UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NEUROLOGICAL SURGERY PRACTICE OF LONG ISLAND, PLLC, Plaintiff, vs UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF THE TREASURY; UNITED STATES DEPARTMENT OF LABOR; XAVIER BECERRA, in his official capacity as Secretary, United States Department of Health and Human Services; JANET YELLEN, in her official capacity as Secretary, United States Department of the Treasury; and JULIE A. SU, in her official capacity as Acting Secretary, United States Department of Labor, Defendants.	Case No. 23-cv-02977-BMC (Judge Cogan)

PLAINTIFF'S NOTICE OF MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT AND A PRELIMINARY INJUNCTION

PLEASE TAKE NOTICE that, upon the accompanying Sealed Declaration of Michael H. Brisman, M.D., dated September 26, 2023, filed under seal, and the Memorandum of Law In Support of Plaintiff's Motion for Leave to File a Second Amended Complaint and for a Preliminary Injunction, dated September 27, 2023; and all the prior proceedings had herein, the Plaintiff, Neurological Surgery Practice of Long Island, PLLC, by its attorneys, Harris Beach PLLC, will move this Court, before The Hon. Brian M. Cogan, United States District Judge, at the United States Courthouse, 225 Cadman Plaza East, Brooklyn, New York 11201, on October 18, 2023 for an Order seeking: (a) leave under Fed. R. Civ. P. 15(a)(2) to file a second amended complaint; and

(b) a preliminary injunction under Fed. R. Civ. P. 65, and for such other relief that the Court deems just and proper.

Dated: Uniondale, New York
September 27, 2023

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UNITED STATES DISTRICT COURT
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NEUROLOGICAL SURGERY PRACTICE OF LONG ISLAND, PLLC, Plaintiff, vs UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF THE TREASURY; UNITED STATES DEPARTMENT OF LABOR; XAVIER BECERRA, in his official capacity as Secretary, United States Department of Health and Human Services; JANET YELLEN, in her official capacity as Secretary, United States Department of the Treasury; and JULIE A. SU, in her official capacity as Acting Secretary, United States Department of Labor, Defendants.	Case No. 1:23-cv-2977 Hon. Brian M. Cogan

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

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PRELIMINARY STATEMENT

Plaintiff, Neurological Surgery Practice of Long Island, PLLC (the "Practice") is one of the largest private neurosurgery practices in New York. It regularly provides medically necessary services on an out-of-network basis to enrollees of all the major health plans. Neurology's provision of these services since January 2022 has been governed in most cases by the No Surprises Act ("NSA"), 42 U.S.C. §§ 300gg-111, *et seq.*

Under the NSA, out-of-network providers are prohibited from billing patients for their services. Rather, health plans have the authority to initial determine whether, and what amount, to pay. The providers' only recourse is to use the independent dispute resolution (IDR) process established by the NSA.

Many of the Practice's services are governed by the NSA. Because health plans, if they pay at all, have decided to pay at rates far below what they historically paid – and far below the providers' costs for rendering the services – out-of-network providers have become heavily dependent on an efficient IDR process to avoid grievous harm.

Unfortunately, the IDR process has not been efficient. The Departments have failed to honor the NSA's mandates regarding the IDR process and require adherence to statutory timelines and other requirements. This has put Practice and other out-of-network providers in serious financial jeopardy, creating a disastrous impact on healthcare access, quality, and cost. Accordingly, Neurology brought this lawsuit this Spring to compel the Departments to honor their statutory obligations.

This Court's July 17th Order (Dkt 21) granted the Departments' motion to dismiss the original Complaint, but also granted the Practice leave to amend its Complaint to state a claim upon which relief can be granted. Accordingly, the Practice filed its Amended Complaint on July

31, 2023 (Dkt 22.) The Amended Complaint narrows the previously asserted claims to claims that the Departments violated the APA and the All Writs Act by:

- Failing to obey the Congressional mandate that the Departments "shall ensure that a sufficient number of [IDR] entities are certified . . . to ensure the timely and efficient provision of [IDR] determinations." 42 U.S.C. § 300gg-111(c)(4)(E).
- Wrongfully determining that the New York Surprise Bill Law is a specified state law under the NSA for all "non-emergency services provided by an out-of-network provider at an in-network facility or surgical center," in direct violation of the NSA, . 42 U.S.C. §§ 300gg-111(a)(3)(H)(i), 300gg-111(a)(3)(I)

The Departments moved to dismiss this Amended Complaint, which motion currently is pending before the Court.

Because of recent extraordinary and *ultra vires* actions undertaken by the Departments, the Practice now makes this motion seeking: (a) leave under Fed. R. Civ. P. 15(a)(2) to file a second amended complaint; and (b) a preliminary injunction under Fed. R. Civ. P. 65. The Practice seeks this urgent relief because, effective August 25, 2023 and continuing to date, the Departments have suspended NSA IDR process operations. This suspension directly contravenes the Departments' obligations under the NSA.

Specifically, through the NSA, Congress mandated that Defendants establish an IDR process to resolve disputes regarding the reimbursement of out-of-network medical claims. 42 U.S.C. § 300gg-111(c)(2)(A). The statutory language is clear: "Not later than 1 year after the date of the enactment of this subsection, [Defendants] *shall establish* by regulation one independent dispute resolution process . . . under which, . . . a certified IDR entity under paragraph (4) determines, . . . the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." *Id*.

On August 25, 2023, the Departments suspended all IDR process operations. While, as of September 21, 2023, the Departments resumed processing pending IDR proceedings (those that had been commenced before August 3, 2023), the IDR process is still suspended indefinitely for new IDR proceedings (those that were or are going to be commenced on or after August 3, 2023. Thus, for this current timeframe no IDR process is operating, and Defendants have, accordingly, failed to take "discrete agency action that [they are] required to take." *Norton v. S. Utah Wildreness All*., 542 U.S. 55, 64 (2004); *Sharkey v. Quarantillo*, 541 F.3d 75 (2d Cir. 2008). Additionally, the Departments have no authority, under the NSA, or the implementing regulations (45 C.F.R. § 149.510) to suspend IDR operations at all.

Given this, the Departments have violated the provisions of the APA and the All Writs Act, and, accordingly, the Practice seeks leave to file a second amended complaint adding claims and allegations challenging this unprecedented and unauthorized action.

Additionally, the suspension of federal IDR operations has caused the Practice – and other similarly situated out-of-network providers – irreparable harm. This is because out-of-network providers are prohibited under the NSA from billing or collecting directly from patients. They therefore depend upon IDR adjudications to obtain appropriate reimbursement for its services. 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. This financial jeopardy has only deepened to crisis portions given the current suspension.

The Practice has previously submitted to the Court documentation explaining the dire nature of its finances resulting from the Departments' actions and inactions. As previously explained, the significant and sudden drop in revenues has created dire consequences for the

Practice. It has, for example, forced the Practice to take urgent and drastic steps to cut expenses and services, including the termination of employee physicians, laying off staff, streamlining operations, reducing insurance premiums on officer life and disability coverage, and terminating subleases and leases for various locations. The Practice has also directed resources to conduct a comprehensive review of pricing, costs, billing procedures, and other financial aspects of operations to identify additional savings. These problems have become far more drastic since the suspension.

No business – much less an independent medical practice in one of the most expensive regions of the country – can long sustain such financial difficulties. Unless the Court steps in and grants the requested injunctive relief, the Practice will be placed in severe financial jeopardy, which will have the serious impact of reducing the availability of high-quality and timely medically necessary health care services for the public in the New York area.

For these reasons, the Practice seeks a preliminary injunction requiring the Departments to lift the suspension and re-start all IDR process operations immediately.

STATEMENT OF FACTS

The facts are set forth more fully in the accompanying Declaration of Michael Brisman, dated September 20, 2023, to which this Court is referred.

ARGUMENT

I. This Court Should Grant The Practice Leave To File Its Proposed Second Amended Complaint

As discussed above, the Practice here seeks leave to file a second amended complaint adding allegations and claims relating to the Departments' unprecedented and unauthorized suspension of NSA IDR process operations. Rule 15(a) requires that leave to amend a complaint

should be freely granted when "justice so requires." Fed. R. Civ. P. 15(a); *Pangburn v. Culbertson*, 200 F.3d 65, 70-71 (2d Cir. 1999) (reversing District Court's denial motion for leave to amend). While futility is a ground for denying leave to amend, this is only true where it is "beyond doubt that the plaintiff can prove no set of facts in support" of its amended claims. *Ricciuti v. N.Y.C. Transit Auth.*, 941 F.2d 119. 123 (2d Cir. 1991).

As discussed above, on August 25, 2023, the Departments suspended all NSA IDR process operations for an indefinite period. This contravenes the NSA, which mandates the Departments to establish an IDR process to resolve disputes regarding the reimbursement of out-of-network medical claims. 42 U.S.C. § 300gg-111(c)(2)(A). The statutory language is clear: "Not later than 1 year after the date of the enactment of this subsection, [Defendants] *shall establish* by regulation one independent dispute resolution process . . . under which, . . . a certified IDR entity under paragraph (4) determines, . . . the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." *Id*.

While, as of September 21, 2023, the Departments resumed processing pending IDR proceedings (those that had been commenced before August 3, 2023), the IDR process is still suspended indefinitely for new IDR proceedings (those that were or are going to be commenced on or after August 3, 2023). Thus, for this current timeframe no IDR process is operating, and Defendants have, accordingly, failed to take discrete agency action that [they are] required to take under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701, *et seq.*, and the All Writs Act ("AWA"), 28 U.S.C. § 1651(a).

APA § 702 states that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. APA § 706 defines the scope of this review,

providing that "[t]he reviewing court shall—(1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be," inter alia, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706.

As the proposed second amended complaint explains in detail, the Practice is entitled under both the APA and the AWA to a declaration and a writ of prohibition or mandamus for the Departments' violation of the NSA. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015). We also note that neither the NSA, nor its implementing regulations, give the Departments any authority to suspend IDR process operations, much less indefinitely. *See* 45 C.F.R. § 149.510.

Indeed, the Departments only explanation for their *ultra vires* action in suspending IDR process operations is that, "on August 24, 2023, the district court issued an opinion and order in *Texas Medical Association, et al. v. United States Department of Health and Human Services*, Case No. 6:22-cv-450-JDK (TMA III), vacating certain portions of 86 Fed. Reg. 36,872, 45 C.F.R. § 149.130 and 149.140, 26 C.F.R. § 54.9816-6T and 54.9817-1T, 29 C.F.R. § 2590.716-6 and 2590.717-1, and 5 C.F.R. § 890.114(a) as well as certain portions of several guidance documents." (Prop. Sec. Amend. Compl. Exh. F.)

This explanation, though, makes little sense given that nothing in that court's decision requires or even suggests suspension of federal IDR operations. The possibility that the Texas court could vacate these provisions should have come as no surprise to Defendants, given the duration the lawsuit was pending, and the court's decisions in prior cases.

And, while on September 21, 2023, the Defendants directed certified IDR entities to proceed with pending pre-August 3, 2023 disputes, all other aspects of IDR operations remain

suspended. This means that, regardless of the September 21st direction, no new (not commenced as of August 3, 2023) IDR proceedings are being accepted for processing until the suspension is lifted.

Each day that the suspension remains in effect, the backlog grows exponentially. No new IDR proceedings can be initiated by the Practice or other similarly out-of-network providers.

Given the Departments' unauthorized actions, this Court should exercise its discretion to grant the Practice leave under Fed. R. Civ. P. 15(a)(2) to file an amended complaint raising allegations and claims arising out of the Departments' suspension of IDR process operations.

II. Given The Grievous and Irreparable Injuries That the Practice Is Suffering Due To the Departments' Conduct, This Court Should Exercise Its Discretion To Grant The Requested Preliminary Injunction

As discussed above, the Practice here seeks a preliminary injunction to redress the irreparable harm caused it because of the Department's unauthorized and unprecedented indefinite suspension of IDR process operations.

Under Fed. R. Civ. P. 65, a preliminary injunction is warranted when a party demonstrates (1) a clear or substantial likelihood of success on the merits; (2) irreparable harm absent injunctive relief; (3) the balance of equities tips in its favor; and (4) that the public's interest weighs in favor of granting an injunction. *Red Earth LLC v. United States*, 657 F.3d 138, 143 (2d Cir. 2011). The Practice established all four requirements and, accordingly, this Court should issue the requested preliminary injunction.

First, regarding the likelihood of success on the merits, the Practice here asserts claims seeking injunctive and declaratory relief under the APA and the AWA. APA § 706(1) authorizes courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

Through the NSA, Congress mandated the Departments to establish an IDR process. 42 U.S.C. § 300gg-111(c)(2)(A). As discussed above, on August 25, 2023, the Departments suspended NSA IDR process operations. This suspension currently remains in effect for new (post-August 3, 2023) IDR proceedings and contravenes the Department's NSA obligations. *Id.* Accordingly, the Departments have failed to take "discrete agency action that [they are] required to take," *Norton*, 542 U.S. at 64; *Sharkey*, 541 F.3d 75, entitling the Practice to relief under the APA and the AWA, *see Armstrong*, 575 U.S. at 327.

Second, the record evidence here demonstrates that the Practice is likely to suffer irreparable harm if the requested preliminary injunctive relief is not granted. This is because out-of-network providers are prohibited under the No Surprises Act from billing or collecting directly from patients. They therefore depend upon IDR adjudications to obtain appropriate reimbursement for its services. 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. This financial jeopardy has only deepened to crisis portions given the current suspension.

Previously submitted declarations from the Practice's President, Michael Brisman, explains the dire nature of the Practice's finances. As previously explained, the significant and sudden drop in revenues has created dire consequences for the Practice. It has, for example, forced the Practice to take urgent and drastic steps to cut expenses and services, including the termination of employee physicians, laying off staff, streamlining operations, reducing insurance premiums on officer life and disability coverage, and terminating subleases and leases for various locations. Plaintiff has also directed resources to conduct a comprehensive review of pricing, costs, billing procedures, and other financial aspects of operations to identify additional savings. These

problems have become far more drastic since the suspension.

No business – much less an independent medical practice in one of the most expensive regions of the country – can long sustain such financial difficulties. Unless the Court steps in and grants the requested injunctive relief, Neurology will be placed in severe financial jeopardy, which will have the serious impact of reducing the availability of high-quality and timely medically necessary health care services for the public in the New York area.

This record establishes irreparable injury. *See Kelco Disposal, Inc. v. Browning Ferris Indus*., 845 F2d 404, 408 (2d Cir. 1988) (recognizing that consistently low prices will drive businesses from market); *Fairfield County Med. Ass'n v. United Healthcare of New Eng*., 985 F. Supp. 2d 262, 271 (D. Conn 2013) (disruption of the physician-patient relationship can cause irreparable harm that justifies issuing preliminary injunctive relief).*see also Semmes Motor Co. v. Ford Motor Co*., 429 F.2d 1197 (2d Cir. 1970) (court upheld issuance preliminary injunction where defendant's actions would destroy plaintiff's business); *see also Henderson v. Bodine Aluminum, Inc*., 70 F3d 958, 961 (8th Cir. 1995) ("It is hard to imagine a greater harm than losing a chance for potentially life-saving medical treatment; *Samele v. Zucker*, 324 F. Supp3d 313, 333 (E.D.N.Y. 2018) ("Loss of medical care constitutes irreparable harm").

Defendants' response to this record is that Neurology should simply stand by and wait for the roadblocks alleviate and it gets its money. Given the very real risks to Neurology's survival, however, this is not a viable path. As stated in *Semmes*, the "contention that Semmes failed to show irreparable injury from termination is wholly unpersuasive. Of course, Semmes' past profits would afford a basis for calculating damages for wrongful termination, and no one doubts Ford's ability to respond. But the right to continue a business in which William Semmes had engaged for twenty years and into which his son had recently entered is not measurable entirely in monetary

terms; the Semmes want to sell automobiles, not to live on the income from a damage award. *Id.* at 429 F.2d at 1205; *see also Tom Doherty*, 60 F.3d at 38 (irreparable harm found where the very viability of the plaintiff's business is threatened).

Third, the balance of equities undoubtedly favors the Practice because its business cannot be sustained in the current environment, which was created by the Departments' complete and utter failure to honor their statutory obligations under the NSA. Moreover, the requested injunction is in the public interest. All the injunction does is fundamentally compel the Defendants to do what they are statutorily obligated to do under the NSA, which was enacted with an important and laudatory purpose in mind; the Departments should be compelled to carry out that purpose.

For all these reasons, this Court should grant the requested preliminary injunction.

CONCLUSION

For the foregoing reasons, this Court should grant the Practice leave under Fed. R. Civ. P. 15(a)(2) to file the proposed second amended complaint, issue the requested preliminary injunction under Fed. R. Civ. P. 65, and provide such other and further relief that the Court deems proper.

Dated: Uniondale, New York
September 27, 2023

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