of the same core claims as *TMA I*, and the challenges to the September 2021 IFR that Plaintiffs raise here could have been raised in that action. And the same attorneys are litigating both cases. Having first challenged the regulations governing IDR proceedings enumerated in the September 2021 IFR, these Plaintiffs cannot now, upon reconsideration nearly a year-and-a-half later, decide they take issue with additional portions of that same IFR. This Court should find Plaintiffs' renewed challenge here barred by principles of claim preclusion and claim splitting, which exist precisely to avoid this sort of senseless duplication of effort.

Claim preclusion, also known as *res judicata*, bars parties from relitigating matters that they had a "full and fair opportunity to litigate" in a prior suit. *Apotex Inc. v. FDA*, 393 F.3d 210, 217 (D.C. Cir. 2004). The doctrine plays a "central role" in ensuring the "conclusive resolution of disputes," and

thereby "'protects . . . adversaries from the expense and vexation attending multiple lawsuits, conserves judicial resources, and fosters reliance on judicial action by minimizing the possibility of inconsistent decisions.'" *Id.* (citation omitted). It bars relitigation not only of matters determined in a previous litigation but also "forecloses relitigation of claims that . . . could have been raised in a prior action." *Davis v. Dallas Area Rapid Transit*, 383 F.3d 309, 312-13 (5th Cir. 2004). The doctrine applies if "(1) the parties are identical or in privity; (2) the judgment in the prior action was rendered by a court of competent jurisdiction; (3) the prior action was concluded by a final judgment on the merits; and (4) the same claim or cause of action was involved in both actions." *Snow Ingredients, Inc. v. SnoWizard, Inc.*, 833 F.3d 512, 521 (5th Cir. 2016) (citation omitted). Plaintiffs cannot dispute the first, second and third factors. As to the first factor, the Texas Medical Association and Dr. Adam Corley were parties in *TMA I*. As to the second and third factors, this Court, which issued the judgment in *TMA I*, is a court of competent jurisdiction, and the *TMA I* case was concluded by a final judgment on the merits.

As to the fourth factor, the Fifth Circuit uses the "transactional test" to determine whether two actions involve the same claim or cause of action. "Under the transactional test, a prior judgment's preclusive effect extends to all rights of the plaintiff 'with respect to all or any part of the transaction, or series of connected transactions, out of which the [original] action arose.'" *Davis*, 383 F.3d at 313 (5th Cir. 2004) (quoting *Petro-Hunt, LLC, v. United States*, 365 F.3d 385, 395-96 (5th Cir. 2004)). What grouping of facts constitutes a "transaction" or a "series of transactions" for claim preclusion purposes "must 'be determined pragmatically, giving weight to such considerations as whether the facts are related in time, space, origin, or motivation, [and] whether they form a convenient trial unit.'" *Davis*, 383 F.3d at 313 (quoting *Petro-Hunt*, 365 F.3d at 395-96).

Plaintiffs in *TMA I* challenged the regulations governing IDR proceedings under the September 2021 IFR. That case brought an APA claim arguing that the regulations issued in the September IFR (the very same September 2021 IFR as the batching regulations and the fee guidance regulations at issue in this case) exceeded the Secretary's authority under the No Surprises Act and were issued without following the APA's notice and comment procedures. Thus, "[b]oth suits revolve

around Plaintiff[s'] claim that the Government is not properly interpreting" the Act and that it failed to follow the notice and comment process. *Williams v. Whitaker*, No. 4:19-CV-85-ALM-CAN, 2019 WL 7859563, at *5 (E.D. Tex. Oct. 28, 2019), *R. & R. adopted*, 2019 WL 6768621 (E.D. Tex. Dec. 12, 2019) (finding claim preclusion where Plaintiff challenged multiple parts of regulations issued under related statutes). That these Plaintiffs challenge different provisions of the regulations in this case does not change this calculus. "Even assuming Plaintiff's argument is correct—that he is now arguing a different statutory section of the [Act] mandates his interpretation of the [requirements] under that Act—his current argument does not provide a basis for re-litigating Plaintiff's claim in this forum." *Id. Res judicata* prohibits a plaintiff from raising a claim in a later action that either "was or could have been raised in support of the claim asserted in the prior action." *Id.* Because TMA and Dr. Adam Corley already challenged the September 2021 IFR in a prior suit, and they chose not to advance the claims they raise here, the doctrine of claim preclusion bars any additional claims they have now decided to litigate.

These Plaintiffs' claims are also barred by the rule against claim splitting, which applies even where a case has not reached a final judgment and "prohibits a plaintiff from prosecuting its case piecemeal and requires that all claims arising out of a single wrong be presented in one action." *Ameritox, Ltd. v. Aegis Scis. Corp.*, CIV. A. 3:08-CV-1168-D, 2009 WL 305874, at *4 (N.D. Tex. Feb. 9, 2009) (quoting *Sensormatic Sec. Corp. v. Sensormatic Elecs. Corp.*, 273 F. App'x 256, 265 (4th Cir. 2008)); *see also Chinn v. Giant Food, Inc.*, 100 F. Supp. 2d 331, 333 (D. Md. 2000) ("The cases are legion that a party may not institute new actions duplicating existing litigation."). Their iterative and piecemeal litigation strategy attacking the implementation of the No Surprises Act therefore requires these Plaintiffs' claims regarding the September 2021 IFR to be dismissed.

II. The December 2022 Fee Guidance Was Lawful.

Plaintiffs do not dispute that the Departments' may assist IDR entities with eligibility determinations to help alleviate the backlog and speed payments to providers. Nor do they deny that the Departments may expend resources to do so, and that such costs are properly passed along to

IDR participants in the form of administrative fees, as Congress directed. The Departments' calculation of a $350 administrative fee for 2023 was both reasonable and reasonably explained, and its announcement via guidance was not only consistent with their regulations and the APA's procedural requirements, but fully in keeping with prior practice, to which Plaintiffs have never previously objected. The APA requires nothing more. *See Prometheus Radio Project*, 141 S. Ct. at 1158.

A. The $350 Administrative Fee Is Not Arbitrary or Capricious.

The administrative fee change was entirely reasonable in light of the realities of administering the costly and backlogged IDR program. To start, as explained above, Congress required the IDR program to be self-funded with administrative fees sufficient to cover its costs. *See* 42 U.S.C. § 300gg-111(c)(8). The December 2022 Fee Guidance 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, including new expenditures to help IDR make eligibility determinations, they promptly updated the fee calculation. Dec. 2022 Fee Guidance 1, 5. 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." Dec. 2022 Guidance 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. The choice to expend these resources to help eliminate the backlog and speed payments to providers was eminently reasonable and explained in plain terms, *see Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (explaining that a court

must "uphold [even] a decision of less than ideal clarity if the agency's path may be reasonably discerned"), and Plaintiffs cannot credibly maintain otherwise.

The amount of the administrative fee is likewise reasonable and fully supported by the administrative record. The Departments' calculations demonstrate that $350 (with rounding) is the estimated amount sufficient to balance the budget, Updated Admin Fee Spend Plan Cash Flow (Dec. 19, 2022) (AR 9885), as summarized in the December 2022 Guidance, *see* Dec. 2022 Guidance 4-6. Moreover, the Departments reasonably set the fee based on the costs to them rather than on the value of the dispute itself. Congress itself required the Departments to base the administrative fee on the estimated costs of carrying out the process, so it can hardly be arbitrary and capricious that the Departments did the just that. Because resolving a dispute generally costs the Departments the same amount regardless of whether it involves a small-dollar claim or a large-dollar claim, the Departments reasonably, and consistent with Congress's goals, set a standard fee for all disputes and did not vary it based on the value of the dispute.

Contrary to Plaintiff's suggestion, nothing in the statute guarantees access to the IDR process for every disputed claim, regardless of whether pursing arbitration would be an economically sensible choice. *See* Pls.' Mot. for Summ. J. & Mem. in Supp. Thereof ("Pls.' Br.") 23, ECF No. 18. After all, Congress prohibited parties from initiating the IDR process against the same opposing parties more than once in 90 days for the same item or service—wholly inconsistent with the guaranteed right to access the IDR process Plaintiffs envision. *See* 42 U.S.C. § 300gg-111(c)(5)(E)(ii). The Act is designed to encourage negotiated resolutions between the parties and to minimize the use of the IDR backstop.

Moreover, Congress deliberately passed a version of the Act that did not guarantee that pursuing arbitration would always be sensible for low-value claims. While Congress debated versions of the Act that would have set a minimum threshold amount for claims to be worth in order to access the IDR process, *see* H.R. 2328, 116th Cong. (2019); H.R. 5800, 116th Cong. (2020); *see also* H.R. Rep. No. 116-615, pt. 1, at 60 (2020) (AR 337), it ultimately rejected a minimum claim threshold. Because claims as low as $1 can be submitted, Congress presumably recognized that in many cases the administrative fee would be higher than the claim at issue. It was hardly arbitrary and capricious for

the Departments to proceed on the same understanding as Congress, that it may not always be sensible to arbitrate a claim in light of the associated costs. Indeed, in the judicial context, litigants often have to make similar economic judgments—namely, whether pursuing a low-value case is worthwhile in light of the filing fee and other costs. And here, because both parties are on the hook for the administrative fee, it is not only providers but also payers who would be expected to consider these costs when deciding whether to resort to arbitration. Consider, for example, a $150 bill from a provider that a payer thinks is worth only $50. While Plaintiffs complain that the $350 administrative fee makes it infeasible for them to pursue arbitration, they fail to grapple with the reality that payers would be subject to the same fee, which may give a payer an incentive to agree to a provider's request during open negotiation rather than arbitrate. In other words, whenever the amount in controversy is $350 or less, it may well be more economical for a payer to accede to a provider's payment demand than to arbitrate. *Cf.* Pls.' Br. 23. In a different provision of the Act, relating to dispute resolution between uninsured patients and providers, Congress mandated that the administrative fee 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), but issued no similar requirement here. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Bates v. United States*, 522 U.S. 23, 29-30 (1997) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

Furthermore, and contrary to Plaintiff's suggestion, Pls.' Br. 22-23, the Departments did not fail to consider an important aspect of the problem, namely that the fee increase would do more harm than good, but simply concluded that raising the fees was necessary in light of the high volume of disputes. Dec. 2022 Fee Guidance 4-5.

Last, it is not arbitrary or capricious to permit IDR entities to collect both the administrative fee, which is remitted to the Departments, and the IDR entity fee, which compensates them for their own work, at the same time. *Cf.* Pls.' Br. 24-25. As the December 2022 Fee Guidance explains, IDR entities invoice parties for the administrative fee at the time the IDR entity is selected, but often do not collect that fee until the time of offer submission, when they also collect the IDR entity fee.

Dec. 2022 Fee Guidance 5 n.22. This is consistent with the Departments' IDR Guidance for Disputing Parties, explaining that IDR entities have "discretion on when to collect the administrative fee (as long as it is collected by the time the offers are submitted, which is when the certified IDR entity fee must be paid)." Federal Independent Dispute Resolution (IDR) Process Guidance for Disputing Parties (Oct. 7, 2022) (AR 9788). The Departments extended this discretion to IDR entities in view of the immense burdens those entities are operating under, based in part on the understanding that the payment processing systems used by IDR entities are currently set up to accept payment of the two fees as a single submission, and that the system changes that may be needed to separate those two submissions would be difficult and time-consuming to implement. *Cf. Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985) (explaining that an "agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities"). IDR entities are already over-worked and underfunded, and it was not unreasonable for the Departments to avoid forcing them to expend even greater resources to collect administrative fees at an earlier time. *See Mobil Oil Exploration & Producing Se., Inc. v. United Distrib. Cos.*, 498 U.S. 211, 230-31 (1991) (explaining that an "agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities").

B. The December 2022 Fee Guidance Was Procedurally Proper.

Plaintiffs' contention that the December 2022 Fee Guidance was procedurally defective is equally mistaken. The administrative fee was set via guidance in a manner consistent with prior practice, which Plaintiffs have never previously questioned, and precisely as set forth in the Departments' regulations, 45 C.F.R. § 149.510(d)(2)(ii) (administrative fee will be "established in guidance published annually"), which Plaintiffs do not substantively challenge. Nothing in the APA required the Departments to undertake notice-and-comment rulemaking to adjust that fee.

1. The Fee Guidance Is an Interpretive Rule Exempt from Notice and Comment.

Even assuming that the December 2022 Fee Guidance amounts to a rule, "[n]ot all 'rules' must be issued through the notice-and-comment process." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92,

96 (2015). The Guidance here is an interpretive rule exempt from the APA's notice and comment procedures. *See* 5 U.S.C. § 553(b)(A).

The D.C. Circuit has set out general principles for determining whether a rule is interpretive, which other circuits generally find instructive. *See Warshauer v. Solis*, 577 F.3d 1330, 1337 (11th Cir. 2009) (relying on *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc)). First, although not dispositive, the agency's characterization of the rule is relevant to the determination. *Warshauer*, 577 F.3d at 1337. Second, "[a]n interpretative rule simply states what the administrative agency thinks the statute means, and only 'reminds affected parties of existing duties.' On the other hand, if by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule." *Id.*

Here, those principles demonstrate that the December 2022 Fee Guidance is interpretive. As an initial matter, the Departments themselves regarded it as interpretive, labeling it "Guidance." Further, rather than imposing any new substantive obligations, the Guidance simply sets forth the amount that the statute and regulations already obligate IDR participants to pay. As noted, the statute requires the parties to pay the administrative fee, 42 U.S.C. § 300gg-111(c)(8), and the September 2021 IFR requires them to pay that fee to the IDR entity and authorizes the Secretary to update the specific amount of fee through annual guidance, specifying the manner in which the Secretary must establish the amount of the fee. 45 C.F.R. § 149.510(d)(2). The December 2022 Fee Guidance simply supplies the specific dollar amount dictated by the statute and regulations. Because the December 2022 Fee Guidance is one that "clarifies, rather than creates, law" it is not subject to notice and comment. *Flight Training Int'l, Inc. v. Fed. Aviation Admin.*, 58 F.4th 234, 240 (5th Cir. 2023). "A rule does not, in this inquiry, become a [legislative rule] merely because it supplies crisper and more detailed lines than the authority being interpreted." *Am. Min. Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). "If that were so, no rule could pass as an interpretation of a legislative rule unless it were confined to parroting the rule or replacing the original vagueness with another." *Id.*

The Act itself mandated the Departments to set the administrative fee amount "in a manner such that the total amount of fees paid under this paragraph for such year is estimated to be equal to

the amount of expenditures estimated to be made by the Secretary for such year in carrying out the IDR process." 42 U.S.C. 300gg-111(d)(8)(B). The Secretary was therefore required to set the amount of fee sufficient to cover the estimated expenditures incurred in carrying out the IDR process. "The interpretative rule exception reflects the idea that public input will not help an agency make the legal determination of what the law already" requires. *Dismas Charities, Inc. v. Dep't of Justice*, 401 F.3d 666, 680 (6th Cir. 2005). Thus, the December 2022 Fee Guidance interpreted the statute, and its mandatory self-funding requirement, to set the administrative fee in an amount mandated by the statute's self-funding mechanism. Public input could not have changed this statutory mandate.

Notice-and-comment procedures are also not required when an updated fee is issued following an established methodology explained in a regulation. *See City of Idaho Falls, Idaho v. FERC*, 629 F.3d 222, 227 (D.C. Cir. 2011). The Departments applied a consistent methodology to set the administrative fee based on the estimated costs of carrying out the IDR process, and the December 2022 Fee Guidance did not deviate from that methodology. "[F]aithfully implementing established regulations does not require renewed notice and comment." *Id.* The methodology used to determine the amount of the administrative fee—which, is required by the Act to be estimated as sufficient to cover the costs—is explained in the September 2021 IFR. *See* 86 Fed. Reg. at 56,001-02 (cost calculation to include "staffing and contracting costs," costs of "providing oversight," "costs of developing and publishing reports" "costs of collecting the administrative fees," "costs of maintaining the Federal IDR portal," and explaining that "[i]n future years, such projected costs will be informed by the actual costs incurred"). The September 2021 IFR outlines a methodology for calculating the costs associated with carrying out the IDR process and explained that the Departments will use those costs to calculate a fee so that "the total administrative fees collected by . . . the Departments during a calendar year are approximately equal to the estimated amount of expenditures." *Id.* Consistent with this established methodology, the Departments relied on new data informed by the actual costs to establish the administrative fee for 2023. *See* Dec. 2022 Fee Guidance 6.

The December 2022 Fee Guidance simply explained how that pre-established methodology requires updating the fee in light of the additional costs. The D.C. Circuit's decision in *Idaho Falls*, is

instructive. There, FERC issued a regulation announcing that "annual charges" would be "subject to adjustments as conditions may warrant" based on a predetermined methodology. 629 F.3d at 224. For more than 20 years, the executive director published the updated fee schedule annually, without going through notice and comment. *Id.* Only when FERC changed the underlying methodology used to calculate annual fees, was the annual fee required to go through notice and comment. *Id.* at 227. Similarly, in *Phillips Petroleum Co. v. Johnson*, which Plaintiffs rely on, only when the Minerals Management Service adopted a new methodology for calculating payment of oil and gas royalties did the revised fees have to go through notice and comment. *See* 22 F.3d 616, 619 (5th Cir.), *opinion modified on reh'g*, 36 F.3d 89 (5th Cir. 1994) (Procedure Paper setting fees for oil and gas royalties was required to go through notice and comment because "it effects a change in the method used" to calculate the fees). Here, the September IFR set the methodology for tabulating the costs, which the statute requires be covered by the administrative fees. Additionally, the Departments explained in the September 2021 IFR, on which Plaintiffs have subsequently had the opportunity to comment, their intention to issue updated fees through guidance based on actual costs. *See SEC v. Alpine Sec. Corp.*, 982 F.3d 68, 81 (2d Cir. 2020) (finding no violation of the APA's notice and comment procedures when SEC issued notice of proposed rule that did "not specify the required reports and records" that would be required under the rule "so as to allow for any revisions" that may be adopted in the future).

That the fee is mandatory does not change the fact that the announcement of its specific amount is an interpretive rule, contrary to Plaintiffs' view. Pls.' Br. 17. Indeed, the Fifth Circuit recently joined "other Circuits in rejecting the proposition that a rule cannot be interpretive if it limits discretion or uses binding language, reasoning that "if the law is mandatory, then it is natural for an agency's restatement of the law to speak in mandatory terms as well." *Flight Training Int'l, Inc. v. Fed. Aviation Admin.*, 58 F.4th 234, 242 (5th Cir. 2023); *see also Stinson v. United States*, 508 U.S. 36 (1993). In other words, to the extent that an interpretive rule is interpreting binding, this effect stems from the binding nature of the statute itself. *See Dismas Charities*, 401 F.3d at 681.

Additionally, there are no enforcement consequences for not paying the administrative fee—another indication that the fee amount is an interpretive, rather than legislative, rule. *See Texas Food*

Indus. Ass'n v. Espy, 870 F. Supp. 143, 147 (W.D. Tex. 1994) (in applying test to determine whether a rule is substantive or interpretive, asking "whether in the absence of the rule there would not be an adequate legislative basis for enforcement action" (quoting *Am. Mining Cong.*, 995 F.2d at 1112)). Here, the only consequences on parties who do not pay the administrative fee is that an IDR entity will not consider their offer. There are no fines or penalties for failure to pay or late payment, nor does the regulations authorize the Secretary to take any enforcement action against parties who fail to pay the fee.

2. The Fee Guidance and Regulation are Exempt from Notice and Comment Because It Would Be Impracticable.

Even if the December 2022 Fee Guidance were not interpretive, both it and the regulation authorizing the administrative fee to be adjusted through annual guidance are exempt from notice-and-comment because that process would have been impracticable.

Under the APA, notice and comment may be excused where "impracticable, unnecessary, or contrary to public interest." 5 U.S.C. § 553(b)(3)(B). This exception "is designed to provide agencies with a safety valve when delay would do real harm." *United States v. Garner*, 767 F.2d 104, 121 (5th Cir. 1985). That is the case here. As explained in the December 2022 Fee Guidance, the Departments only obtained the actual cost data necessary to calculate the annual fee after October 2022—leaving them with only a matter of weeks to update the guidance for 2023. Dec. 2022 Fee Guidance 1 (updating fee "due to supplemental data analysis"). This is not a case where "timeframes were held sufficient to provide notice and comment." Pls.' Br. 20. Furthermore, it would be eminently "impracticable" for the Departments to go through notice-and-comment rulemaking regularly to adjust the administrative fee amount. After all, notice-and-comment can take up to a year, sometimes longer, meaning that if the agency were to update the administrative fee annually, as contemplated by the Departments' regulations, it could be continuously engaged in the notice-and-comment process. None of the cases Plaintiffs cite deal with adjustments, rather than rulemakings, *see, e.g.*, *United States v. Rainbow Fam.*, 695 F. Supp. 294, 305 (E.D. Tex. 1988) (cited in Ps.' Mem. 20), and their proposed approach would have the Departments conducting notice and comment in *perpetuity*.

The agencies specifically invoked this exception when promulgating the September 2021 IFR explaining the Departments' plan to update the fee through annual guidance. *See N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 768 (4th Cir. 2012) ("Although we do not impose a rigid requirement that an agency must explicitly invoke the good cause exception, the contemporaneous agency record must manifest plainly the agency's reliance on the exception in its decision to depart from the required notice and comment procedures."). The Departments explained here that notice-and-comment rulemaking would be "impracticable and contrary to the public interest." 86 Fed. Reg. at 56,043. Parties needed advance notice of how fees would be set and to whom the fees would be paid in order to prepare for the IDR process to take effect. The Departments thus had good cause to forgo notice and comment rulemaking for the portions of the 2021 September IFR establishing the processes for setting the administrative fee through guidance.

3. Any Failure To Undertake Notice-and-Comment Was Harmless.

Even if this notice and comment were required, Plaintiffs fail to show that they were harmed by its absence. *See City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013); *see also* 5 U.S.C. § 706 (in reviewing agency action, "due account shall be taken of the rule of prejudicial error") "The harmless error rule requires the party asserting error to demonstrate prejudice from the error." *City of Arlington*, 668 F.3d at 243 (internal quotation omitted). The Plaintiffs here, however, fail to even argue prejudice. They had an opportunity to comment on the Departments' stated intention in the September 2021 IFR to set the administrative fees annually through guidance, and they did not do so. Nor did they complain when the Departments issued two prior guidance documents setting the administrative fee without notice and comment. *See* Sept. 2021 Fee Guidance (AR 8733); Oct. 2022 Fee Guidance (AR 9869).

Regardless, Plaintiffs cannot meet their burden. The harmless error inquiry is informed by "a number of potentially relevant factors, including (1) 'an estimation of the likelihood that the result would have been different'; (2) 'an awareness of what body (jury, lower court, administrative agency) has the authority to reach that result'; (3) 'a consideration of the error's likely effects on the perceived

fairness, integrity, or public reputation of judicial proceedings'; and (4) 'a hesitancy to generalize too broadly about particular kinds of errors when the specific factual circumstances in which the error arises may well make all the difference.'" *City of Arlington*, 668 F.3d at 244 (quoting *Shinseki v. Sanders*, 556 U.S. 396, 411-12 (2009)). Each of these factors shows that any procedural error here was harmless.

First, there is no indication the Departments' conclusions would have been materially different had they first engaged in notice and comment. Because the amount of fee is required by statute to be sufficient to cover the estimated annual costs in administering the IDR process, the Departments could not have set a fee insufficient to cover the costs even if Plaintiffs had an opportunity to comment. Thus, under the first factor, there is nothing to suggest a meaningful "likelihood that the result would have been different." *City of Arlington*, 668 F.3d at 244. Second, Congress expressly entrusted the Departments with the authority to establish the administrative fees under the Act, *see* 42 U.S.C. § 300gg-111(c)(8), and Plaintiffs offer no basis to second-guess that amount. Third, there is no reason to believe that any "error" would affect the "perceived fairness, integrity, or public reputation of judicial proceedings." *Id.* Finally, the "specific factual circumstances in which the [alleged] error arises" also point against finding any prejudice here. *Id.* The Departments adequately explained their reasoning in setting the December 2022 Fee Guidance. They considered whether to take on additional costs to address the backlog, and reasonably explained their decision, even if they ultimately reached an outcome that differs from Plaintiffs' preference. Thus, even if Plaintiffs had commented on the December 2022 Fee Guidance, or the portion of the September 2021 IFR announcing the decision to set the annual fee through guidance, Plaintiffs cannot show they suffered any prejudice.

III. The Batching Regulation Is Lawful.

A. The Batching Regulation Is Reasonable and Not Arbitrary or Capricious.

The Departments also issued reasonable regulations permitting certain claims to be submitted jointly for a single IDR proceeding only in certain circumstances to avoid unnecessarily complicated and inefficient payment determinations that combine multiple unrelated claims and require consideration of a multitude of factors. The preamble to the September 2021 IFR explains that the

Departments considered, and rejected, many of the arguments the Plaintiffs make here. The regulation is therefore both reasonable and reasonably explained.

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," otherwise referred to as "batching." 42 U.S.C. § 300gg-111(c)(3)(A). The statute sets minimum requirements that must be met before any items or services may be considered jointly in a single IDR process, but also authorizes the Secretary to specify additional criteria on top of those minimum requirements. *Id.* § 300gg-111(c)(3)(A)(i)-(iv) (permitting batching "only if" items and services "are furnished by the same provider or facility," payment "is required to be made to the same group health plan or health insurance issuer," the items and services "are related to the treatment of a similar condition," and the "items and services were furnished during a 30 day period").

The Secretary reasonably explained the criteria under which multiple items or services may be "batched" into a single IDR dispute in the September 2021 IFR. The IFR provides that "[b]atched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if [among other requirements] [t]he qualified IDR items and services are the same or similar items and services." 45 C.F.R. § 149.510(c)(3)(i)(C). "Same or similar items or services" is a term of art used throughout the regulations, and the regulations define that term to have a consistent meaning everywhere it is used, consistent with the caution to "avoid interpretations that would 'attribute different meanings to the same phrase.'" *Cochise Consultancy, Inc., v. United States*, 139 S. Ct. 1507, 1512 (2019) (quoting *Reno v. Bossier Par. Sch. Bd.*, 528 U.S. 320, 329 (2000)). "[U]nder the interim final rules, the term 'same or similar item or service' means a health care item or service billed under the same service code[.]" 86 Fed. Reg. at 36,890.

The decision to issue regulations allowing batching of claims in the IDR process in only these circumstances was reasonable and not arbitrary or capricious. As the Departments explained in the preamble, this rule "will 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. Each service code carries a unique qualifying payment amount ("QPA"), which the arbitrator must consider during the IDR process. Likewise, arbitrators must consider information under the statutory factors unique to the item or service, patient, payer, provider, or facility, as well as any information the arbitrator requests. 42 U.S.C. § 300gg-111(c)(5). Once multiple claims (each of which carry multiple unique pieces of information an arbitrator must consider) begin to be consolidated in IDR proceedings, the factors an IDR entity must consider quickly grow exponentially. Resolving just a single claim for a single patient relating to a single service code already requires an arbitrator to consider potentially six or more pieces of information—considering additional unrelated claims in the same IDR proceeding might require considering multiple QPAs and multiple patient acuities or other additional information unique to each individual claim. This runs the risk of making IDR proceedings unduly complex and time-consuming.

Additionally, the regulations permit "bundled" items or services to be resolved in a single IDR proceeding. 86 Fed. Reg. at 55,994. Bundling refers to the practice of making "a single payment for multiple services an individual received during an episode of care." *Id.* Thus, the Departments did consider the fact pattern that Plaintiffs present in their brief—of a provider who provides multiple services to a single patient during an episode of care—and explained that if those services are bundled, *i.e.*, billed or paid as part of a bundled payment arrangement, they may be resolved in a single IDR proceeding. *See* Pls' Br. 26. The Departments did not "fail[] to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

The regulations relating to the "batching" of claims into a single IDR proceeding are therefore reasonable and reasonably explained. *Prometheus Radio Project*, 141 S. Ct. at 1158. This interpretation of the statute was within the Secretary's authority, and not arbitrary or capricious.

B. The Batching Regulation is Exempt from Notice and Comment Because It Is a Rule of Agency Procedure.

The batching regulation is a "rule[] of agency organization, procedure, or practice" exempt from notice-and-comment requirements. 5 U.S.C. § 553(b)(3)(A); *see U.S. Dep't of Lab. v. Kast Metals Corp.*, 744 F.2d 1145, 1152 (5th Cir. 1984) ("In exempting procedural rules, Congress has placed a

premium on efficiency by avoiding the often cumbersome and time-consuming mechanisms of public input.") To determine whether a rule is covered by this exception, courts ask whether it "encodes a substantive value judgment" about something other than "what mechanics and processes are most efficient." *Public Citizen v. Dep't of State*, 276 F.3d 634, 640 (D.C. Cir. 2002); *JEM Broad. Co. Inc., v. FCC*, 22 F.3d 320, 326-28 (D.C. Cir. 1994) (explaining that "rules of agency organization, procedure, and practice" often "embody a judgment" about "what mechanics and processes are most efficient"). The Fifth Circuit, in particular, applies a "substantial impact" test to determine if a rule is procedural or substantive: if the rule "modifies substantive rights and interests" then it is appropriately characterized as substantive. *Kast Metals Corp.*, 744 F.2d at 1153.

Here, the batching regulation is a rule of agency procedure because it is based on an evaluation of "what mechanics and processes are most efficient" and it concerns internal organizational procedures, not the substantive rights of the parties. *JEM Broad.*, 22 F.3d at 328. Much like the Federal Rules of Civil Procedure, the batching regulation describes when claims can appropriately be joined for resolution in a single proceeding, but it does not impact the underlying rights and interests of the parties, *i.e.*, the right to payment, or the amount of payment, that a particular claim entails. *See e.g.*, Fed. R. Civ. P. 18. The Departments' explanation for the batching regulation confirms that it is a rule grounded in procedural efficiencies. The batching regulation was issued to avoid the risk that submission of multiple unrelated claims would "unnecessarily complicate an IDR payment determination and create inefficiencies in the Federal IDR process." 86 Fed. Reg. at 55,994. As a rule of agency procedure designed to make the IDR process more procedurally efficient, the batching regulation was properly exempted from the notice-and-comment process.

C. The Departments Had Good Cause to Forgo Notice and Comment when Issuing the Batching Regulation.

Even if the September interim final rule were subject to notice and comment, there was "good cause" to forgo it here—especially given that the "congressional deadlines are very tight and . . . the statute is particularly complicated." *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, 422 (6th Cir. 2009) ("A deadline imposed by

Congress before which an agency must regulate may support a finding of good cause, which makes sense because Congress can implicitly set aside the APA when it specifically requires rapid action."). Although the Fifth Circuit has stated that a statutory deadline does not by itself constitute good cause, it has held that such a deadline "is a factor to be considered." *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 213 (5th Cir. 1979).

Here, the Departments explained that notice and comment would be impracticable and contrary to the public interest. 86 Fed. Reg. at 56,043. Although Congress gave the Departments one year to promulgate rules relating to the IDR process, the Departments recognized that providers, facilities, plans, and issuers, would need months of lead time to prepare for the new legal regime. *Id.* at 56,043-4. And this concern about inadequate time to implement major policy changes was shared by industry stakeholders. *See, e.g.,* Letter from E. Linda Villarreal, President, Tex. Med. Ass'n, et al., to Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., et al., at 16 (Sept. 7, 2021) (AR 7832) (noting that "there will be a very short turnaround for physicians and other providers to implement changes to their policies and procedures"); *see also, e.g.*, Letter from Katy Johnson, Senior Counsel, Health Policy, American Benefits Council, to Carol Weiser, Benefits Tax Counsel, U.S. Dep't of Treasury, et al., at 28 (June 11, 2021) (AR 5822) (noting that the forthcoming rules on the arbitration process "will, by necessity, be incredibly complicated" and will "require significant time and effort [for employers, health plans, and issuers] to implement").

Second, the Departments found that providers would need lead time to respond to the September IFR's new standards regarding the policies and procedures for resolving payment disputes through the Act's new IDR process. 86 Fed. Reg. at 56,044. Given the Act's prohibition on balance billing, effective January 1, 2022, facilities and providers needed advance notice to prepare for the Act's IDR process or face the risk that some of their services could go uncompensated. *Id.* In particular, providers would need advance notice of how to properly submit batched and bundled claims for payment, particularly given the Act's 90-day prohibition on the parties initiating subsequent IDR disputes against the same parties relating to the same item or service. 42 U.S.C. § 300gg-111(c)(5)(E)(ii).

Third, the Departments found that prompt rulemaking was required to allow time for arbitrators to "acquire the necessary expertise and evidence of qualification." 86 Fed. Reg. at 56,044. Arbitrators, like parties to the payment disputes, would need time to understand the policies and procedures governing the IDR process, including time to familiarize themselves with the rules to determine whether claims are properly batched and bundled.

These circumstances demonstrate that the Departments had good cause to forgo notice and comment as to the batching regulations. It generally takes federal agencies more than a year to complete the process of preparing a proposed rule; submitting a proposed rule to the Office of Management and Budget ("OMB") for that agency's review; publishing a proposed rule; allowing for a comment period; reviewing the comments that are submitted; preparing a final rule; submitting the final rule again to OMB; and publishing the final rule. *See* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 N.W. L. Rev. 471, 513-19 (2011) (on average, even routine rulemakings take 1.3 years to complete, and significant rulemakings on average take four months longer). The Departments did not have the option to wait that long to issue their rules, given the need for advance planning shared by insurers, providers, and arbitrators alike.

D. Any Failure To Undertake Notice and Comment Was Harmless.

Regardless, any procedure error was harmless. *See City of Arlington*, 668 F.3d at 243 (not deciding whether the FCC abused its discretion by failing to use notice-and-comment rulemaking or whether the rulemaking was interpretative rulemaking of the type excepted from the APA's notice-and-comment requirements because failure to follow APA's procedures was harmless). Once again, nowhere in Plaintiffs' complaint or in their motion for summary judgment do the Plaintiffs assert that they suffered any harm from the Departments' issuance of the September IFR without first providing for notice and comment. And, to the best of the Departments' knowledge, neither TMA nor any of the other Plaintiffs submitted a comment on the rulemaking record in response to the September IFR or submitted any comments on the issue of batching. This forecloses any possible claim that they suffered prejudice from the Departments' rulemaking procedures. *See Am. Bankers Ass'n v. Nat'l Credit*

Union Admin., 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (finding harmless error where the plaintiff "did not explain what it would have said had it been given an opportunity to respond").

Nonetheless, each of the relevant factors points toward a finding that any error was harmless. *See City of Arlington*, 668 F.3d at 244; *see also Shinseki*, 556 U.S. at 411-12. The goal of the notice and comment process is to allow "the agency to disclose its thinking on matters that will affect regulated parties." *Johnson*, 632 F.3d at 931. This goal, however, "may be achieved in cases where the agency's decision-making process 'centered on the identical substantive claims' as those proposed by the party asserting error, even if there were APA deficiencies." *Id.* "It follows that when a party's claims were considered, even if notice was inadequate, the challenging party may not have been prejudiced." *Id.*

here, the preamble to the September 2021 IFR demonstrates that the Departments considered Plaintiffs' arguments regarding the batching regulation, but ultimately disagreed with Plaintiffs. The preamble explains the justification behind the batching rule (avoiding inefficient and complex IDR proceedings) and addresses Plaintiffs' concerns of convenience of submitting multiple services an individual received during an episode of care by explaining the rule permitting bundled services to be considered in a single IDR proceeding. 86 Fed. Reg. at 55,994. Moreover, the September 2021 IFR invited comments from the public, *see id.* at 55,980, and the Departments will consider these comments prior to the promulgation of final rules. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020).

IV. Any Remedy Should Be Limited to Remand Without Vacatur.

In the event the Court disagrees with Defendants on the merits, remand without vacatur is the appropriate remedy. Even Plaintiffs recognize, "[o]f course, the Departments have authority under the NSA to 'establis[h]' the 'amount' of administrative fees in order to cover the Departments' estimated expenditures in carrying out the IDR process." Pls.' Br. 17 (quoting 42 U.S.C. § 300gg-111(c)(8)(B)). And their own cited cases support remanding without vacating in order to allow the agency to address any procedural error. *See Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1135 & n.4 (D.C. Cir. 1995) (remanding without vacating so that agency may "provide the requisite opportunity for

meaningful comment and explanation"). So too with the batching regulation—the Departments have authority to specify criteria for batching after following the proper procedures and explaining their reasoning.

At most, the Court should remand the matter to the Departments without vacatur of the challenged provisions because there is "at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so." *Tex. Ass'n of Mfrs. v. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 389-90 (5th Cir. 2021) (remanding without vacatur to permit an agency to cure a notice-and-comment violation); *see also Engine Mfrs. Ass'n v. EPA*, 20 F.3d 1177, 1184 (D.C. Cir. 1994) (remanding without vacatur where "the [defendants'] error was one of form and not of substance, i.e., . . . it will be able to provide the information necessary to explain its cost allocation decisions"). Vacatur would be highly disruptive, as it would leave the Departments with vastly insufficient funding to administer the IDR process, and could lead to chaos in the IDR process as providers seek to batch disputes for as many items and services as possible, potentially adding further delays to the already-growing backlog and threatening the viability of the IDR program. These interests counsel heavily against vacatur. *See Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).

This Court should also reject Plaintiffs' request for a refund of administrative fees, as this Court lacks jurisdiction over claims for money damages. The APA does not waive sovereign immunity for awards of money "given to the plaintiff to substitute for a suffered loss." *Bowen v. Massachusetts*, 487 U.S. 879, 895 (1988) (quotation omitted). The key distinction for purposes of Section 702 of the APA is between "specific relief and substitute relief, not between equitable and nonequitable categories of remedies." *Dep't of the Army v. Blue Fox, Inc.*, 119 S. Ct. 687, 691 (1999). The APA only waives immunity only for "specific" relief, and ordering Defendants to return an unspecified amount of "unlawfully exacted" fees, possibly already comingled with other funds and expended in carrying out the IDR process, is not "specific" relief. *Modoc Lassen Indian Hous. Auth. v. U.S. Dep't of Hous. & Urb. Dev.*, 881 F.3d 1181, 1196 (10th Cir. 2017) (concluding that district court effectively awarded money damages when it ordered HUD to compensate plaintiffs for "wrongfully collected . . . alleged

overpayments" using agency grant funds).[4] Plaintiffs also provide no basis for this Court to determine how much of the administrative fees that Plaintiffs have paid in 2023 were "unlawfully exacted" in excess of the appropriate amount, Pls.' Br. 30, (indeed, did they not take issue with the $50 fee in 2022) nor is it this Court's role to set the administrative fees. That task is reserved for the Secretary. 42 U.S.C. § 300gg-111(c)(8)(B). This Court should likewise reject Plaintiffs' request to modify, or to order the Departments to modify, the statutory and regulatory deadlines for the IDR process. Pls.' Br. 30. A court can only compel agency action "where a plaintiff asserts that an agency failed to take a discrete agency action that it is *required to take*." *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004). "[W]hen a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995); *see also Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005).

CONCLUSION

For the foregoing reasons, the Defendants respectfully request that the Court grant summary judgment in their favor.

Dated: March 15, 2023

Respectfully submitted,

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[4] Plaintiffs' cited cases on disgorgement theory are inapt. In *Texas v. United States*, 336 F. Supp. 3d 664, 675 (N.D. Tex. 2018) the court only ordered disgorgement to accomplish the "ACA's statutory mandate exempting the *states* from payment." (emphasis added). And in *America's Community Bankers v. FDIC*, 200 F.3d 822, 831 (D.C. Cir. 2000) the court specifically declined to order plaintiffs a "cash refund of past assessments" and instead permitted the agency to formulate prospective relief.

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CERTIFICATE OF SERVICE

I hereby certify on this 15th day of March, 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