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*.	Case No.: 6:23-cv-00059-JDK

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii
INTRODUCTION 1
ARGUMENT 2
I. TMA's And Dr. Corley's Claims Are Not Precluded. 2
II. The December 2022 Fee Guidance Is Unlawful. 3
A. The December 2022 Fee Guidance is a substantive rule that was unlawfully issued without notice and comment. 3
1. The December 2022 Fee Guidance is not an interpretive rule. 3
2. The Departments lacked good cause to bypass notice and comment. 7
3. The error was not harmless. 8
B. The December 2022 Fee Guidance was unreasoned and unlawful. 9
III. The Same-Service-Code Batching Rule Is Unlawful. 13
A. The Departments unlawfully bypassed notice and comment. 13
1. The batching rule is not a rule of agency procedure. 13
2. The Departments lacked good cause to bypass notice and comment. 15
3. The error was not harmless. 16
B. The same-service-code batching rule is arbitrary and capricious. 16
IV. The Court Should Grant Plaintiffs' Requested Remedies. 19
CONCLUSION 20

TABLE OF AUTHORITIES

Cases **Page(s)**

AFL-CIO v. NLRB,
57 F.4th 1023 (D.C. Cir. 2023) 13, 14

Air Transp. Ass'n of Am. v. DOT,
900 F.2d 369 (D.C. Cir. 1990), *vacated as moot*, 933 F.2d 1043 (D.C. Cir. 1991) 14, 15

Am. Med. Ass'n v. Reno,
57 F.3d 1129 (D.C. Cir. 1995) 6, 19

Am. Mining Cong. v. Mine Safety & Health Admin.,
995 F.2d 1106 (D.C. Cir. 1993) 5, 6

American Community Bankers v. FDIC,
200 F.3d 822 (D.C. Cir. 2000) 20

Bank of N.Y. Mellon v. Riley,
No. 21-40383, 2022 WL 1773364 (5th Cir. June 1, 2022) 2

Bowen v. Massachusetts,
487 U.S. 879 (1988) 20

Brown Exp., Inc. v. United States,
607 F.2d 695 (5th Cir. 1979) 4, 15

California v. Azar,
911 F.3d 558 (9th Cir. 2018) 9, 16

Cath. Legal Immigr. Network, Inc. v. Exec. Off. for Immigr. Rev.,
513 F. Supp. 3d 154 (D.D.C. 2021) 10

City of Idaho Falls v. FERC,
629 F.3d 222 (D.C. Cir. 2011) 6

Defy Ventures, Inc. v. U.S. Small Bus. Admin.,
469 F. Supp. 3d 459 (D. Md. 2020) 20

Dep't of Lab. v. Kast Metals Corp.,
744 F.2d 1145 (5th Cir. 1984) 14

Engine Mfrs. Ass'n v. EPA,
20 F.3d 1177 (D.C. Cir. 1994) 9, 19

Five Flags Pipe Line Co. v. DOT,
No. 89-119, 1992 WL 78773 (D.D.C. Apr. 1, 1992) 5, 6

Gomez v. Trump,
490 F. Supp. 3d 276 (D.D.C. 2020) 20

Hoctor v. Dep't of Agric.,
82 F.3d 165 (7th Cir. 1996) 5

Interstate Nat. Gas Ass'n of Am. v. FERC,
285 F.3d 18 (D.C. Cir. 2002) 8

JEM Broad. Co. v. FCC,
22 F.3d 320 (D.C. Cir. 1994) 14

Kisor v. Wilkie,
139 S. Ct. 2400 (2019) 4

Methodist Hosp. of Sacramento v. Shalala,
38 F.3d 1225 (D.C. Cir. 1994) 15

Michigan v. EPA,
576 U.S. 743 (2015) 10

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983) 9, 10

N.C. Growers' Ass'n, Inc. v. United Farm Workers,
702 F.3d 755 (4th Cir. 2012) 7

NRDC v. EPA,
22 F.3d 1125 (D.C. Cir. 1994) 20

Nw. Immigr. Rts. Project v. U.S. Citizenship & Immigr. Servs.,
496 F. Supp. 3d 31 (D.D.C. 2020) 10

Phillips Petrol. Co. v. Johnson,
22 F.3d 616 (5th Cir. 1994) 4, 14

Pub. Citizen v. Dep't of State,
276 F.3d 634 (D.C. Cir. 2002) 14

Safari Club Int'l v. Zinke,
878 F.3d 316 (D.C. Cir. 2017) 16

SEC v. Alpine Sec. Corp.,
982 F.3d 68 (2d Cir. 2020) 6

SEC v. Chenery Corp.,
318 U.S. 80 (1943) 9, 11

Spirit Airlines, Inc. v. DOT,
997 F.3d 1247 (D.C. Cir. 2021) 10

Students for Fair Admissions, Inc. v. Univ. of Tex. at Austin,
37 F.4th 1078 (5th Cir. 2022) 2

Tex. Med. Ass'n v. HHS,
587 F. Supp. 3d 528 (E.D. Tex. 2022) ..... *passim*

Texas Med. Ass'n v. HHS,
No. 6:22-CV-372-JDK, 2023 WL 1781801 (E.D. Tex. Feb. 6, 2023) 14, 19

Texas v. United States,
336 F. Supp. 3d 664 (N.D. Tex. 2018) 20

Texas v. United States,
497 F.3d 491 (5th Cir. 2007) 13

Transitional Hosps. Corp. of La. v. Shalala,
222 F.3d 1019 (D.C. Cir. 2000) 17

U.S. Steel Corp. v. EPA,
595 F.2d 207 (5th Cir. 1979) 7

Union of Concerned Scientists v. Nuclear Regul. Comm.,
711 F.2d 370 (D.C. Cir. 1983) 13

United States v. Brewer,
766 F.3d 884 (8th Cir. 2014) 16

United States v. Garner,
767 F.2d 104 (5th Cir. 1985) 7, 17

United States v. Johnson,
632 F.3d 912 (5th Cir. 2011) 8, 16

United States v. Menasche,
348 U.S. 528 (1955) 14

United States v. Rainbow Fam.,
695 F. Supp. 294 (E.D. Tex. 1988) 7

W & T Offshore, Inc. v. Bernhardt,
946 F.3d 227 (5th Cir. 2019) 3

Warshauer v. Solis,
577 F.3d 1330 (11th Cir. 2009) 5

Whole Woman's Health v. Hellerstedt,
136 S. Ct. 2292 (2016) 3

Yakima Valley Cablevision, Inc. v. FCC,
794 F.2d 737 (D.C. Cir. 1986) 9, 10

Statutes

5 U.S.C. § 553(b)(A) 13

5 U.S.C. § 553(b)(B) 13

5 U.S.C. § 553(d) 7

42 U.S.C. § 300gg-111(a)(3)(E) 17

42 U.S.C. § 300gg-111(c)(2)(A) 3

42 U.S.C. § 300gg-111(c)(3)(A) 17

42 U.S.C. § 300gg-111(c)(3)(A)(iii) 17, 19

42 U.S.C. § 300gg-111(c)(5)(E)(iii) 12

42 U.S.C. § 300gg-111(c)(8)(A), (B) 4

42 U.S.C. § 300gg-137(c) 12

Other Authorities

45 C.F.R. § 149.510(c)(3)(i)(C) 17

45 C.F.R. § 149.510(d)(1)(i) 11

45 C.F.R. § 149.510(d)(2)(ii) 4

86 Fed. Reg. 55,980 (Oct. 7, 2021) ..... *passim*

87 Fed. Reg. 69,404 (Nov. 18, 2022) 7

INTRODUCTION

Without warning at the end of last year, the Departments increased *sevenfold*—from $50 to $350—the nonrefundable administrative fee that out-of-network healthcare providers must pay to obtain reimbursement for their services through the NSA's IDR process. As plaintiffs showed, and the Departments do not dispute, this 600% fee increase will make IDR cost-prohibitive for significant numbers of small-value claims—including for the vast majority of radiology claims—with devastating consequences for the viability of these providers' practices.

In imposing this massive fee increase, the Departments flouted their fundamental obligations under the APA to give affected parties notice of and an opportunity to comment on the proposed fee increase; to grapple with the adverse effects the fee increase would have on providers; and to consider viable alternatives that would have eliminated or mitigated those adverse effects. None of the justifications the Departments now offer can excuse these fatal flaws. Most of them are barred by the bedrock rule of administrative law that agency action must stand or fall based on the rationale set forth by the agency in the challenged action and cannot be upheld based on post-hoc justifications offered by agency counsel in litigation. And all of them are wrong in any event.

Nor can the Departments' batching rules solve the problem. To the contrary, the Departments' restrictive same-service-code batching rule is part and parcel of the problem. And it too was issued in violation of the APA's notice-and-comment requirement and its requirement of reasoned decisionmaking. As to the former, the Departments' contrary arguments are little more than an attempt to relitigate this Court's decision in *TMA I*. And as to the latter, the Departments have no persuasive response to plaintiffs' showing that the batching rule is arbitrary and capricious.

The Court should thus vacate the challenged actions and exercise its authority under the APA to grant an effective remedy for the harms inflicted by the Departments' unlawful actions.

ARGUMENT

I. TMA's And Dr. Corley's Claims Are Not Precluded.

At the outset, the Departments' claim-preclusion and claim-splitting arguments are meritless. *See* Opp. 10–12. For one thing, the arguments do not touch plaintiffs' challenge to the December 2022 Fee Guidance, only their challenges to provisions of the September Rule. For another, they relate to only two of the five plaintiffs. Plaintiffs Tyler Regional Hospital, Texas Radiological Society, and Houston Radiology Associated were neither parties to *TMA I* nor in privity with TMA and Dr. Corley, so their claims cannot possibly be barred. *See Students for Fair Admissions, Inc. v. Univ. of Tex. at Austin*, 37 F.4th 1078, 1087 (5th Cir. 2022). As a result, it is unclear why the Departments even press this issue—the Court would still have to decide all of plaintiffs' challenges even if the Departments were correct about TMA's and Dr. Corley's claims.

In any event, the Departments are incorrect. Preclusion rules do not bar TMA's and Dr. Corley's claims because "the same claim[s]" were not "involved in both actions." *Id*. Claims are not the same unless they "aris[e] from the same nucleus of operative facts as the prior claims." *Id.* at 1089; *accord Bank of N.Y. Mellon v. Riley*, No. 21-40383, 2022 WL 1773364, at *3 (5th Cir. June 1, 2022). Here, the substantive challenges to the batching and fee rules have nothing in common with the challenge to the QPA presumption in *TMA I*. The "operative facts"—*i.e.*, what the regulations require and the Departments' proffered justifications for them—are completely different. Even as to the Departments' failure to provide notice and comment, while the issue presented here is obviously similar to the one in *TMA I*, it is not the same because good cause is assessed regulation-by-regulation. *See Tex. Med. Ass'n v. HHS*, 587 F. Supp. 3d 528, 546 (E.D. Tex. 2022) ("*TMA I*"). Moreover, since *TMA I*, there has been a material change in facts, with the Departments' new $350 administrative fee dramatically changing the stakes and, thus, the "motivation" for bringing the litigation. *Students for Fair Admissions*, 37 F.4th at 1089.

At bottom, the Departments assert that a plaintiff must challenge *all* regulations issued in a single rulemaking in one lawsuit—even if the regulations address distinct subjects, rest on distinct rationales, inflict distinct harms, and raise distinct legal issues. That is not the law. "[C]ourts normally treat challenges to distinct regulatory requirements as 'separate claims,' even when they are part of one overarching '[g]overnment regulatory scheme.'" *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2308 (2016) (quoting 18 C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure § 4408, p. 52 (2d ed. 2002, Supp. 2015)). A contrary rule "would encourage a kitchen-sink approach to any litigation challenging the validity of [regulations]" by requiring parties injured by one regulation to challenge every other potentially harmful regulation issued in the same rulemaking in the first suit or be forever precluded. *Id.* "That outcome is less than optimal—not only for litigants, but for courts." *Id.* TMA's and Dr. Corley's claims are not barred.

II. The December 2022 Fee Guidance Is Unlawful.

A. The December 2022 Fee Guidance is a substantive rule that was unlawfully issued without notice and comment.

The Departments do not dispute that the December 2022 Fee Guidance is a "rule." Nor do they suggest that the NSA exempts fee rules from their duty to proceed "by regulation." 42 U.S.C. § 300gg-111(c)(2)(A). Instead, they argue that (1) the "guidance" was an "interpretive" rule, (2) notice and comment is "impractical," and (3) the error was harmless. All three arguments fail.

1. The December 2022 Fee Guidance is not an interpretive rule.

The December 2022 Fee Guidance cannot be shoehorned into the APA's exemption for "interpretive" rules. *See* Mot. 18. The Departments first ask this Court to give weight to the "Guidance" label. Opp. 17. But "while the Fifth Circuit may accord some deference to the agency's characterization of its own rule, this deference is minimal." *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019) (cleaned up). Moreover, the agencies did not say (until now)

that their fee rule was interpretive. Nor does the rule itself purport to "interpret" anything. *Phillips Petrol. Co. v. Johnson*, 22 F.3d 616, 619 (5th Cir. 1994). So, while the label evinces an intent to avoid notice and comment, it does little to support the Departments' interpretive-rule framing.

What really matters, of course, is not the "label" an agency assigns but "what the agency [action] does in fact." *Brown Exp., Inc. v. United States*, 607 F.2d 695, 700 (5th Cir. 1979). The Departments say their "guidance" is interpretive because it does not "create new law" and instead "simply sets forth the amount that the statute and regulations already obligate IDR participants to pay." Opp. 17. Not so. The statute mandates only that "[e]ach party to a[n] [IDR] determination" must pay a fee and "that the total amount of fees paid" must cover the Departments' estimated annual expenses. 42 U.S.C. § 300gg-111(c)(8)(A), (B). And the regulation just parrots the statute with the added (and unlawful) gloss that the agencies can proceed by "guidance." 45 C.F.R. § 149.510(d)(2)(ii).[1] Neither establishes an obligation to pay a particular amount or mandates any of the discretionary decisions underlying the December 2022 Fee Guidance. *See* Mot. 17–18.

The December 2022 Fee Guidance does not "interpret" anything; rather, it "create[s] law." *Brown Exp.*, 607 F.2d at 700 ("substantive rules" are "usually implementary to an existing law"). "An interpretive rule itself … does not impose any 'legally binding requirements' on private parties." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019). But the December 2022 Fee Guidance *does* impose a legally binding requirement on private parties: without it, there would be no lawful basis to require providers to pay a $350 administrative fee to access IDR. Unlike in the Departments' cases, here the agencies could not simply point to the statute and regulation and demand that IDR participants pay $350 based on the Departments' "interpretation" of those provisions' terms. *Cf.*

[1] The Departments briefly suggest that this regulation can sustain their fee because plaintiffs "do not substantively challenge" it. Opp. 16. *But see* Mot. 19–20 (challenging this regulation as "substantively unlawful" because it purports to authorize the agencies "to violate the APA").

Warshauer v. Solis, 577 F.3d 1330, 1340 (11th Cir. 2009) (rule establishing $250 reporting threshold was interpretive because it represented the agency's *interpretation* of the regulatory term "insubstantial value"). Rather, Congress delegated the task of establishing the amount of the fee to the Departments, and without further action on their part to do so, no fee could lawfully be assessed. For this reason alone, the fee "guidance" is a substantive rule. *See Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (a rule is substantive if "in the absence of the rule there would not be an adequate legislative basis" for enforcing an obligation); *Five Flags Pipe Line Co. v. DOT*, No. 89-119, 1992 WL 78773, at *4 (D.D.C. Apr. 1, 1992) (fee rule was not an interpretive rule because it "created an entirely new obligation to pay fees in precise amounts based on a specific mathematical computation that did not previously exist").

The December 2022 Fee Guidance is also substantive, not interpretive, because it "can[not] be derived from the [statute or] regulation by a process reasonably described as interpretation," but instead requires the Departments to make "choice[s] among methods of implementation." *Hoctor v. Dep't of Agric.*, 82 F.3d 165, 170 (7th Cir. 1996). To establish the amount of the administrative fee an IDR participant must pay, the Departments have to do more than just math. At a minimum, they have to decide (1) what activities to undertake; (2) how much those activities are projected to cost; (3) which of those costs properly relate to administration of the IDR process; (4) how many cases are projected to be filed in the upcoming year; (5) what is the projected collection rate; and (6) on what basis to spread the projected costs across IDR participants (*e.g.*, through a fixed fee paid equally by each IDR participant, through a variable fee keyed to the value of the dispute or some other factor, etc.). None of this can simply be read off the statute and regulations through an act of "interpretation." For this very reason, courts have rejected the notion that the APA's notice-and-comment requirements do not apply to agency decisions implementing a

statutory mandate to set fees in an amount sufficient to fund a program. *See Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1132–35 (D.C. Cir. 1995); *see also Five Flags Pipe Line Co.*, 1992 WL 78773, at *4 (statutory mandate to establish user fees sufficient to cover costs "was not so precise that it left the [agency] with no task other than to 'interpret' the statute and carry out its mandate").

The Departments' argument that their "guidance" simply applied a "methodology" set out in the September Rule fails for the same reasons. *See* Opp. 18–19 (citing *City of Idaho Falls v. FERC*, 629 F.3d 222, 227 (D.C. Cir. 2011)). Nothing in the Departments' fee regulation predetermined the resolution of any of the above decisions. Nor, assuming it is even relevant, did the rule's preamble predetermine those decisions merely by listing categories of potential costs the Departments would consider in setting fees. *See* 86 Fed. Reg. 55,980, 56,001 (Oct. 7, 2021). The preamble (like the statute and regulation) required the Departments to set fees "in a manner" so as to cover those costs—but left the "manner" up to the Departments. *Id.* And even if the preamble's list of potential costs were considered "a legally-binding methodology for setting future" fees, then the Departments "change[d] [their] methodology" when they decided to expand the list to include the costs of pre-eligibility review, *City of Idaho Falls*, 629 F.3d at 227, rather than having IDR entities undertake the needed review, *see* 86 Fed. Reg. at 55,993. And such changes must go through notice and comment. *See City of Idaho Falls*, 629 F.3d at 227; *SEC v. Alpine Sec. Corp.*, 982 F.3d 68, 83 (2d Cir. 2020) (noting need for "public comment … whenever such changes occur").

Finally, the lack of "enforcement consequences" does not suggest the Departments' "guidance" is interpretive. Opp. 19–20. In examining whether a rule has such consequences, courts are merely trying to gauge "whether [a] purported interpretive rule has 'legal effect.'" *Am. Mining Cong.*, 995 F.2d at 1112 (asking "whether in the absence of the rule there would not be an adequate legislative basis for enforcement action *or other agency action* to confer benefits or ensure the

performance of duties" (emphasis added)). Because the Departments' "guidance" provides the necessary legal basis for excluding providers unable or unwilling to pay $350 from the "benefits" of IDR, its "legal effect"—and substantive nature—is obvious. It is a substantive rule.

2. The Departments lacked good cause to bypass notice and comment.

The APA's good cause exemption cannot save the $350 fee. Opp. 20. "[A]n agency invoking the good cause exception must 'incorporate[] the finding and a brief statement of reasons therefor in the rules issued.'" *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985) (quoting 5 U.S.C. § 553(b)(B)); *see also N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 767 (4th Cir. 2012). The "guidance" includes no "finding" or "statement of reasons" regarding the exception, so the Departments cannot invoke it now. *See United Farm Workers*, 702 F.3d at 768.

Regardless, complying with the APA's 30-day notice-and-comment period, *see* 5 U.S.C. § 553(d), would not have been "impractical," Opp. 20. The good cause exception generally covers "true emergencies only," *United States v. Rainbow Fam.*, 695 F. Supp. 294, 305 (E.D. Tex. 1988), "where delay would do real harm," *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979). The Departments identify no "harm" that would flow from complying with the APA.[2]

Nor is it unusual for an agency to conduct annual rulemakings. *Contra* Opp. 20 (seemingly rejecting this notion as absurd). Indeed, the Department that has functionally taken the lead on NSA implementation and borne the highest implementation costs, HHS, *see* AR 9884, routinely engages in major annual rulemakings to set Medicare payment rules for the upcoming year, *see, e.g.*, 87 Fed. Reg. 69,404 (Nov. 18, 2022) (1,297-page rule). Noticing the fees for public comment

[2] The Departments also claim good cause for bypassing notice and comment with regard to the regulation authorizing the agencies to set the fees via guidance. Opp. 21. This argument fails for the same reasons as the identical one regarding the batching regulation. *See infra*, Part III.A.2.

may require a little extra work. But it is not "impracticable." Opp. 20. "This is not Point[e] du Hoc." *Interstate Nat. Gas Ass'n of Am. v. FERC*, 285 F.3d 18, 31 (D.C. Cir. 2002).

3. The error was not harmless.

The Departments' APA violation was not harmless. Unlawfully bypassing notice and comment can be deemed "harmless" only when "it is clear that the lack of notice and comment did not prejudice the petitioner." *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011). And as this Court held in *TMA I*, "courts should rarely find harmless error" in these circumstances "because the vast majority of agency rulemaking greatly benefits from expert and regulated entity participation." 587 F. Supp. 3d at 546–47 (cleaned up). This case is no exception.

The Departments claim "there is no indication [their] conclusions would have been materially different had they first engaged in notice and comment" because the fee was "required" by the NSA. Opp. 22. But plaintiffs have already refuted the notion that the statute required the $350 fee, *supra* at 5–6, and this Court has already rejected the argument that agencies can "bypass notice and comment by claiming after the fact that they would not have changed anything," *TMA I*, 587 F. Supp. 3d at 547 (citing cases). If plaintiffs had been given notice and an opportunity to comment, they could have explained that there were multiple alternative ways to address the eligibility-dispute morass and increase fee collection without impairing providers' IDR access. The Departments considered none of those alternatives. And so this case is nothing like those where a procedural error was deemed harmless because the agency "nevertheless considered the [plaintiff's] arguments … and responded to those arguments during the … rulemaking." *Johnson*, 632 F.3d at 932. Instead, because "the Departments cannot demonstrate that they considered and fully addressed these issues," their error was not harmless. *TMA I*, 587 F. Supp. 3d at 547.

It is immaterial that plaintiffs did not comment on the fee regulation (after its promulgation) or challenge the first two "guidance" documents (which set the administrative fee at $50). Opp.

21. A "post-promulgation comment period" cannot "cur[e]" the Departments' error in issuing the September Rule without notice and comment. *TMA I*, 587 F. Supp. 3d at 548. Nor were plaintiffs required to object to that rule or the earlier fees to preserve their present challenge to the 600% fee increase. *See California v. Azar*, 911 F.3d 558, 580 (9th Cir. 2018) (opportunities to comment in a prior rulemaking "are irrelevant" where the "prior rules were materially different").

B. The December 2022 Fee Guidance was unreasoned and unlawful.

Because the Departments "entirely failed to consider" the adverse effects of a 600% increase in the nonrefundable administrative fee on providers' ability to access IDR, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), and ignored "obvious alternatives" to the fee increase, *Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737, 746 n.36 (D.C. Cir. 1986), the December 2022 Fee Guidance was arbitrary and capricious.

The Departments try to defend the reasonableness of their fee on the ground that it was "required," Opp. 13, and "necessary" given the high dispute volume, Opp. 15. But the fee was not "required." And as their own cases prove, a statutory requirement that an agency set fees to cover program expenses does not excuse the agency from engaging in reasoned decisionmaking. *See Engine Mfrs. Ass'n v. EPA*, 20 F.3d 1177, 1181 (D.C. Cir. 1994) (holding "that the agency failed to provide a reasonable explanation of the cost basis for its fee proposal"). Nor can the Departments now argue that the NSA (or the dispute backlog) made the $350 fee "necessary" when they said nothing of the kind in their decision document. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943).

Beyond their necessity point, the Departments claim the fee increase was "not arbitrary" simply because they gave a "reason" for the decision (*i.e.*, covering the costs of pre-eligibility reviews) and because their only-now-disclosed financial projections suggest the $350 fee could indeed cover those costs. Opp. 13, 14. But agencies must consider the "disadvantages of [their] decisions" not just the reasons *for* them. *Michigan v. EPA*, 576 U.S. 743, 753 (2015). And courts

have consistently invalidated similar fee increases not because the agencies lacked reasons to raise fees, but because they failed to "grapple with the … extent to which the fee increases would impose barriers to obtaining the benefits at issue." *Nw. Immigr. Rts. Project v. U.S. Citizenship & Immigr. Servs.*, 496 F. Supp. 3d 31, 78 (D.D.C. 2020); *see also Cath. Legal Immigr. Network, Inc. v. Exec. Off. for Immigr. Rev.*, 513 F. Supp. 3d 154, 172 (D.D.C. 2021). The Departments' after-the-fact assertion that they "did not fail to consider" the adverse impact on access to IDR "but simply concluded that raising the fees was necessary," Opp. 15, does not cut it. An agency's consideration of an issue must be reasonably discernible from what it says. *State Farm*, 463 U.S. at 43. Nothing in the December 2022 Fee Guidance so much as hints at any assessment of the devastating effect the fee increase would have on providers' access to IDR. Even now, the Departments continue burying their heads in the sand—their brief does not mention radiologists even once.

The Departments also simply ignore plaintiffs' cases proving that "[t]he failure of an agency to consider obvious alternatives has led uniformly to reversal." *Yakima Valley Cablevision*, 794 F.2d at 746 & n.36. Under these cases, the only way to determine whether it was "eminently reasonable," Opp. 13, for the Departments to incur the costs of pre-eligibility reviews, to deem those costs recoverable through administrative fees (as opposed to through the IDR entity fees that the NSA envisions will cover the cost of arbitration), or to impose an across-the-board 600% fee increase is to consider whether there was "another reasonable path forward," *Spirit Airlines, Inc. v. DOT*, 997 F.3d 1247, 1255 (D.C. Cir. 2021). Here, plaintiffs have identified many such "obvious and less drastic alternative" paths. *Yakima Valley Cablevision*, 794 F.2d at 746. Because the Departments considered none of them, their decision "was arbitrary and capricious." *Id.*

The Departments belatedly try to address some alternatives. Opp. 14–16. They still ignore several of plaintiffs' proposals entirely. For example, they give no reason why they could not have

reduced eligibility disputes by enforcing insurers' compliance with existing disclosure requirements. *See* Mot. 24. But they now concede they could have "var[ied]" the fee "based on the value of the dispute" but did not because "a dispute generally costs the Departments the same amount regardless of" the size of the claim. Opp. 14. That the Departments must set fees to cover their annual expenses, however, does not dictate that each individual fee must correspond to the costs of resolving each individual dispute. And the fact that the Departments' discussion of this plausible alternative fee structure appears for the first time in their litigation brief simply underscores their complete failure to grapple with reasonable alternatives in the December 2022 Fee Guidance.[3]

The Departments also cannot justify ignoring the most obvious way to address their under-collection problems—*i.e.*, enforcing their regulation requiring parties to pay administrative fees at the outset of IDR, 45 C.F.R. § 149.510(d)(1)(i)—based on their "understanding" that the IDR entities' "payment processing systems … are currently set up to accept payment of" both the administrative fee and the IDR entity fee "as a single submission." Opp. 16. They did not give this reason in either their decision document or in the prior guidance authorizing IDR entities to violate the regulation. *See Chenery Corp.*, 318 U.S. at 87. And even if the Departments' post-hoc "understanding" is correct, the obvious solution is to amend the regulations so as to permit collection of both fees at the outset—not to violate a regulation intended to prevent the under-collection issues the agencies now face. Indeed, the financial data the Departments have now disclosed for the first time in this litigation underscore just how far enforcing this regulation would go in addressing the

[3] In another post-hoc rationale, the Departments fault plaintiffs for "fail[ing] to grapple with the reality" that the higher fee may also lead insurers to avoid IDR by compromising with providers. Opp. 15. But providers cannot engage in IDR unless it is cost-effective. Payers know this. So increasing the cost of IDR simply increases the pressure on providers to accept what insurers offer.

low collection rate the Departments cited as a justification for their 600% fee increase. *See* AR 9880 (estimating that both parties had paid the administrative fee in only 13% of initiated disputes).

Finally, the Departments give three textual reasons why making IDR cost-prohibitive for many providers is not, in fact, inconsistent with the NSA's purpose and structure. They first note that Congress "rejected a minimum claim threshold." Opp. 14–15. But that decision suggests an intent to *cover* small-dollar claims, not to *exclude* them. *See* Mot. 4, 29–30.

Similarly, Congress's mandate that administrative fees "not create a barrier to" accessing patient-provider IDR, 42 U.S.C. § 300gg-137(c); Opp. 15, does not suggest—in fact it refutes—the notion that the agencies need not even *consider* providers' access to IDR when setting administrative fees. The (absurd) upshot of the Departments' contrary inference is that they could set administrative fees so high as to exclude 50% or even 90% of claims from IDR—and never need to take that into account. Indeed, for all we know, that is what they have done here, because despite possessing the data to determine the answer, *see* Mot. 23, the Departments remain conspicuously silent as to the percentage of cases in which the amount in controversy is $350 or less. The Departments' failure even to analyze this issue was patently arbitrary and capricious.

The Departments also misconstrue the NSA's provision for a 90-day cooldown period for filing certain IDR claims as "wholly inconsistent with the guaranteed right to access the IDR process." Opp. 14 (citing 42 U.S.C. § 300gg-111(c)(5)(E)(ii)). In fact, the paragraph immediately after the one the Departments cite expressly provides that all the deadlines for filing claims are tolled during the cooldown period. 42 U.S.C. § 300gg-111(c)(5)(E)(iii). The cooldown provision thus underscores Congress's unwillingness to exclude *any* viable claims from IDR.

In the end, the Departments' post-hoc rationales reinforce that Congress intended to make IDR broadly available to as many claims as possible, regardless of their dollar amount. And they

confirm that by imposing a massive access fee (along with a restrictive batching rule) that severely curtails access to IDR for providers with small-value claims—including closing the door to the vast majority of radiology claims, *see* Mot. 14–15—the Departments have "not reasonably effectuate[d] Congress's intent." *Texas v. United States*, 497 F.3d 491, 506, 509 (5th Cir. 2007). The agencies' actions are thus not only unreasoned but contrary to law as well.

III. The Same-Service-Code Batching Rule Is Unlawful.

A. The Departments unlawfully bypassed notice and comment.

1. The batching rule is not a rule of agency procedure.

In the September Rule, the Departments asserted they had "good cause" to bypass the APA's notice-and-comment requirement. 86 Fed. Reg. at 56,043; *see* 5 U.S.C. § 553(b)(B). They now claim the batching regulations are exempt from that requirement altogether because they are "rules of agency, organization, procedure, or practice." 5 U.S.C. § 553(b)(A); *see* Opp. 23–24. But the Court is "foreclosed from affirming … on a ground" not "relied on by the agency," and the September Rule "relied on the 'good cause' exception"—*not* the one "for 'procedural rules.'" *Union of Concerned Scientists v. Nuclear Regul. Comm.*, 711 F.2d 370, 382 n.27 (D.C. Cir. 1983).

Regardless, the Departments' new theory fails because the exception for "rules of *agency* … procedure" applies only to "rules of *agency* … procedure." 5 U.S.C. § 553(b)(A) (emphases added). The exemption is a "limited carveout" for rules addressing "agency activities" and "internal house-keeping measures." *AFL-CIO v. NLRB*, 57 F.4th 1023, 1034 (D.C. Cir. 2023). It does not extend to rules that neither "govern internal agency operations" nor regulate how "parties present themselves or their viewpoints to the agency." *Id.* at 1036. To classify such rules—which regulate conduct *outside* the agency—as "rules of agency … procedure" would deprive the word "agency" of meaning. *See United States v. Menasche*, 348 U.S. 528, 538–39 (1955) ("It is [the court's] duty to give effect, if possible, to every clause and word of a statute.").

The batching rules are plainly *not* rules of *agency* procedure. IDR proceedings are not "agency-conducted adjudications"; they are "independent arbitrations"—in which private adjudicators resolve disputes between private parties. *Texas Med. Ass'n v. HHS*, No. 6:22-CV-372-JDK, 2023 WL 1781801, at *12 (E.D. Tex. Feb. 6, 2023) ("*TMA II*"). Procedural rules governing these proceedings address neither agency activities nor the public's interactions with an agency. Nor does the Departments' role in "supervising" the IDR process "convert every provision regarding [that] process into a rule of agency procedure." *AFL-CIO*, 57 F.4th at 1042. At bottom, the batching rules "facilitate" interactions among private parties in private arbitrations "outside the context of any agency proceeding," *id.* at 1036, so they are subject to notice and comment.

The Departments cite no authority applying the exception to an analogous rule. *See* Opp. 25–26 (citing cases about internal agency rules). Just the opposite: their cases say that the exception is for "agency housekeeping rules," *Pub. Citizen v. Dep't of State*, 276 F.3d 634, 640 (D.C. Cir. 2002); *JEM Broad. Co. v. FCC*, 22 F.3d 320, 328 (D.C. Cir. 1994), that "do not directly guide public conduct," *Dep't of Lab. v. Kast Metals Corp.*, 744 F.2d 1145, 1153 (5th Cir. 1984).

In any event, the batching regulation would not fall within the procedural-rule exception even if the exception extended to rules governing conduct outside of agencies. As the Departments acknowledge, Opp. 25, courts have long held that rules that have a "substantial impact" on private parties must go through notice and comment—even if the rules are procedural in character, *Phillips Petrol. Co.*, 22 F.3d at 620; *see also Air Transp. Ass'n of Am. v. DOT*, 900 F.2d 369, 375–78 (D.C. Cir. 1990), *vacated as moot*, 933 F.2d 1043 (D.C. Cir. 1991) (holding that rules governing internal agency adjudications were not procedural because they "substantially affected" private parties). And under those precedents, the batching rule does not qualify for the exception because it "substantially affect[s] [healthcare providers'] right to avail themselves of an … adjudication" of their

statutory right to reimbursement under the NSA, *Air Transp. Ass'n*, 900 F.2d at 375, and inflicts severe "economic consequences" on providers with small-value claims, *Brown Exp.*, 607 F.2d at 702. Those providers and other affected parties were entitled to notice and a chance to comment.

2. The Departments lacked good cause to bypass notice and comment.

The Departments also seek to defend their good cause determination, raising virtually the same arguments this Court rejected in *TMA I*. Once again, they invoke the statutory deadline for adopting IDR rules. Opp. 25–26. But a "deadlin[e] … does not in itself constitute good cause." *TMA I*, 587 F. Supp. 3d at 545. And, just as in *TMA I*, the Departments "fail to justify why they could not have provided notice and comment in the time" Congress allotted—"a full year." *Id.* Even if, as the Departments claim, the average rulemaking takes longer, Opp. 27, they still have no persuasive explanation for why they waited nine months to act or why they could not have used the remaining three months before the deadline to observe the proper procedures, *see* Mot. 21. Quoting *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994), the Departments assert that the "congressional deadlines [were] very tight" and the NSA "is particularly complicated." Opp. 25. But *Methodist* is still not "apposite here": it involved a much shorter deadline, plus a statutory exemption from notice and comment. *TMA I*, 587 F. Supp. 3d at 546.

The Departments' contention that providers, insurers, and arbitrators "need[ed] months of lead time to prepare," Opp. 26–27, also remains meritless. They still give no reason why they should be allowed to override Congress's determination that issuing rules in December 2021 would give sufficient "lead time." And the Departments' professed commitment to "reducing uncertainty is undercut by" their request "for post-promulgation comments, which could resul[t] in a [final] rule change." *TMA I*, 587 F. Supp. 3d at 546. Finally, even if parties needed "lead time" for *some* of the regulations adopted in the September Rule, "good cause [did] not exist to rush the provisions

… at issue here." *Id.* Parties did not need five or six months to plan how to group their claims. Providing notice and comment was neither impracticable nor contrary to the public interest.

3. The error was not harmless.

As in *TMA I* and with the fee increase, the Departments' failure to provide notice and comment was not harmless. Given the opportunity, providers "could have submitted the specific reasons … for why they believed" the Departments' batching rule is unduly narrow, presented alternatives to that restrictive approach, and explained "how the Rule would impact them." *Id.* at 547. The Departments assert that they "considered" plaintiffs' arguments, Opp. 28, but they did not. As already outlined, *see* Mot. 26–28, among the consequential issues never "considered," let alone "fully addressed," *TMA I*, 587 F. Supp. 3d at 547, are: (1) the statutory language on which the same-service-code rule is based and its relationship to the rule; (2) obvious alternatives, including allowing batching by provider sub-specialty and/or by service-code section; and (3) the impact on providers with small-value claims. Stakeholders pointed out these and similar issues in the post-promulgation comment period. *See, e.g.*, AR 6621–22, 7672, 7729–30, 8449.[4] It is far from "clear" that the failure to think through these fundamentals was harmless. *Johnson*, 632 F.3d at 931.

B. The same-service-code batching rule is arbitrary and capricious.

The same-service-code batching rule is also invalid because it is arbitrary and capricious. The Departments muster no excuse for their failure to address the statutory language on which the rule is premised. That language, which the rule nowhere mentions, authorizes the Departments to allow broad batching of claims for all the treatments or procedures provided to one or more patients

[4] The Departments err in arguing that plaintiffs are "foreclose[d]" from showing "prejudice" because they did not submit a post-promulgation comment. Opp. 27–28. Submitting a comment "is not required to find prejudice." *Johnson*, 632 F.3d at 933; *accord California*, 911 F.3d at 580; *Safari Club Int'l v. Zinke*, 878 F.3d 316, 335 (D.C. Cir. 2017); *United States v. Brewer*, 766 F.3d 884, 891 (8th Cir. 2014). Plaintiffs were not required to duplicate the comments submitted by other providers on the September Rule's batching criteria to preserve their ability to challenge the rule.

with "similar condition[s]." 42 U.S.C. § 300gg-111(c)(3)(A)(iii). Yet the Departments decided instead to strictly limit batching to claims involving the same service code. The Departments still refuse to acknowledge the gap between the statute and their regulation. And their failure to do so in the rule itself is fatal. The Departments may not leave this Court to guess at their "path." *See, e.g., United States v. Garner*, 767 F.2d 104, 123 (5th Cir. 1985). And principles of reasoned decisionmaking required the Departments to at least signal whether they were engaged in interpretation or policymaking. *See Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1029 (D.C. Cir. 2000); *see also* Mot. 27 (citing cases). Because of this alone, the rule violates the APA.

The Departments point out that the language they chose for their rule—"same or similar items and services," 45 C.F.R. § 149.510(c)(3)(i)(C)—is a "term of art used throughout the regulations" and given a "consistent meaning," Opp. 23. This is misdirection. The critical question the Departments failed to answer is how they got from the statute's "related to the treatment of a similar condition" requirement, 42 U.S.C. § 300gg-111(c)(3)(A), to their "same or similar items and services" requirement, 45 C.F.R. § 149.510(c)(3)(i)(C), when those phrases are plainly not coterminous. The Departments still do not say. Moreover, as the Departments are aware, Congress knew how to use "same or similar item or service" when it meant that—for example, in the definition of the QPA. *See* 42 U.S.C. § 300gg-111(a)(3)(E). That Congress chose different words for the batching provision highlights that the QPA and batching regulations need not mirror each other and that Congress authorized broader batching than the Departments permitted.

The rule also entirely failed to consider the serious adverse consequences of the restrictive batching rule or any alternatives to it. *See* Mot. 14–15. The Departments still do not acknowledge

that their rule restricts providers' ability to pursue IDR for certain claims, instead dismissing plaintiffs' "concerns" as matters of "convenience." Opp. 28. And they still have not clued in to the many alternatives that could have alleviated these negative effects. *See* Mot. 27.

The Departments did not address the rule's impacts or these alternatives in permitting "bundled payments" for items and services furnished in a single episode of care to be resolved in a single arbitration. *Contra* Opp. 24. The *statute* requires the Departments to provide that "items and services included in [a] bundled payment may be part of a single determination," 42 U.S.C. § 300gg-111(c)(3)(B), and in carrying out that instruction, the Departments said nothing about how the bundled-payment rule would impact access to IDR, *see* 86 Fed. Reg. at 55,994.

Nor does the bundled-payment rule fix the substantive problems with the same-service-code rule. Bundled payments are special "arrangements" between providers and insurers—not a model providers may opt for whenever they would like to join multiple claims arising out of a single episode of care. *See id.* Furthermore, as implemented, the bundled-payment rule is *also* limited by service code. Departmental guidance to IDR entities defines "a bundled arrangement" as "an arrangement under which … a provider … bills for multiple items or services under *a single service code*" or a "plan or issuer makes" a payment "under *a single service code* that represents multiple items or services." AR 8720 (emphases added).[5] Thus, parties may submit more than one item or service furnished during an episode of care for resolution in a single arbitration only if the

[5] In their guidance, the Departments gave the example of a claim for a "bilateral mammography." AR 8720. Under the bundled-payment rule, the parties need not separately arbitrate claims for a unilateral left mammography and a unilateral right mammography performed on the same patient because, although each has its own CPT code, there is also a separate CPT code for a "bilateral mammography." *Id.* Needless to say, this example—which did not appear in the rule itself—does not address the "fact pattern[s]" plaintiffs have pointed to. Opp. 24; *see, e.g.*, Compl., Doc. 1, ¶ 110 (describing patient encounter involving multiple CT scans and x-rays of different body parts).

payment was bundled *and* there is a service code corresponding to the items and services provided to that patient. The bundled-payment rule is a same-service-code rule by another name.

The Departments' original rationale for adopting a service-code-only approach—to "avoid combinations of unrelated claims that could … unnecessarily complicate" arbitrations, 86 Fed. Reg. at 55,994—was utterly conclusory. *See* Mot. 28–29. The Departments did not say what they meant by "unrelated," 86 Fed. Reg. at 55,994, or how considering multiple items and services "related to the treatment of a similar condition," 42 U.S.C. § 300gg-111(c)(3)(A)(iii), would be needlessly complex. The Departments' post-hoc elaborations hardly clarify: They still do not define "unrelated." And they now claim that complexity would arise if arbitrators had to "conside[r] multiple QPAs." Opp. 24. But there is no reason to think that arbitrators could not manage to evaluate multiple QPAs for related treatments, and indeed the Departments have acknowledged that under the current batching rules, arbitrators may consider batches involving "different QPAs." 86 Fed. Reg. at 55,994. This sort of illogic cannot justify the same-service-code batching rule.

IV. The Court Should Grant Plaintiffs' Requested Remedies.

The Departments maintain that the Court should remand without vacatur. Opp. 28–29. But "'by default, remand with vacatur is the appropriate remedy' when agency action is successfully challenged under the APA." *TMA II*, 2023 WL 1781801, at *13 (quoting *TMA I*, 587 F. Supp. 3d at 548). Unlike in cases where the agency's "error was one of form and not of substance," *Engine Mfrs. Ass'n*, 20 F.3d at 1184; *Am. Med. Ass'n*, 57 F.3d at 1135, here "the seriousness of the deficiency weighs heavily in favor of vacatur," *TMA I*, 587 F. Supp. 3d at 548. And vacatur would cause minimal disruption. Vacating the same-service-code batching rule would simply require arbitrators to apply a good faith interpretation of the statute's similar-condition batching requirement until the Departments' rulemaking concludes. And vacating the December 2022 Fee Guidance

would simply mean that the administrative fee would revert to $50 until the Departments substantiate a different amount through notice and comment. Of course, insofar as the Departments are concerned with under-collection in the interim, they can always adopt plaintiffs' proposals for increasing collection and decreasing the number of eligibility disputes. *See* Mot. 24–25.

The Departments' arguments against the requested refund fare no better. APA actions may seek "specific relief—which may include the recovery of specific property or monies." *Bowen v. Massachusetts*, 487 U.S. 879, 893 (1988) (cleaned up). The requested refund qualifies as such because plaintiffs seek the specific dollars—$300 out of every $350—they have paid since the fee increase, dollars the Departments do not say have been expended or comingled with other funds. *See, e.g.*, *Texas v. United States*, 336 F. Supp. 3d 664, 672 (N.D. Tex. 2018). Similarly, the NSA does not allow the Departments to exact an administrative fee until they have issued a valid fee rule, and a refund enforces that statutory mandate. *See id.* at 675 ("a district court may grant equitable disgorgement as a form of specific relief to enforce compliance with a statutory mandate").[6]

Lastly, courts have authority to extend statutory deadlines based on their powers to fashion appropriate equitable relief. *See, e.g.*, *Gomez v. Trump*, 490 F. Supp. 3d 276, 286–87 (D.D.C. 2020); *Defy Ventures, Inc. v. U.S. Small Bus. Admin.*, 469 F. Supp. 3d 459, 478 (D. Md. 2020). Here, for those providers who forwent claims they would otherwise have submitted but for the $350 administrative fee, the Court should extend IDR deadlines to effectuate Congress's intent that providers have access to IDR. *See, e.g.*, *NRDC v. EPA*, 22 F.3d 1125, 1135 (D.C. Cir. 1994).

CONCLUSION

For these reasons, the Court should grant plaintiffs' motion and deny the Departments'.

[6] Contrary to the Departments' suggestion, nothing in *Texas* turned on the fact the plaintiffs were states. Opp. 30 n.4. And although the court in *American Community Bankers v. FDIC*, 200 F.3d 822, 830 (D.C. Cir. 2000), ultimately declined to grant relief, it affirmed that a refund under the APA would have been available if the plaintiffs had been "correct" about the statute's meaning.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served on all counsel of record in accordance with the Federal Rules of Civil Procedure and this Court's CM/ECF filing system on March 27, 2023.

/s/ *Eric D. McArthur*
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