IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

NEUROLOGICAL SURGERY PRACTICE OF LONG ISLAND, PLLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No.1:23-cv-2977-BMC

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT AND MOTION FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

INTRODUCTION

On August 3, 2023, and August 24, 2023, a federal district court in Texas issued rulings that vacated—on a nationwide basis—key regulations implementing the No Surprises Act ("NSA" or the "Act") and its Independent Dispute Resolution ("IDR") process. *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs*. ("TMA IV"), No. 6:23-cv-59-JDK, 2023 WL 4977746 (E.D. Tex. Aug. 3, 2023); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs*. ("TMA III"), No. 6:22-cv-450-JDK, 2023 WL 5489028 (E.D. Tex. Aug. 24, 2023). Those orders required careful analysis, technological and systems updates to the IDR portal (the web-based platform used to initiate IDR disputes), and the issuance of guidance to IDR entities and other stakeholders about how to proceed. These steps could not be accomplished overnight, and the Texas court expressly recognized as much in its August 24 opinion, observing that a "pause in the [IDR] proceedings" might be the necessary result of its decision, but concluding that such an interruption in the resolution of disputes claims would not be "so disruptive that the Court should bypass the 'default rule' of vacatur." *TMA III*, 2023 WL 5489028, at *18.

Accordingly, Defendants, the Departments of Health and Human Services, Labor, and the Treasury ("Departments") temporarily paused IDR proceedings so that they could make the needed systems updates and issue updated guidance. But beginning on September 5, 2023—less than two weeks after Texas court's second opinion—the Departments began a phased reopening of IDR operations. The Departments have continued to reopen the IDR process in phases as each set of updates are made and further guidance is ready to be issued. As of this filing, the Departments have reopened the IDR portal for the initiation of new non-air ambulance single and bundled disputes and have directed IDR entities to resume processing all single and bundled disputes submitted on or before August 3, 2023. Additionally, parties impacted by the pause have been given additional time to submit and respond to new disputes. The Departments are working

as quickly as possible to make necessary systems updates and issue guidance to get the IDR process fully operational as soon as feasible.

Plaintiff's motions for leave to file a second amended complaint and for a preliminary injunction give short shrift to this crucial context. Plaintiff entirely fails to acknowledge the disruptive consequences of the nationwide vacatur of regulations governing the IDR process, claiming that the Departments should have perfectly predicted the Texas court's orders, which granted summary judgment for the defendants on some issues and for the plaintiffs on others. Pl.'s Mem. of Law in Supp. of Mot. for Leave to File a Second Am. Compl. and for a Prelim. Inj. at 6, ECF No. 36 ("Pl.'s Mem"). Indeed, Plaintiff goes so far as to claim that "nothing in that court's decision . . . even suggests suspension of federal IDR operations"—an assertion fundamentally at odds with the decision itself. *See TMA III*, 2023 WL 5489028, at *18 (noting that in response to prior decisions the Departments had found it necessary to "pause[] arbitration proceedings until issuing further guidance conforming to the statute and the Court's orders," and contemplating that "a temporary pause in the proceedings" might be necessary here as well).

The basis for Plaintiff's motion for leave to amend is a bit unclear in the absence of a proposed second amended complaint. But Plaintiff appears to seek to add two claims: (1) alleging that the Department's temporary pause of the IDR process violated the statutory command to "establish" an IDR process, Pl.'s Mem. at 5, and (2) alleging that the Departments' temporary pause on IDR proceedings while the Texas court's vacaturs could be implemented was without statutory or regulatory authority, *id*. Leave to amend should be denied, as neither claim would survive a motion to dismiss. This Court has already held that the Departments fulfilled their statutory duty to establish an IDR process, and the Departments' decision to temporarily pause IDR proceedings to make systems updates and issue guidance needed to implement the Texas

court's decisions was not only a practical necessity, but well within their discretion and entirely consistent with that court's order, which this Court should hesitate to contradict.

Plaintiff is also not entitled to an injunction. Not only do its claims have no likelihood of success on the merits, but Plaintiff has fallen well short of its burden to show that it will suffer irreparable harm without the requested injunction, or that the public interest and balance of equities favor reopening the entire IDR process right away—without necessary systems updates or guidance in place. The Departments share Plaintiff's desire to get the IDR process fully operational as soon as possible, and they are working diligently to make that happen. But the sort of order Plaintiff seeks, effectively directing a government agency to "hurry up," is not a proper injunction. Plaintiff's motions should be denied.

BACKGROUND

I. Congress enacted the No Surprises Act to protect patients from devastating 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). 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 receives care at certain types of in-network facilities, health care providers are generally prohibited (absent, in certain circumstances, the patient's consent) from balance billing the patient for any part of their care that is furnished by an out-of-network provider or facility. *See* 42 U.S.C. §§ 300gg-131, 300gg-132, 300gg-135.[1] Crucially, to effectuate the statute's goal of "No

[1] The Act makes parallel amendments to the Public Health Service Act ("PHSA") (administered by the Department of Health and Human Services ("HHS")), the Employee Retirement Income Security Act ("ERISA") (administered by the Department of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). In addition, the Act requires the Office of

Surprises," the patient's cost-sharing responsibilities are calculated "as if the total amount that would have been charged for such services by such participating provider or participating emergency facility were equal to the recognized amount." *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(B). The "recognized amount" is a term of art under the statute. If no All-Payer Model Agreement is in place in a given state, and no specified state law applies, the "recognized amount" is the "qualifying payment amount" ("QPA"), which is "determined in accordance with rulemaking" issued by the Departments. *Id.* § 300gg-111(a)(3)(H)(ii); *see also id.* § 300gg-111(a)(2)(B) (directing the Departments to issue rules setting the methodology for determining the QPA). The QPA is a statutory term of art. It is generally defined, for a given item or service and for a given plan or issuer, as "the median of the contracted rates recognized" by the group health plan or issuer, measured with respect to the payment rates for "the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished," under all the plans offered by that issuer in a given insurance market, "consistent with the methodology established by the Secretary under paragraph (2)(B)." *Id.* §§ 300gg-111(a)(3)(E)(i)(I), 300gg-112(c)(2). Thus, the statutory text treats the QPA as a reasonable proxy for what the in-network payment rate would have been for a given out-of-network service, for the purposes of calculating an insured patient's cost-sharing responsibilities.

In addition to setting the rules to determine a patient's payment obligations for a particular out-of-network medical service, the Act also establishes a process, in which the QPA also plays a central role, to resolve disputes between providers and plans over the amount of payment for such

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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 to the Act's amendments to the PHSA.

a service when no specified state law or All-Payer Model Agreement applies.[2] The Act specifies that a plan will issue an initial payment, or notice of a denial of payment, to a provider within 30 calendar days after the provider submits a bill to the plan for an out-of-network service. *Id*. § 300gg-111(a)(1)(C)(iv), (b)(1)(C). If the provider 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—a system of arbitration established by the Act. *Id*. § 300gg-111(c)(1)(B). Over 97% of out-of-network medical bills are resolved between the parties and fewer than 3% of payment disputes are resolved through the IDR process. *See*, AHIP, *New Study: No Surprises Act Protects 9 Million Americans from Surprise Medical Bills* (Nov. 17, 2022), https://perma.cc/KUV6-SE9D (1 million medical bills per month subject to the Act's procedures in each of the first 9 months of the Act); CMS.gov, *Federal Independent Dispute Resolution Process—Status Update* (Apr. 27, 2023), https://perma.cc/3XSJ-GL5F (334,828 disputes initiated through the federal IDR portal in the first year of operation).

The Act specifies that the Departments "shall establish by regulation," no later than December 27, 2021, "one independent dispute resolution process . . . under which[]" a private, independent arbitrator, known in the statute as a "certified IDR entity," "determines, . . . in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." 42 U.S.C. § 300gg-111(c)(2)(A). The Act employs a system of "baseball-style" arbitration under which the provider and the health plan will each submit an offer for a proposed payment amount and the

[2] In New York, the Emergency Medical Services and Surprise Bill Law, N.Y. Fin. Serv. Law § 601 *et seq*., prohibits balance billing under certain circumstances and provides a dispute resolution process to resolve payment disputes over certain out-of-network medical bills.

arbitrator will, within 30 business days, select one or the other offer as the amount of payment for the item or service 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). Among these considerations are the QPA and any additional information the parties submit or the arbitrator requests, such as information about the provider's training or the acuity of the patient's condition, among other things. *Id*. § 300gg-111(c)(5)(C)(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). Following an arbitrator's decision, a plan has 30 days to make the necessary payment. *Id*. § 300gg-111(c)(6).

The statute also requires that parties to the IDR process pay a fee for participating in the IDR process. These fees are used to fund the Departments' efforts to carry out the IDR process. *Id*. § 300gg-111(c)(8)(A)-(B). State and federal authorities share enforcement authority over provisions of the No Surprises Act. *See Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872, 36,899 (July 13, 2021) (explaining spheres of federal and state enforcement authority). The Act went into effect on January 1, 2022, and the first IDR proceedings began just over three months later.

II. The Departments issued rules to implement the Act's framework to protect patients and control health care costs.

Congress instructed the Departments to issue one set of rules no later than July 1, 2021, to establish "the methodology . . . to determine the qualifying payment amount," 42 U.S.C. § 300gg-111(a)(2)(B)(i), and to issue a second set of rules no later than December 27, 2021, to "establish . . . one independent dispute resolution process" for an arbitrator to determine the payment owed by a group health plan or health insurance issuer to an out-of-network provider, *id*. §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A).

The Departments released their first set of interim final rules on July 1, 2021 ("July 2021 IFR"). 86 Fed. Reg. at 36,872. Those rules implemented the Act's provisions that prohibit providers from balance billing their patients for out-of-network medical services in certain situations; limit patients' cost-sharing responsibilities for these services; require providers to make disclosures to patients about federal and state protections against balance billing; codify certain additional patient protections; set forth complaint processes for violations of the Act's balance-billing and out-of-network cost-sharing protections; and, most relevant here, set the methodology for determining the QPA. *See id*. at 36,876.

The second set of rules exercised Congress's delegation of authority to the Departments to "establish by regulation one independent dispute resolution process," 42 U.S.C. § 300gg-111(c)(2)(A), for the resolution of disputes between providers and health plans over the amount of payment for out-of-network services. In particular, the rules set forth procedures for IDR entities to be certified, and for providers and health plans to invoke the Act's IDR system. *See Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980, 55,985 (Oct. 7, 2021) ("September 2021 IFR"). 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. 45 C.F.R. § 149.510(c)(3)(i)(A)-(D).

In August 2022, the Departments issued final rules providing guidance to the IDR entities in deciding between the competing offers to be submitted by providers and health plans and setting the out-of-network payment amount for a given medical service.[3] Under the final rules, the

[3] Several provisions of the September 2021 interim final rule and subsequent August 2022 final rules were vacated by the Eastern District of Texas on February 23, 2022 and February 6, 2023, respectively. *See Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs*., 587 F. Supp. 3d 528 (E.D. Tex. 2022) *appeal dismissed*, No. 22-40264, 2022 WL 15174345 (5th Cir. Oct. 24, 2022);

certified IDR entity considers the QPA and any additional information the parties have submitted, and "must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate." *Id.* § 149.510(c)(4)(ii)(A).

In December 2022, the Departments issued guidance setting the administrative fee at $350 for disputes initiated during calendar year 2023 due to rising costs incurred by the Departments in an effort to help the IDR process run more efficiently. *See* CMS.gov, *Amendment to Calendar Year 2023 Fee Guidance or the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee* (Dec. 23, 2022), https://perma.cc/YZ9U-YTP8.

III. The *TMA III* and *TMA IV* opinions vacated rules nationwide.

On November 30, 2022, a group of plaintiffs consisting of a medical association, a physician, and a hospital filed a lawsuit in the Eastern District of Texas challenging the Departments' regulations governing how plans and issuers calculate the QPA. *See TMA III*, 2023 WL 5489028, at *2. On January 30, 2023, those same plaintiffs (with a few additional plaintiffs) filed a lawsuit before the same court challenging the amount of the statutorily required fee that each party to the IDR process must pay to participate in IDR proceedings, as well as the regulations that governed which items and services may permissibly be combined and submitted jointly for resolution in a single IDR proceeding (called "batching"). *TMA IV*, 2023 WL 4977746, at *2. In both cases, the Departments argued that, if the court disagreed with the Departments on the merits, the court should remand without vacatur because vacatur would disrupt the IDR process, requiring

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Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs., __ F Supp. 3d __ , 2023 WL 1781801 (E.D. Tex. Feb. 6, 2023), *appeal filed*, No. 23-40217 (5th Cir. Apr. 11, 2023). The IDR portal opened in April 2022, but after portions of the final rules were vacated in February 2023, there was a pause on payment adjudications for several weeks while the Departments drafted new guidance for arbitrators. *See* CMS.gov, *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities* (updated March 2023), https://perma.cc/GQ82-DKGF ("March 2023 Guidance").

an immediate pause of all IDR proceedings. *See* Defs.' Mem. in Supp. of Cross-Mot. for Summ. J. at 50, *TMA III*, No. 6:22-cv-450 (E.D. Tex. Mar. 3, 2023) ECF No. 41 ("Vacatur would be highly disruptive, as it would require an immediate pause of all . . . IDR proceedings under the Act[.]"); Defs.' Mem. in Supp. of Cross-Mot. for Summ. J. at 29, *TMA IV*, No. 6:23-cv-059 (E.D. Tex. Mar. 15, 2023) ECF No. 41 ("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[.]").

On August 3, 2023, in *TMA IV*, the Texas court vacated both the $350 administrative fee and the batching regulations. *TMA IV*, 2023 WL 4977746, at *15 (vacating 45 C.F.R. § 149.510(c)(3)(i)(C)). On August 24, 2023, in *TMA III*, the Texas court vacated regulations that set forth the methodology for calculating the QPA. *TMA III*, 2023 WL 5489028, at *18.[4] As discussed above, the QPA plays several key roles under the Act, including in the IDR process where IDR entities consider the QPAs when resolving payment disputes. 42 U.S.C. § 300gg-111(c)(5)(C)(i)(I). In *TMA III*, the court recognized that the Departments had argued that vacatur would be disruptive, but concluded that, in its view, a "pause in the [IDR] proceedings" would not be more harmful than allowing the challenged regulations to remain in place. 2023 WL 5489028, at *18. The court noted that, following prior decisions, "the Departments simply paused arbitration proceedings until issuing further guidance conforming to the statute and the Court's orders" and it suggested that "a temporary pause in the proceedings" was an available course here as well. *Id*.

Thus, the Departments temporarily suspended IDR operations in order to make changes

[4] The court granted the defendants' motion for summary judgment on two claims: upholding the regulations specifying what information plans must disclose concerning their QPA calculations, *id*. at *10, and defining geographic area for purposes of calculating air ambulance QPAs, *id*. at *16.

necessary to comply with the Texas court's decisions in *TMA III* and *TMA IV*. *See* CMS.gov, *Federal Independent Dispute Resolution (IDR) Process Partial Reopening of Dispute Initiation Guidance* (Oct. 6, 2023), https://perma.cc/SP5Y-KGA4 ("IDR Reopening Guidance"). The Texas court's decisions required technological and systems updates to the IDR portal (the web-based platform used to initiate disputes and submit information to IDR entities), *id*. at 3 (describing changes necessary to ensure that parties were not charged the vacated administrative fee amount), as well as the promulgation of guidance to aid parties and IDR entities in understanding their obligations and the state of the law in light of the vacated regulations, *see* CMS.gov, *FAQs About Consolidated Appropriations Act, 2021 Implementation Part 62*, (Oct. 6, 2023), https://perma.cc/GJ8F-SU5Q. But in early September 2023, just two weeks after the Texas court's decision in *TMA III*, the Departments began a phased reopening of the IDR process. Effective September 5, 2023, the Departments directed certified IDR entities to proceed with eligibility determinations for single and bundled disputes submitted on or before August 3, 2023. CMS.gov, *Payment disputes between providers and health plans*, (Oct. 6, 2023) https://perma.cc/LEV9-LA4S. On September 21, 2023, the Departments directed certified IDR entities to resume processing all single and bundled disputes submitted on or before August 3, 2023. IDR Reopening Guidance at 1. And on October 6, 2023, the Departments completed the necessary guidance and system updates related to the administrative fee and the QPA and reopened the IDR portal for the initiation of single disputes, including single disputes involving bundled payment arrangements, other than air ambulance disputes. *Id*. at 3.[5] The Departments are working as quickly as possible

[5] The Departments have also extended the deadlines for initiating IDR disputes for parties impacted by the temporary suspension of the IDR process, and parties for whom the IDR initiation deadline fell between August 3, 2023 and November 3, 2023 will have until November 3, 2023 to initiate a new dispute. IDR Reopening Guidance at 3.

to issue additional guidance and system updates necessary to reopen the IDR portal for the initiation and processing of batched disputes and the initiation of disputes involving air ambulance services. *Id*.

IV. This litigation.

Plaintiff is an independent neurosurgery practice group. Pl.'s Mem. at 1. It has chosen to remain out-of-network with most health plans, and accordingly some of the items and services it provides are subject to the provisions of the Act. *Id*. Plaintiff alleges that its practice relies on the reimbursement from health plans subject to the Act's processes, including the IDR process. *Id*. The Court previously dismissed Plaintiff's original complaint and denied Plaintiff's first preliminary-injunction motion, but granted Plaintiff leave to file an amended complaint. *See* Mem. Decision & Order, ECF No. 21. While Defendants' motion to dismiss Plaintiff's first amended complaint was pending, *see* ECF Nos. 25, 26, 28, Plaintiff filed a motion for leave to file a second amended complaint and for a preliminary injunction. ECF Nos. 34, 36.

LEGAL STANDARDS

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that the "court should freely give leave [to amend] when justice so requires." However, a court may deny leave if "there is a substantial reason to do so, such as excessive delay, prejudice to the opposing party, or futility." *Friedl v. City of New York*, 210 F.3d 79, 87 (2d Cir. 2000).

"The preliminary injunction 'is one of the most drastic tools in the arsenal of judicial remedies.'" *Doe v. U.S. Merch. Marine Acad.*, 307 F. Supp. 3d 121, 142 (E.D.N.Y. 2018) (citations omitted). It "is an extraordinary remedy never awarded as of right," *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), "one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion," *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) (citation omitted). A plaintiff must establish that four factors have been met: "that he is

likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 486 (2d Cir. 2013) (quoting *Winter*, 555 U.S. at 20).

A plaintiff that seeks a mandatory injunction—that is, an injunction that commands some positive act—must "meet a heightened legal standard by showing 'a clear or substantial likelihood of success on the merits.'" *N. Am. Soccer League, LLC v. U.S. Soccer Fed'n*, 883 F.3d 32, 37 (2d Cir. 2018). Additionally, where a party seeks injunctive relief that "will affect government[al] action taken in the public interest pursuant to a statutory or regulatory scheme, the injunction should be granted only if the moving party meets the more rigorous likelihood-of-success standard." *Sussman v. Crawford*, 488 F.3d 136, 140 (2d Cir. 2007) (citations omitted). This heightened requirement "reflects the idea that governmental policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly." *Otoe-Missouria Tribe of Indians v. N.Y. State Dep't of Fin. Servs.*, 769 F.3d 105, 110 (2d Cir. 2014) (quoting *Able v. United States*, 44 F.3d 128, 131 (2d Cir.1995)).

ARGUMENT

I. The Court should deny Plaintiff's motion for leave to file a second amended complaint.

Plaintiff has not submitted a draft second amended complaint, so the exact basis for the new claims it wishes to add is unclear. However, Plaintiff appears to seek to add two claims challenging a temporary pause of the IDR process that has since largely been lifted. First, Plaintiff seems to seek to add a claim that the temporary pause of the IDR process violated the Departments' statutory obligation to "establish by regulation" the IDR process. Pl.'s Mem. at 2. Second, Plaintiff

seems to argue that the temporary pause on the IDR process in order to respond to the Texas court's vacaturs was done without statutory or regulatory authority and that the Departments have failed to take a discrete, mandatory action in not keeping the IDR process running continuously. *Id*. at 3.

Plaintiff's proposed amendment would be futile, as neither claim would survive a motion to dismiss. Not only have subsequent events overtaken Plaintiff's new allegations, but this Court has already found that the Departments discharged their obligation to establish an IDR process long ago, and the temporary pause—implemented solely to respond to changes required by adverse judgments entered by a district court in separate litigation—was not only a practical necessity but well within the Departments' discretion. Plaintiff essentially seeks to add claims, and request an injunction, ordering the Departments to make technological and systems updates and issue guidance *faster*. But an order that is "not much more than a direction to 'hurry up' . . . is not a proper injunction." *L.V.M. v. Lloyd*, 318 F. Supp. 3d 601, 621 (S.D.N.Y. 2018). The Departments are already working diligently to make the changes necessitated by the orders of a sister district court, as demonstrated by their progress in reopening much of the IDR portal. Plaintiff fails to meet its heavy burden to show that this Court's emergency intervention is appropriate.

A. Plaintiff's proposed amendment is largely moot and futile because it has been overtaken by subsequent events.

Plaintiff's proposed amendment challenges the largely-now-lifted pause of IDR proceedings. As a result, it is largely moot and futile, as it largely seeks to compel actions that have already been undertaken. *See Winzler v. Toyota Motor Sales U.S.A., Inc.*, 681 F.3d 1208, 1210 (10th Cir. 2012) ("[I]f events so overtake a lawsuit that the anticipated benefits of a remedial decree no longer justify the trouble of deciding the case on the merits, equity may demand not decision but dismissal."). As of October 6, 2023, the Departments have reopened the IDR portal for the initiation of new single and bundled disputes (other than air ambulance disputes) and certified IDR

entities have resumed processing all single and bundled disputes already submitted to the IDR portal and assigned to a certified IDR entity. *See generally* IDR Reopening Guidance. The only IDR processes that remain unavailable relate to air ambulance services (which Plaintiff cannot challenge, as it is not an air ambulance provider) and batched disputes (*i.e.*, multiple items and services submitted jointly for resolution in a single IDR proceeding). Plaintiff has not submitted evidence that it intends to submit either air ambulance or batched disputes, and so it has not demonstrated that the remaining aspects of the pause injure it at all, depriving it of standing to challenge them. Article III's injury-in-fact component requires that a plaintiff's alleged injury "must be 'concrete and particularized' as well as 'actual or imminent, not conjectural or hypothetical.'" *Baur v. Veneman*, 352 F.3d 625, 632 (2d Cir. 2003) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)); *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (holding that a plaintiff seeking prospective relief must show that he or she is "likely to suffer future injury" from the defendant's conduct). And the Departments are in the process of issuing guidance and making technological and systems updates to the IDR portal to resume operations of air ambulance disputes and batched disputes as soon as possible. The Departments will continue to update Plaintiff and this Court as additional aspects of the IDR process resume operations.

B. The Departments have complied with their statutory obligation to "establish" an IDR process.

Plaintiff's proposed new claim alleges that the Departments' temporary pause in the IDR Process violates their statutory duty to "establish" the IDR process. This claim fails as a matter of law and, as such, amendment to include this claim would be futile. In this Court's July 17, 2023 Opinion and Order, this Court held that "Defendants have undisputedly established an IDR process[.]" ECF No. 21 at 10. As it recognized, the statute requires only that the Departments

"shall establish" an IDR process, *id*. (citing 42 U.S.C. § 300g-111(c)(2)(A)), nothing more. "[W]hen an agency is compelled by law to act within a certain time period, but the manner of its action is left to the agency's discretion, a court can compel the agency to act, but has no power to specify what the action must be." *Id*. (quoting *Norton v. S. Utah Wilderness All.* ("*SUWA*"), 542 U.S. 55, 65 (2004)). The IDR process has been established, and the temporary pause on certain IDR proceedings has not nullified the regulations establishing the process or abolished the IDR process. Even Plaintiff's framing of the issue recognizes that the Departments have "suspended IDR process operations," not abolished the IDR process entirely. *See* Pl.'s Mem. at 8. And Plaintiff seemingly recognizes that, to succeed on this claim, it would have to meet the high standard for mandamus, which it has not come close to meeting. *Id*. at 5 (citing the All-Writs Act, 28 U.S.C. § 1651(a)). And the IDR process has largely resumed operations, as the temporary pause has been lifted for all but a few categories of disputes, none of which Plaintiff has claimed impact it.

C. The Departments acted lawfully and within their authority in responding to the Texas court's vacaturs.

Plaintiff's proposed claim alleging that the temporary pause exceeds the Departments' statutory and regulatory authority likewise fails. As discussed above, the Texas court's decisions in *TMA III* and *TMA IV* disrupted the IDR process, requiring the Departments to make system updates and issue guidance to conform to the Court's orders. Implementing a temporary pause of IDR proceedings to do so was not only a practical necessity, but well within the Departments' discretion and fully consistent with the Texas court's order. When a court vacates and sets aside an unlawful agency action, "it is the prerogative of the agency to decide in the first instance how best to provide relief." *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013) (citing *N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012)). Under settled principles of administrative law, "when 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." *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). The practice of remand to an agency, even following vacatur, is in keeping with "the fundamental principle that agency policy is to be made, in the first instance, by the agency itself—not by courts, and not by agency counsel." *New York v. U.S. Dep't of Health & Hum. Servs*., 414 F. Supp. 3d 475, 578 (S.D.N.Y. 2019) (quoting *Harmon v. Thornburgh*, 878 F. 2d 484, 494 (D.C. Cir. 1989)).

After the Texas court's orders, the challenged regulations were vacated and remanded to the Departments so that they could take further action made necessary by that court's opinions—which, as a practical matter, required a temporary pause in the IDR process so that needed systems changes could be implemented, and guidance could be drafted. Plaintiff insists that the temporary pause of the IDR process "makes little sense given that nothing in [the Texas court's] decision requires or even suggests suspension of federal IDR operations.". Pl.'s Mem. at 6. But, to the contrary, the Texas court *expressly* recognized that a result of its order might be "a temporary pause in the [IDR] proceedings," suggesting in that court's view that such an interruption would not be "more disruptive" than the Departments' requested remedy of remand without vacatur. *TMA III*, 2023 WL 5489028, at *18. Indeed, the court acknowledged that when it vacated rules in prior No Surprises Act cases, the Departments had taken just this course and "simply paused arbitration proceedings until issuing further guidance conforming to the statute and the Court's orders." *Id*. The Texas court thus explicitly acknowledged that a temporary pause in the IDR process would likely be the natural consequence of its decision, and, despite the fact that the Departments had argued that such an interruption would be disruptive, blessed the same course here. *Id*. Indeed, the alternative that Plaintiff urges—essentially, to reopen the IDR portal immediately, before needed

systems changes have been fully implemented—could raise compliance issues with the Texas court's orders and generate a separate set of legal challenges in a sister district court. This Court should hesitate before entering injunctive relief at odds with the Texas court's expectations about how the Departments would comply with its decisions. *Cf. Zambrana v. Califano*, 651 F.2d 842, 844 (2d Cir. 1981) ("Generally, principles of comity and judicial economy make courts reluctant to exercise jurisdiction over claims involving the orders of coordinate courts.").

Plaintiff ignores not only the Texas court's own words, but also the practical reality of implementing that court's orders—something that could not simply be accomplished overnight, as Plaintiff seems to imply. For example, the Texas court vacated the $350 administrative fee that parties must pay to participate in the IDR process. *TMA IV*, 2023 WL 4977746 at *13. In light of the vacatur, the administrative fee reverted to the previous $50 fee. *See* CMS.gov, *Federal Independent Dispute Resolution (IDR) Process Administrative Fee FAQ*, (Aug. 11 2023), https://perma.cc/Q8WM-8XFA. However, the practical aspects of implementing that change into the real world was a time-consuming and complex process that necessitated drafting and issuing guidance on a number of issues. *See id*. The Departments issued guidance addressing the effects of the Texas court's decision and, as the Administrative Fees FAQ guidance shows, the questions raised by the court's decisions are complex and require careful analysis and explanation. *Id*. Additionally, the IDR portal had been programmed in accordance with the now-vacated guidance to request payment of a $350 fee, which was then remitted to the Departments by IDR entities, and accordingly technological and systems updates needed to be made to ensure that parties were not charged the vacated administrative fee amount. *See* IDR Reopening Guidance at 3. This necessitated a temporary suspension of the ability to initiate new disputes in the Federal IDR portal. *Id*. This is just one illustrative example why a temporary pause in IDR proceedings was necessary

following the nationwide vacaturs effected by the *TMA III* and *TMA IV* court decisions. The Departments continue to make further systems changes to the IDR portal, including removing screen language and system validations that reflected the vacated batching regulations and air ambulance batching guidance. *Id* at 4-5.

Plaintiff cannot reasonably dispute that such updates must be made, and guidance issued, in light of the Texas court's opinions. Especially when implementing a complex program like the IDR process that is undergoing rapid regulatory change required by court order, guidance to regulated parties is necessary to provide clarity and reduce confusion. As the D.C. Circuit has recognized, "the absence of specific and immediate guidance from the Department in the form of new standards" following a vacatur of regulations "would have . . . create[ed] confusion . . . and caused economic harm and disruption to" regulated parties. *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1157 (D.C. Cir. 1981). Here, the Departments opted for a short pause in the IDR process in order to prevent the widespread confusion that would have resulted in the absence of specific guidance on the impacts of the Texas court's decisions.

Plaintiff dislikes that it has taken the Departments several weeks to implement these necessary systems updates and issue necessary guidance, and evidently believes the Departments should have done so faster. But Plaintiff points to no basis in law—least of all the text of the No Surprises Act—to require the Departments to implement the complex changes required by the Texas court's order on the time frame Plaintiff would prefer. And for good reason—agencies need the administrative flexibility to make necessary changes after a highly disruptive court order. And as much as Plaintiff seems to believe these changes should have happened overnight, or the Departments should have perfectly predicted the contours of the Texas court's rulings in these cases, the reality is that complicated technological updates and guidance documents take time to

complete.

Because Plaintiff's proposed new claims could not survive a motion to dismiss, leave to amend would be futile and should be denied.

II. Plaintiff is not entitled to a preliminary injunction.

Plaintiff has in any event fallen well short of its heavy burden to establish entitlement to emergency injunctive relief. Not only are its claims likely to fail on the merits, as discussed above, but it cannot establish irreparable harm, or show that the equities and the public interest favor issuing the requested injunction. Furthermore, while Plaintiff's requested injunction lacks both specificity and clarity, it largely appears to seek to speed up the reopening of the IDR process. But an injunction generally requesting that the government act faster is not a proper injunction. *See Lloyd*, 318 F. Supp. 3d at 621. "In these circumstances, an order to expedite the processing is not much more than a direction to 'hurry up' and that is not a proper injunction." *Id*. (citing *Petrello v. White*, 533 F.3d 110, 115 (2d Cir. 2008) ("[A]n order for specific performance that lacks specificity is not a proper injunction.")).[6]

A. Plaintiff has not established irreparable harm.

"Irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction[.]" *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005) (quoting *Rodriguez v. DeBuono*, 175 F.3d 227, 233-34 (2d Cir. 1999)). To satisfy this requirement, Plaintiff "must demonstrate that absent a preliminary injunction [it] will suffer 'an injury. . . that

[6] Plaintiff did not file a copy of the proposed second amended complaint, nor has it provided proposed language for an injunction. Defendants therefore cannot properly evaluate whether the requested relief satisfies Federal Rule of Civil Procedure 65 which requires that injunctive relief "state its terms specifically" and "describe in reasonable detail . . . the act or acts restrained or required." Fed. R. Civ. P. 65(d); *Petrello*, 533 F.3d at 115 (holding that "an order for specific performance that lacks specificity is not a proper injunction."). If the requested relief is to simply "reopen" the IDR process, it would lack the requisite specificity.

cannot be remedied 'if [the Court] waits until the end of trial to resolve the harm."' *Spitzer*, 408 F.3d at 114 (quoting *Rodriguez*, 175 F.3d at 234-35). Monetary harm alone is generally insufficient. *See Kamerling v. Masssanari*, 295 F.3d 206, 214 (2d. Cir. 2002).

Plaintiff has failed to substantiate any of its allegations that it will suffer irreparable harm in the absence of an emergency injunction. *See Nosik v. Singe*, 40 F.3d 592, 595 (2d Cir. 1994) ("To get a preliminary injunction, [the movant] bears the burden of showing that she will suffer irreparable harm without it."). To do so, it must show that the alleged harm is both *caused* by the temporary (and, as of this filing, largely lifted) pause of IDR proceedings and would be relieved by lifting the limited portion of that pause that remains in effect—the pause on air ambulance disputes and batched disputes. "A plaintiff may be irreparably harmed by all sorts of things, but the irreparable harm considered by the court must be caused by the conduct in dispute and remedied by the relief sought." *Sierra Club v. U.S. Dep't of Energy*, 825 F. Supp. 2d 142, 153 (D.D.C. 2011); *id*. at 151 (denying injunction where Plaintiff "failed to show a likelihood that an injunction . . . would redress their members' injuries"). Here, however, Plaintiff has not come close to establishing that its alleged harm would be alleviated by the requested injunction. To the contrary, Plaintiff bases its allegations of harm on its generalized complaints about the IDR process overall and about delays by plans and issuers—the same complaints raised in its initial preliminary injunction motion, which this Court has already addressed. *See* ECF No. 21.

Importantly, Plaintiff does not allege that its harms are traceable to the ongoing remaining pause on batched disputes and air ambulance services; indeed, Plaintiff does not even claim that it has submitted or intends to submit batched disputes for IDR resolution such that the remaining pause has any impact on Plaintiff at all. *See generally*, ECF No. 35 [filed under seal]; *see also Wisdom Imp. Sales Co., v. Labatt Brewing Co*., 339 F.3d 101, 113 (2d Cir. 2003) (The "question .

. . [is] whether the evidence supports the . . . conclusion that [the movant] has demonstrated irreparable harm."). Indeed, Plaintiff acknowledges that its claimed harm flows from the same IDR process flaws upon which it based its first complaint and preliminary injunction motion. *See* Pl.'s Mem. at 8 ("The IDR process delays, low initial reimbursements, and unpaid additional reimbursement awarded in IDR decisions before this current suspension all combined to place Plaintiff and other similarly situated out-of-network providers in serious financial jeopardy."); *id*. (relying on "[p]reviously submitted declarations" and the same harms "[a]s previously explained"). Plaintiff's harm is therefore not traceable to the conduct it seeks to challenge in the proposed new claims and would therefore not be remedied by the requested injunction here. *See Mostaghim v. Fashion Inst. of Tech*., No. 01-cv-8090, 2001 WL 1537545, at *3 (S.D.N.Y. Dec. 3, 2001) ("[E]ven if [Plaintiff] were ultimately to prevail on his . . . claim, the Court could not upon this finding prevent [the irreparable harm Plaintiff alleges].").

Furthermore, Plaintiff has failed to identify any harm that cannot be remedied by monetary compensation from health plans—compensation which, if awarded in an IDR proceeding, it will eventually receive. Plaintiff's declarations describe nothing more than financial injuries that are making the practice less profitable, but the purely financial nature of this injury makes injunctive relief inappropriate. *See CRP/Extell Parcel I, L.P. v. Cuomo*, 394 F. App'x 779, 781 (2d Cir. 2010) ("We have long held that an injury compensable by money damages is insufficient to establish irreparable harm."). What Plaintiff challenges through its preliminary injunction motion is not the denial of payment, but instead a slight delay in having its payment disputes adjudicated in the IDR process. Because Plaintiff has failed to show that it will suffer non-monetary harm, or that its harm is not merely temporary, it has failed to meet its burden to show irreparable harm.

B. The equities and the public interest disfavor injunctive relief.

The public interest and the balance of the equities also weigh strongly against granting

Plaintiff's motion. *See Nken v. Holder*, 556 U.S. 418, 435 (2009) (noting that these factors merge when the government is a party). As discussed above, Plaintiff does not show any injury, much less irreparable harm, caused by what remains of the temporary pause. *See supra* II.A. Plaintiff's requested injunction, however, would impose a significant burden on the Defendants and disserve the public. The Departments issued the challenged pause in the IDR process in order to make systems changes and issue guidance necessitated by the Texas court's decisions—the Departments could not simultaneously comply with those orders and leave the IDR process continuing uninterrupted. The balance of the equities and the public interest weigh in favor of allowing the Departments to complete the steps needed to respond to that court's orders.

As explained above, the Texas court's decisions have required a variety of complex technological and systems updates, which take time to implement correctly. Moreover, the Departments have needed to provide crucial guidance to stakeholders, IDR entities, and the public to help them understand the implications of that court's decisions and their rights and obligations under the remaining regulations. Plaintiff, however, urges the Court to enjoin the Departments to somehow immediately resume all IDR process operations in the absence of the necessary updates and guidance—a task that, even if possible, would require a massive reallocation of agency resources. This request, if granted, threatens to introduce even greater uncertainty into the IDR process, as disputing parties could be forced to attempt to navigate that process without the needed technological updates or guidance about their obligations, which would further stymie their efforts to effectively use the IDR portal.

Furthermore, Plaintiff's requested injunction would effectively mandate that three federal agencies train their efforts on Plaintiff's preferred policy goals, rather than exercising their expertise to ensure the best possible functioning of the No Surprises Act. Redirecting already

limited and strained resources to immediately reopening the IDR process would mean fewer resources available, for example, for investigation and enforcement actions against plans and issuers that fail to meet payment deadlines, and fewer resources to assist the certified IDR entities to alleviate the backlog of disputes. Plaintiff's proposed injunction would hamstring the Departments' ability to administer a complex statutory and regulatory framework that is a vital piece of Congress's goal to protect against surprise billing and is decidedly not in the public interest.

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiff's motions for leave to file a second amended complaint and for a preliminary injunction.

Dated: October 11, 2023

Respectfully submitted,

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