Multiple Documents

Part	Description
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2	Exhibit Ex. A Decl. of William Barron
3	Exhibit Ex. B. Decl. of Jeff Wu

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

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

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Millions of Americans, at one time or another, may face a critical decision whether to seek health care services "in network" or "out of network," in other words, from a provider that has a contract with the patient's health plan, or from a provider that does not. As anyone familiar with health insurance can attest, the cost difference between receiving care from an in-network versus an out-of-network provider can be substantial. And, in many cases, a patient might not be able to avoid extra costs by choosing an in-network provider.

For example, in an emergency, the patient might be taken to an emergency department at a hospital that turns out not to be in-network. Or the patient might carefully schedule a procedure at an in-network facility but, unbeknownst to him or her, a portion of the services could be performed by an out-of-network provider. Cases like these have often led to staggering, and sometimes ruinous, medical bills. What is more, this phenomenon of surprise billing has also inflated the cost of in-network care, because many providers have simply refused to negotiate for fair payment rates in advance, knowing that they could fall back on the option of demanding exorbitant out-of-network payments.

In late December 2020, Congress enacted the No Surprises Act ("NSA" or the Act). The principal aim of the Act is to address this "surprise billing" problem at a nationwide level. The Act limits a patient's share of the cost of emergency services delivered by out-of-network providers, or of the cost of certain non-emergency services provided by out-of-network providers at in-network facilities. The Act also addresses how a payment dispute in these situations between an out-of-network provider or facility and a group health plan or issuer will be resolved. If no applicable state law or All-Payer Model Agreement applies to the claim, and if the parties are unable to reach an agreement through negotiation, the Act creates an arbitration mechanism, called the Independent Dispute Resolution ("IDR") process, whereby each party submits its proposed

payment amount and an independent private arbitrator, known as a "certified IDR entity," will select between the two.

The principal provisions of the Act went into effect on January 1, 2022, and claims began to reach the arbitration process in April 2022. The Defendants here—the Departments of Health and Human Services, Labor, and the Treasury (the "Departments")—have worked tirelessly over the past two years to build, from the ground up, the regulatory framework needed to implement the Act. This has been a tremendous, multifaceted undertaking. The Departments have, for example, issued regulations and guidance setting forth how to calculate patient cost-sharing, explaining how payers and providers can negotiate out-of-network payments and participate in the IDR process, and implementing other provisions of the law. And these efforts have been paying off for patients every month. *See* Press Release, Am. Health Ins. Plans, *New Study: No Surprises Act Protects 9 Million Americans from Surprise Medical Bills*, (Nov. 17, 2022) (the Act protects patients from one million surprise medical bills every month).

Plaintiff here makes a variety of vague and unsupported allegations that the Departments' efforts to implement the Act and oversee regulated entities have been insufficient. It requests a sweeping injunction ordering the Departments to take a long list of actions, including devoting more financial resources to the IDR process, and asks the Court to oversee the Departments' compliance with that injunction through intrusive weekly status reports. Plaintiff's claims fail, however, because its alleged injuries result from delays by health plans and arbitrators, not the Departments, and it therefore lacks standing to pursue these claims against the Departments. Plaintiff's claims also fail because it cannot point to any specific and unequivocal statutory command requiring the Departments to take the requested actions, as is required in a case challenging agency inaction. Furthermore, to the extent Plaintiff alleges that the Departments have

inadequately exercised their enforcement authority to compel these third parties to comply with statutory deadlines, an agency's enforcement discretion is not subject to judicial review. What Plaintiff ultimately appears to seek is wholesale improvement of a government program by court order. But the APA does not permit such claims, and for good reason. The implementation of the No Surprises Act requires a careful balancing of limited resources and complex policy choices that Congress charged the Departments, not courts, to make. For these reasons, the Court should deny Plaintiff's Motion for a Preliminary Injunction and dismiss this case for failure to state a claim.

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). Most health plans and health insurance issuers "have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services." *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872, 36,874 (July 13, 2021).[1] When an individual receives care from a provider outside of their plan network, however, the plan could decline to pay for the services, or could pay an amount lower than the provider's billed charges, leaving the patient responsible for the balance of the bill. *Id*. This practice, where the provider bills the patient for the difference between the charges the provider billed and the amount paid by the patient's health plan, is known as balance billing or, where the patient did not select the provider, surprise billing. This out-of-network billing phenomenon had been rapidly growing before Congress acted, indeed, "becoming

[1] For ease of reference, this brief uses "health plan" to refer to group health plans and health insurance issuers, and "provider" to refer to both providers and facilities.

more common and potentially more costly in both the emergency department and inpatient settings." Eric C. Sun et al., *Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals*, 179 JAMA INTERN. MED. 1543, 1544 (2019) (finding mean potential liability to patients from balance bills increased from $804 to $2040 between 2010 and 2016).

The Act protects insured patients from unexpected liabilities arising from the most common forms of balance billing. If an insured patient receives emergency care, or receives care that is scheduled 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.[2] Likewise, the patient's cost-sharing responsibilities for out-of-network services may not exceed their financial responsibilities "that would apply if such services were provided by a participating provider or a participating emergency facility[.]" *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(A). For example, if the patient's health insurance policy would require them to pay coinsurance of 20% of the cost of an in-network service, the patient's responsibility for any out-of-network service would be limited to the same 20% co-insurance. *Id.* § 300gg-111(a)(1)(C)(ii), (iii), (b)(1)(A), (B).

In addition to setting the rules to determine a patient's payment obligations for a particular

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[2] 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 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.

out-of-network medical service, the Act also establishes a procedure to resolve disputes between providers and plans over the amount of payment for such a service when no specified state law or All-Payer Model Agreement applies.[3] 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. *Id.* § 300gg-111(c)(1)(B).

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." *Id.* § 300gg-111(c)(2)(A). The Act further instructs the Departments to "establish a process" to certify arbitrators, *id.* § 300gg-111(c)(4)(A), under which such an entity "meets such other requirements as determined appropriate by the Secretary," such as sufficient medical, legal, and other expertise and sufficient staffing, *id.* § 300gg-111(c)(4)(A). IDR entities' certifications may be revoked by the Departments for noncompliance with statutory requirements. *Id.* § 300gg-111(c)(4)(C).

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 arbitrator will, within 30 business days, select one or the other offer as the amount of payment for the item or service in

[3] 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.

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 which is generally defined as the median of the in-network contracted rates for a given item or service from 2019, adjusted for inflation, the provider's training, and the patient's acuity, among other things. *Id*. § 300gg-111(a)(3)(H)(ii); (a)(2)(B). 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). State and federal authorities share enforcement authority over provisions of the No Surprises Act. *See, e.g.*, Letter from Ellen Montz, Director, Center for Consumer Information and Insurance Oversight to Governor Hochul, at 2 (July 29, 2022), https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/CAA-Enforcement-Letters-New-York.pdf (explaining spheres of enforcement authority). The Act went into effect on January 1, 2022, and the first IDR proceedings began three months later.

II. The Departments issued rules to establish the IDR process.

Congress instructed the Departments to issue one set of rules no later than July 1, 2021, addressing the No Surprises Act's patient protections, and to issue a second set of rules no later than December 27, 2021, addressing the procedures for resolving payment disputes. 42 U.S.C. § 300gg-111(a)(2)(B), (c)(2)(A). This second set of rules exercises Congress's delegation of authority to the Departments to "establish by regulation one independent dispute resolution process," *id*. § 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.[4] Under the final rules, the certified IDR entity "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). After certain portions of the August 2022 final rules were vacated in separate litigation, the Departments issued updated guidance to certified IDR Entities that reflected that court's order. *See* March 2023 Guidance, at 5.

The Departments originally estimated that 22,000 disputes would be initiated in the Federal IDR process each year and 50 IDR entities would be certified. *See* 86 Fed. Reg. 56,002 n.41, 56,056, 56,069-70. However, between April 15, 2022 and March 31, 2023, disputing parties initiated 334,828 disputes through the Federal IDR portal, exponentially greater than the initial estimates, and only 13 IDR entities have been certified. Ctrs. For Medicare & Medicaid Servs., Federal Independent Dispute Resolution Process—Status Update (April 27, 2023),

[4] 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); *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, 2023 WL 1781801 (5th Cir. Apr. 11, 2023). After portions of the final rules were vacated, there was a pause on payment adjudications for several weeks while the Departments drafted new guidance for arbitrators. *See* Ctrs. for Medicare & Medicaid Servs., Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities (updated March 2023), https://www.cms.gov/files/document/federal-idr-guidance-idr-entities-march-2023.pdf ("March 2023 Guidance").

https://www.cms.gov/files/document/federal-idr-processstatus-update-april-2023.pdf; Ctrs. for Medicare & Medicaid Servs., List of Certified Independent Dispute Resolution Entities, https://www.cms.gov/nosurprises/help-resolve-payment-disputes/certified-idre-list (last visited May 25, 2023). Although the certified IDRE entities have closed 106,615 disputes as of March 31, 2023, the Departments have recognized that there remains a growing backlog of disputes awaiting resolution. Federal Independent Dispute Resolution Process—Status Update at 2. To address this issue, the Departments announced their intention to devote more resources to the IDR process to assist overburdened arbitrators and help alleviate the backlog. *See* Ctrs. for Medicare & Medicaid Servs., Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee, 3-4 (Dec. 23, 2022), https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/Amended-CY2023-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf (explaining goal of increased resources was to "ensure more timely processing of disputes assigned to certified IDR entities").[5] The Departments are continuing to listen to public input and make improvements to the IDR process.

III. This litigation is brought.

Plaintiff is an independent neurosurgery practice group. Compl. ¶ 1, ECF 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*. ¶ 3. Plaintiff alleges that its practice relies

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[5] Because the Departments' funding for carrying out the IDR process comes from the administrative fees paid by parties who participate in the IDR process, 42 U.S.C. § 300gg-111(c)(8)(B), the Departments increased the administrative fee to fund these additional expenditures. That fee increase is currently being challenged in the Eastern District of Texas. *See Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs*., No. 23-cv-59-JDK (E.D. Tex. Jan 30, 2023).

on the reimbursement from health plans subject to the Act's processes and that it is being injured by low and delayed reimbursement from these payers which it attributes to a failure to better implement and enforce the Act. *Id.* ¶ 8. Plaintiff's complaints fall into three general categories: (1) "The Departments are not processing IDR claims in the required timeframe"; (2) "The Departments are routinely allowing IDR eligible claims to be rejected"; and (3) "The Departments are allowing health plans to avoid paying claims they lose at IDR." *Id.* ¶ 9.

The day after it filed this case, Plaintiff filed five lawsuits against various health plans claiming that they violated the No Surprises Act by failing to pay claims after losing at IDR.[6] In those lawsuits, Plaintiff seeks to enforce the arbitration award and compel the insurers to make payments to Plaintiff. *See, e.g., Empire Blue Cross Blue Shield*, 2:23-cv-3050-JS-LGD, Compl. ¶ 1, ECF No. 1 ("Defendant violated federal law by failing to timely pay hundreds of thousands of dollars in out-of-network payment awards issued to the Practice . . . under the No Surprises Act.").

In this lawsuit, Plaintiff alleges that the Departments have failed to appropriately implement the No Surprises Act in 13 ways and seeks an injunction and writ of mandamus ordering the Departments to take 13 actions. Compl. ¶¶ 86, 87, 88, 91, 95, 108, 112, 125, 129. Plaintiff generally alleges that the Departments have violated their statutory obligations by failing to compel health plans to comply with the statutory deadlines for making payments imposed by the Act and failing to adopt procedures to monitor health plans' compliance with those deadlines; failing to compel health plans to comply with the statutory obligation to make payments to providers directly

[6] *See Neurological Surgery Prac. of Long Island, PLLC v. UnitedHealthCare Ins. Co. of N.Y.*, No. 1:23-cv-3007-NRM-PK (E.D.N.Y. Apr. 21, 2023); *Neurological Surgery Prac. of Long Island, PLLC v. Emblemhealth, Inc.*, No. 1:23-cv-3029-JS-SIL (E.D.N.Y. Apr. 21, 2023); *Neurological Surgery Prac. of Long Island, PLLC v. Cigna Health & Life Ins. Co.*, No. 2:23-cv-3047-GRB-SIL (E.D.N.Y. Apr. 21, 2023); *Neurological Surgery Prac. of Long Island, PLLC v. Cigna Health & Life Ins. Co.*, No. 2:23-cv-3048-GRB-JMW (E.D.N.Y. Apr. 21, 2023); *Neurological Surgery Prac. of Long Island, PLLC v. Empire Blue Cross Blue Shield*, No. 2:23-cv-3050-JS-LGD (E.D.N.Y. Apr. 21, 2023).

and failing to adopt procedures to monitor health plans' compliance with that requirement; failing to institute certain requirements for information that health plans must include on their explanation of benefits ("EOB") forms; failing to require health plans to engage in "meaningful" negotiations during the 30-day open negotiation period; failing to compel IDR entities to comply with the statutory deadlines imposed by the Act; failing to establish a standardized process for IDR entities to determine eligibility issues and failing to impose requirements on IDR entities to provide explanations for eligibility determinations; failing to issue a "reasonable" batching regulation; and failing to require IDR entities to adjudicate claims for non-emergency services for which a patient was provided notice and consented to out-of-network care. *Id*. In addition to bringing claims under the APA and the All-Writs Act, Plaintiff alleges that the health plans' delays in making payments after an IDR decision is entered have deprived it of property without due process of law and constitute a taking, in violation of the Fifth Amendment to the Constitution. Compl. ¶¶ 111, 128-29.

The motion for a preliminary injunction seeks an order requiring the Departments to take 10 actions that largely cover the same ground, and also asks this Court to order the Departments to "[d]evote sufficient monetary and other resources required to ensure that the IDR process time frames established by the No Surprises Act are complied with" and to "[r]equire Defendants to provide a status report to the Court weekly regarding compliance with this Order." Pl.'s Mem. of Law in Supp. of Injunctive Relief at 1-2, ECF No. 11, at 1-2 ("Pl.'s Mot. for PI").

LEGAL STANDARDS

"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 "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 disrupts the status quo—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)).

On a motion to dismiss under Rule 12(b)(1), "the plaintiff[] bear[s] the burden of demonstrating that [it] ha[s] standing." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207 (2021). "The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc v. Robins*, 578 U.S. 330, 338 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555,

560-61 (1992)).

Dismissal under Rule 12(b)(6) for failure to state a claim is proper when the complaint does not "contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

ARGUMENT

I. The Court should dismiss the Complaint for lack of subject-matter jurisdiction because Plaintiff lacks standing to pursue claims against Defendants where its injuries were caused by third parties.

Standing requires that Plaintiffs demonstrate an injury-in-fact that is "fairly traceable to the challenged action of the defendant" and that "it is likely," not merely speculative, "that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Env't Servs.*, 528 U.S. 167, 180-81 (2000). Given that Plaintiff does not allege that the Departments have harmed it directly—for example, by issuing a specific regulation that harms Plaintiff—but instead that it has failed to regulate third parties in a way that indirectly affects Plaintiff, standing will be "'substantially more difficult' to establish." *Lujan*, 504 U.S. at 562 (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)). As always, it is "the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id.*

Here, Plaintiff cannot establish causation or redressability because its claimed injury—health plans' and arbitrators' failure to meet statutory deadlines—"results from the independent action of some third party not before the court," namely, the health plans and arbitrators themselves. *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41-42 (1976). The Complaint is replete

with complaints of health plans' and arbitrators' failure to meet statutory deadlines, and of health plans' failure to engage in good faith negotiations, make payments to the proper entities, and otherwise comply with *their* obligations under the Act. *See* Compl. ¶¶ 32, 36, 37, 38, 43, 44, 49, 57, 58, 70, 71, 74. The only injury that Plaintiff identifies in the Complaint is financial harm from delayed payments and delayed IDR arbitration decisions. *Id*. ¶¶ 73-80. Plaintiff has also failed to establish that its alleged injuries are redressable by the Departments—*even if* the Departments fined every health plan or revoked the certification of every IDR entity that has failed to meet statutory deadlines, Plaintiff could not demonstrate that these actions would result in payment disputes getting resolved faster or its claims getting paid sooner.

Indeed, seemingly recognizing that its injuries were caused by health plans, the day after filing this suit, Plaintiff filed five other cases against the allegedly offending health plans—cases now pending before four other judges of this Court. *See supra* n.6 (citing cases). Plaintiff's filing of these lawsuits effectively concedes that it is these third parties, not the Departments, that are causing its alleged injuries. And it is likewise fatal to Plaintiff's request for mandamus, which requires a showing that Plaintiff has no other available remedy at law. *In re United States*, 10 F.3d 931, 933 (2d Cir.1993) (petitioner must show "the inadequacy of other available remedies").

II. The Court should dismiss the Complaint for failure to state a claim upon which relief can be granted.

A. Plaintiff fails to identify an unambiguous statutory obligation that the Departments have violated.

Even if Plaintiff could establish standing, its Complaint would fail on several independent grounds. To start, Plaintiff's Complaint challenges not agency action, but *in*action. Plaintiff brings claims under the APA, 5 U.S.C. § 706(1) and the All-Writs Act, 28 U.S.C. § 1651(a). To meet the high burden under either of these statutes, Plaintiff must show that Defendants failed to take a discrete action that they are unambiguously required to take. Plaintiff cannot make that showing.

Plaintiff argues that the Departments failed to compel health plans to comply with their statutory payment deadlines and failed to adopt procedures to monitor health plans' compliance with those deadlines; failed to compel health plans to make payments directly to providers and failed to adopt procedures to monitor health plans' compliance with that requirement; failed to require health plans to include certain information on their EOB forms; failed to require health plans to engage in "meaningful" negotiations during the negotiation period; failed to compel IDR entities to decide payment disputes within the statutory deadline, failed to establish a "streamlined process" for IDR entities' eligibility determinations and failed to require IDR entities to provide an explanation for eligibility decisions; failed to "allow a reasonable batching" of claims for resolution in a single IDR dispute; and failed to require the federal IDR process to adjudicate claims for non-emergency services where the patient consented to out-of-network care. *See* Compl. ¶¶ 86, 87, 88, 91, 95, 108, 112, 125, 129.

While the APA authorizes courts to "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), it does so "only within strict limits," *Anglers Conservation Network v. Pritzker*, 809 F.3d 664, 668, 670 (D.C. Cir. 2016). Courts can compel only "*discrete* agency action that [an agency] is *required to take*," *Norton v. S. Utah Wilderness All.* ("*SUWA*"), 542 U.S. 55, 64 (2004)—that is, where a statute or regulation imposes a "ministerial or non-discretionary" duty amounting to a "specific, unequivocal command," *id*. at 63-64; *see also Benzman v. Whitman*, 523 F.3d 119, 131 (2d Cir. 2008) (holding general duties imposed by statute or regulation failed to constitute a discrete legal obligation). This standard reflects the common-law writ of mandamus, which the APA "carried forward" in Section 706(1). *Id*. at 63 ("The mandamus remedy was normally limited to . . . the ordering of a precise, definite act . . . about which [an official] had no discretion whatever[.]") (citation omitted); *see Indep.*

Mining Co. v. Babbitt, 105 F.3d 502, 507 (9th Cir. 1997) (relief authorized by mandamus statute and under APA Section 706(1) "is essentially the same"). "[W]here an alleged 'duty is not . . . plainly prescribed, but depends on a statute or statutes the construction or application of which is not free from doubt, it is regarded as involving the character of judgment or discretion which cannot be controlled by mandamus.'" *Power v. Barnhart*, 292 F.3d 781, 786 (D.C. Cir. 2002) (quoting *Consol. Edison Co. of N.Y. v. Ashcroft*, 286 F.3d 600, 605 (D.C. Cir. 2002)).

Here, Plaintiff does not even attempt to cite to specific statutory provisions that it claims mandate the requested actions. *See SUWA*, 542 U.S. at 66 (holding that "general deficiencies in compliance . . . lack the specificity requisite for agency action"). As an initial matter, the bulk of Plaintiff's claims amount to allegations that the health plans and arbitrators failed to comply with *their own* statutory obligations.[7] But to the extent that Plaintiff alleges that the Departments themselves failed to take certain actions, its claims fail because the Departments have fully complied with all of their statutory obligations under the Act. The Act requires the Departments to "establish by regulation one independent dispute resolution process . . . under which . . . 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 only constraint Congress imposed on the Departments is that the regulations be "in accordance with" the succeeding

[7] As mentioned above, the Departments have acknowledged that the certified IDR entities have experienced an overwhelming volume of disputes and lack the resources to resolve every dispute within the 30-day statutory deadline. The Departments are in the process of devoting more resources to assist the certified IDR entities to expedite processing of disputes and reduce the backlog. But the backlog affects all parties to the IDR process, and Plaintiff does not allege that it has experienced unique delays that are the result of anything other than overburdened IDR entities. *See Pesantez v. Johnson*, No. 15-cv-1155-BMC, 2015 WL 5475655, at *4 (E.D.N.Y. Sept. 17, 2015) (holding whether petitioner was treated differently than similarly situated parties is an important factor in evaluating whether overburdened government system unreasonably delayed action).

provisions of subsection (c). *Id.* § 300gg-111(c)(2)(A). Consistent with this statutory directive, the Departments did establish an IDR process, and none of the succeeding provisions of that subsection speak to or purport to require the actions that Plaintiff demands, such as establishing a "streamlined process" for deciding eligibility disputes or mandating that IDR entities provide a written explanation for eligibility decisions. *See, e.g.*, Compl. ¶ 86(i).

There are likewise no statutory provisions that require the Departments to adopt specific procedures to monitor health plans' compliance with the statutory payment deadlines. *See, e.g.*, Compl. ¶ 86(b), (m).[8] Although Congress did require the Departments to assess whether health plans "have a pattern or practice of routine denial [or] low payment," it did so in the form of an "interim report" to be submitted by January 1, 2024, with a "final report" to be submitted two years later. 42 U.S.C. § 300gg-111(C)(5)(E)(iv). The Departments have clearly not violated that statutory obligation, which has not yet come due, even in interim form. And although the Act lists several requirements for information that health plans must include on the *advanced* EOB forms (which are different from EOB forms), information about the QPA or whether the claim is eligible for the Federal IDR process are not among them. *Compare* 42 U.S.C. § 300gg-111(f)(1)(A)-(H) *with* Compl. ¶ 86(e), (f); *see also* 45 C.F.R. §149.140(d) (requiring disclosure of QPA elsewhere). Similarly, although Plaintiffs allege that the Departments failed to provide specific guidance to IDR entities, *see, e.g.*, Compl. ¶¶ 60-61, Plaintiff cannot point to an unambiguous statutory command requiring that the specific guidance they request be provided, nor does Plaintiff allege

[8] Congress knows how to require the Departments to monitor health plans' compliance with the Act's requirements. For example, the Act requires the Departments to establish an audit process to monitor health plans' compliance with QPA calculations, and Departments have already established such a process and are in the process of conducting audits. 42 U.S.C. § 300gg-111(A)(2); 86 Fed. Reg. at 36,899. There is no similar requirement that the Departments establish an audit process to monitor health plans' compliance with payment deadlines.

that the guidance provided to IDR entities is legally inaccurate in any way.

Plaintiff's allegation that the Departments have improperly failed to require that claims for non-emergency services, for which a patient "was aware before he or she came to the hospital that the provider was out-of-network, but chose to proceed anyway," be adjudicated in the Federal IDR process, *see* Pl.'s Mot. for a PI at 16, Compl. ¶ 86(k), is also incorrect. When a specified state law, such New York's surprise billing law, applies to a claim, it applies regardless of whether a patient has waived her state law balance billing protections by providing consent to receive out-of-network care, and the Act specifically excludes from its protections, in certain circumstances, patients who have provided notice and consent. *See* 42 U.S.C. § 300gg-111(b)(1). The Departments have provided guidance to assist IDR entities in understanding when the Federal IDR process or a specified state law applies to a claim, guidance which Plaintiff does not contest or even mention. *See* Ctrs. For Medicare & Medicaid Servs., Chart Regarding Applicability of the Federal Independent Dispute Resolution Process in Bifurcated States, (Jan. 13, 2023) https://www.cms.gov/files/document/applicability-federal-idr-bifurcated-states.pdf.

Similarly, Plaintiff's allegation that the Departments failed to promulgate a "reasonable" regulation relating to the batching of claims fails to identify an unambiguous statutory requirement and fails to explain how the current regulation is unreasonable or what Plaintiff thinks a "reasonable" regulation would even look like. *See* Compl. ¶ 54. The statute sets minimum requirements that must be met before any items or services may be considered jointly in a single IDR proceeding, but also authorizes the Secretary to "specify criteria" on top of those minimum requirements. *Id.* § 300gg-111(c)(3)(A). The Secretary issued regulations specifying the criteria for batching, 45 C.F.R. § 149.510(c)(3)(i)(C), and reasonably explained the decision in the September 2021 IFR, 86 Fed. Reg. at 55,994. Plaintiff does not allege that these regulations violate

any *specific* statutory command.

Because Plaintiff fails to identify an unambiguous, non-discretionary statutory obligation that the Departments have failed to comply with, the Court should dismiss Plaintiff's APA and All-Writs Act claims.

B. Plaintiff's claims that the Departments have failed to compel third parties to comply with their obligations under the Act are not reviewable.

To the extent that Plaintiff seeks an injunction requiring the Departments to "enforce" and "monitor" health plans' and arbitrators' compliance with various statutory deadlines and requiring the Departments to "devote sufficient monetary and other resources required to ensure that the IDR process time frames established by the No Surprises Act are complied with," *see* Pl.'s Mot for a PI at 1-2, its Complaint fails for another threshold reason: an agency's enforcement decisions are "committed to [its] discretion," 5 U.S.C. § 701(a)(2), and thus generally immune to judicial review.

In a similar suit seeking to compel the Secretary of Health and Human Services to take specific enforcement actions, the Supreme Court unequivocally held that an agency's enforcement decisions are presumptively unreviewable. *Heckler v. Chaney*, 470 U.S. 821, 832 (1985). Plaintiffs there challenged an agency decision not to take enforcement action against alleged violations, seeking to compel "various investigatory and enforcement actions to prevent these perceived violations," and "the prosecution of all those" who knowingly violated the regulatory scheme. *Id.* 823-24. The Supreme Court rejected that attempt to force the agency's hand, concluding that the decision whether to bring an enforcement action is the paradigmatic example of presumptively unreviewable action committed to agency discretion by law. *Chaney*, 470 U.S. at 828-33 (citing 5 U.S.C. § 701(a)(2)).

As the Court explained, it "has recognized on several occasions over many years that an

agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion," "attributable in no small part to the general unsuitability for judicial review of agency decisions to refuse enforcement." *Id.* at 831. Such choices "often involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Id.* at 831-32. Absent a command from Congress directing how an agency will exercise its enforcement authority, "an agency refusal to institute proceedings is a decision 'committed to agency discretion by law' within the meaning of [the APA]." *Id.* at 835. Indeed, an order requiring a federal agency to take enforcement action would trench on the executive's Article II authority and raise significant separation-of-powers concerns. "When the judiciary orders an executive agency to enforce the law it risks arrogating to itself a power that the Constitution commits to the executive branch." *Baltimore Gas & Elec. Co. v. FERC*, 252 F.3d 456, 459 (D.C. Cir. 2001). For that reason, "*Chaney*'s recognition that the courts must not require agencies to initiate enforcement actions may well be a requirement of the separation of powers commanded by our constitution." *Id.*

Heckler v. Chaney thus obligates courts to decline review of an agency's enforcement efforts. Indeed, as the Second Circuit has observed, "it is rare that agencies lack discretion to choose their own enforcement priorities." *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 760 F.3d 151, 171 (2d Cir. 2014). "The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Riverkeeper, Inc. v. Collins*, 359 F.3d 156, 165 (2d Cir. 2004) (quoting *Chaney*, 470 U.S. at 831-32). The Departments have taken enforcement actions against plans and issuers for violations of statutory payment deadlines. *See* Ex. A (Decl. of William Barron); Ex. B (Decl. of Jeff Wu). This is thus far from a case where the agency has "'consciously and expressly adopted a general policy' that is so extreme as to

amount to an abdication of its statutory responsibilities." *Chaney*, 470 U.S. at 833 n.4 (citation omitted).[9] Furthermore, millions of medical bills subject to the No Surprises Act are generated every month, and a monitoring of every single claim, and enforcement of every single statutory violation, would be impossible. *See Chaney*, 470 U.S. at 831 (noting that "an agency generally cannot act against each technical violation of the statute it is charged with enforcing").

Plaintiff's request that the Departments devote additional monetary resources to the IDR process is likewise not reviewable under the APA. *See Lincoln v. Vigil*, 508 U.S. 182, 192 (1993) (holding that an agency's allocation of appropriated funds is typically committed to agency discretion by law because "the very point . . . is to give an agency the capacity to adapt to changing circumstances and meet its statutory responsibilities in what it sees as the most effective or desirable way"). And the IDR process is funded by the administrative fees paid by parties who participate in the IDR process—the Departments do not have an unlimited pool of funding on which to draw. *See* 42 U.S.C. § 300gg-111(c)(8).

C. The APA does not permit claims for wholesale improvement of a government program.

What Plaintiff essentially seeks in this action is the "wholesale improvement of this program by court decree, rather than in the offices of the Department[s] or the halls of Congress, where programmatic improvements are normally made"—precisely the sort of broadside attack on agency operations that the Supreme Court has repeatedly rejected. *SUWA*, 542 U.S. at 64; *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 879 (1990). Plaintiff claims that the Departments have "destroyed the timeliness, effectiveness, and efficiency of the federal IDR process." Compl. ¶ 76. But the list of 13 indistinct actions that it asks this Court to order the Departments to take amounts

[9] There is no formal statutory mechanism for "enforcement" actions against IDR entities other than revoking certification of the IDR entity, which would not alleviate Plaintiff's injuries but result in *fewer* IDR entities available to resolve the backlog of claims.

to little more than a request to generally improve the IDR process and administration of the Act. And Plaintiff even goes so far as to ask this Court to "[r]equire Defendants to provide a status report to the Court weekly regarding compliance with" any injunction." Pl.'s Mot. for a PI at 2. Such a programmatic attack is not permitted under the APA. As the Supreme Court has explained:

> If courts were empowered to enter general orders compelling compliance with broad statutory mandates, they would necessarily be empowered, as well, to determine whether compliance was achieved—which would mean that it would ultimately become the task of the supervising court, rather than the agency, to work out compliance with the broad statutory mandate, injecting the judge into day-to-day agency management.

SUWA, 542 U.S. at 66-67. "The prospect of pervasive oversight by federal courts over the manner and pace of agency compliance with such congressional directives is not contemplated by the APA." *Id*. at 67. The APA's limitations on judicial review "protect agencies from undue judicial interference with their lawful discretion, and . . . avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve." *Id*. at 66. Plaintiff's request for the Court to insert itself into the management of the Departments' administration of this large and complex statutory scheme—on a weekly basis, no less—is thus squarely foreclosed by unambiguous Supreme Court precedent.

The proper procedure for pursuit of Plaintiff's grievance is set forth explicitly in the APA: "a petition to the agency for rulemaking, [5 U.S.C.] § 553(e), denial of which must be justified by a statement of reasons, [*id*.] § 555(e), and can be appealed to the courts, [*id*.] §§ 702, 706." *Auer v. Robbins*, 519 U.S. 452, 459 (1997); *see also United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952) (objections to how an agency conducts its business should generally be presented to the agency so that it may correct any error). Plaintiff's claims here are thus much like seeking review of a denial of a petition for rulemaking—a petition it never claims to have filed. If it had, any denial would be separately reviewable under the APA, but under a standard of deference

"so high as to be 'akin to non-reviewability.'" *New York v. U.S. Nuclear Regul. Comm'n*, 589 F.3d 551, 554 (2d Cir. 2009) (quoting *Cellnet Commc'n, Inc. v. FCC,* 965 F.2d 1106, 1111 (D.C. Cir. 1992).

D. Plaintiff's constitutional claims fail as a matter of law.

Plaintiff also purports to bring two constitutional claims, under the due process and taking clauses of the Fifth Amendment. *See* Compl. ¶¶ 97-113 (count 3, due process), 114-130 (count 4, taking). Given that the APA likewise supplies the cause of action for these claims, *see* 5 U.S.C. §§ 702 (granting judicial review of agency action), 706(2) (authorizing the review of agency action "contrary to constitutional right, power, privilege, or immunity"), and both seek relief identical to that for Plaintiff's APA and All-Writs Act claims—namely, to compel agency action "unlawfully withheld," *id.* § 706(1); *compare, e.g.*, Compl. ¶ 112 (requested injunction for due process claim) *with id.* ¶ 88 (requested injunction for APA claim)—the constitutional claims are subject to dismissal for the same threshold reasons as the APA and All-Writs Act claims.

Plaintiff's constitutional claims also fail as a matter of law for other reasons. Plaintiff alleges that health plans' delayed and inadequate payments have deprived it of property without adequate process or compensation. But a court in this district has already rejected the notion that "a health care provider's entitlement to 'reasonable payment' is a cognizable property interest for the purposes of a due process claim" involving the No Surprises Act. *Haller v. U.S. Dep't of Health & Hum. Servs.*, 621 F. Supp. 3d 343, 356-57 (E.D.N.Y. 2022), *appeal filed*, No. 22-3054 (2d Cir. Nov. 30, 2022). To the extent providers have an enforceable property interest *after* an arbitrator's decision ordering a health plan to make a payment, it is the health plans, not the Departments, who are withholding payment to Plaintiff and thus depriving it of property. *See Benzman*, 523 F.3d at 130 (recognizing no constitutional violation for government's failure to interfere when misconduct takes place, "even where such aid may be necessary to secure life, liberty or property interests of

which the government itself may not deprive the individual"); *see also Mehta v. Surles*, 905 F.2d 595, 598 (2d Cir.1990) (per curiam) (plaintiff must show government caused the deprivation).[10]

III. Plaintiff is not entitled to a preliminary injunction.

Even if Plaintiff's Complaint is not dismissed in its entirety, Plaintiff has fallen well short of establishing any entitlement to a preliminary injunction. To start, there is nothing preliminary about the relief Plaintiff seeks. On the contrary, Plaintiff urges the Court to grant the full panoply of relief requested in its Complaint under the guise of an extraordinary, emergency motion. Even if this Court had authority to order such relief at some stage of the litigation, it clearly would not be appropriate in the form of an emergency motion. "[I]t is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits," *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981), and a preliminary injunction that effectively would grant full relief accordingly is improper. *See, e.g.*, *Senate of State of Cal. v. Mosbacher*, 968 F.2d 974, 978 (9th Cir. 1992) (explaining that granting "judgment on the merits in the guise of preliminary relief" is "highly inappropriate"). Plaintiff's motion for preliminary relief must fail on this ground alone.[11]

For the reasons given above, the Court should deny Plaintiff's motion for a preliminary injunction and should dismiss the Complaint because Plaintiff cannot establish any likelihood of success on the merits. *See Nken v. Holder*, 556 U.S. 418, 438 (2009) (Kennedy, J., concurring) ("When considering success on the merits and irreparable harm, courts cannot dispense with the

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[10] Defendants do not concede that Plaintiff has established any other element of a due process or taking claim.

[11] Plaintiff's broad requests for injunctive relief are also at odds with Rule 65(d), 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); *see, e.g., Keyes v. Sch. Dist. No. 1*, 895 F.2d 659, 668 & n.4 (10th Cir. 1990) (striking an injunction requiring the defendants "to use their expertise and resources to comply with the constitutional requirement of equal education opportunity for all").

required showing of one simply because there is a strong likelihood of the other."). But even if the Court were to conclude otherwise, it should still deny an injunction because Plaintiff has neither established irreparable harm nor shown that the equities tip in its favor.

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 cannot be remedied 'if [the Court] waits until the end of trial to resolve the harm.''" *Id.* (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 that cannot be remedied by monetary compensation from health plans—compensation which it is already seeking through five other lawsuits. 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."). Because Plaintiff has failed to show that it will suffer non-monetary harm, or that its harm is caused by the Departments, 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*, 556 U.S. at 435 (merging these factors merge when the government is a party). As discussed above, Plaintiff does not show any injury, much less irreparable harm,

caused by the Departments. *See supra* III.A. Plaintiff's requested injunction, however, would impose a significant burden on the Defendants and disserve the public.

Where the elected branches have enacted a statute based on their understanding of what the public interest requires, this Court's "consideration of the public interest is constrained . . . for the responsible public officials . . . have already considered that interest." *Golden Gate Rest. Ass'n v. City & Cnty. of San Francisco*, 512 F.3d 1112, 1126-27 (9th Cir. 2008) (internal quotation omitted). Here, pursuant to Congress's directive, the Departments have issued a series of rules faithfully implementing the IDR process that Congress crafted. Plaintiff, however, urges the Court to enjoin the Departments to reallocate resources on a massive scale, without tying those requests to any specific commands in the statutory text. And its request, if granted, would effectively mandate that three federal agencies train their efforts on Plaintiff's preferred policy goals, rather than focusing on their own priorities under the No Surprises Act and other statutes. Redirecting resources to investigation and enforcement actions would mean fewer resources available, for example, to assist the IDR entities to alleviate the backlog of disputes, to ensure that the patient-provider dispute resolution mechanism functions smoothly, 42 U.S.C. § 300gg-137, or to audit health plans' QPA methodologies, *id.* § 300gg-111(a)(2), among the Departments' many other obligations under the Act. Plaintiff's proposed injunction would radically upend the status quo and 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 Motion for a Preliminary Injunction and dismiss the Complaint in its entirety.

Dated: May 29, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

<u>/s/ Anna Deffebach</u>
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Counsel for Defendants

EXHIBIT A

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

NEUROLOGICAL SURGERY PRACTICE OF LONG ISLAND, PLLC,

Plaintiffs,

v.

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

Defendants.

Civil Action No.1:23-cv-2977-BMC

DECLARATION OF WILLIAM BARRON

I, William Barron, pursuant to 28 U.S.C.§ 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Acting Director of the Office of Outreach, Education, and Assistance (OEA), with the United States Department of Labor, Employee Benefits Security Administration (EBSA). In my role as the Acting Director, I oversee EBSA's benefits advisor program.

2. EBSA's benefits advisor program is staffed by approximately 115 benefits advisors in EBSA's 13 field offices. The benefits advisor program is also supported by the Field Operations and Technical Assistance division within OEA. Benefits advisors answer questions and take complaints relating to the Employee Retirement Income Security Act, as amended, and other related laws. The aim of the program is to both provide compliance assistance to employee

benefit plans and to help participants and beneficiaries informally resolve potential benefit disputes with employee benefit plans.

3. Among other requests and complaints handled by benefits advisors, the program reviews complaints from participants, beneficiaries, and medical providers who believe an ERISA-governed group health plan has failed to comply with the provisions of the No Surprises Act. After reviewing such complaints, the benefits advisors generally contact the group health plan's claims administrator to ascertain whether the plan owes an initial payment or notice of denial of payment to a medical provider, owes an additional payment to a medical provider as a result of an IDR determination, or has potentially failed to comply with some other aspect of the No Surprises Act. This informal dispute resolution can result in the plan issuing a payment to a medical provider.

4. Since January 2022, EBSA, through its benefits advisors, has facilitated the payment of $4,640,798 in payments to hospitals, air ambulance providers and other medical providers. This amount includes instances where the plan did not issue an initial payment within 30 days of receipt of a clean claim and instances where the plan did not issue a payment within 30 days after an IDR determination.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 26, 2023

William Barron
Acting Director
Office of Outreach, Education, and Assistance
Employee Benefits Security Administration

EXHIBIT B

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

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

DECLARATION OF JEFF WU

I, Jeff Wu, pursuant to 28 U.S.C.§ 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Deputy Director for Policy in the Center for Consumer Information & Insurance Oversight (CCIIO) at the Centers for Medicare & Medicaid Services (CMS). In my role as the Deputy Director, I oversee implementation of the No Surprises Act (NSA) and the federal Independent Dispute Resolution (IDR) process.

2. CMS is responsible for enforcing issuer and non-federal governmental plan compliance with certain private health insurance market reforms and other market-wide consumer protections in the Public Health Service Act (PHS Act), in accordance with the division of enforcement authority between states (either direct enforcement or through a collaborative enforcement agreement) and CMS.

3. CMS receives complaints alleging that plans or issuers are not complying with the

No Surprises Act through a variety of sources including CMS email boxes, the No Surprises Help Desk, stakeholders, political leadership, and Congressional inquiries. If the complaint is within its jurisdiction, CMS launches an investigation when it receives such a complaint to determine whether a violation occurred as outlined in that complaint. If the complaint falls within the jurisdiction of one of its sister agencies, such as the U.S. Department of Labor, or a state, CMS will refer the complaint to the appropriate regulator.

4. In these investigations, CMS uses the same investigation process for all complaints alleging a violation of any health insurance market reforms and other market-wide consumer protections in the PHS Act. CMS's authority to investigate is outlined in regulations at 45 C.F.R. § 150.301-347.

5. After completing its investigation, CMS determines whether a violation occurred and may seek compliance by directing specific corrective actions in response to any findings. If an investigated entity completes the corrective actions and the entity under investigation has provided proof of corrections, CMS closes the case. The complainant and investigated entity are informed of the outcome of the investigation. Enforcement actions may include corrective actions to correct practices and procedures, re-adjudication of claims, or imposition of civil money penalties.

6. Some complaint investigations may result in a more in-depth market conduct examination (MCE) of a plan or issuer. CMS may conduct MCEs, including Qualifying Payment Amount (QPA) audits of issuers of individual or group health insurance coverage in states where CMS has enforcement authority over such provisions, non-federal plans in all states, and states with a collaborative enforcement agreement at the request of the state, to verify compliance with specific market-wide PHS Act requirements.

7. Between January 2022 and May 2023, CMS received approximately 1,300 complaints against plans and issuers under CMS jurisdiction alleging that an issuer or non-federal plan was in violation of an NSA provision. Approximately 750 of those complaints were investigated through standard complaint investigations and approximately 550 were investigated through a QPA audit or targeted MCE. Of these complaints, approximately 350 are closed. Of these closed complaints, approximately 90 resulted in a violation finding where the issuer or plan was directed to conduct a self-audit and remedy the issue by, for example, reprocessing claims or updating internal operations to ensure that the required disclosures are included in initial claim payments or denials. The remaining complaints are open and under investigation, including QPA audits, MCEs, and complaint investigations.

8. The majority of the closed cases where a violation of an NSA provision was found were violations of an issuer's or plan's obligation to pay providers in a timely manner.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 26, 2023

Jeffrey C. Wu -S

Digitally signed by Jeffrey C. Wu -S
Date: 2023.05.26 16:33:02 -04'00'

Jeff Wu
Deputy Director for Policy
Center for Consumer Information & Insurance Oversight (CCIIO)
Centers for Medicare & Medicaid Services (CMS)