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. 1:23-cv-2977 Hon. Brian M. Cogan

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

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PRELIMINARY STATEMENT

Under the No Surprises Act ("NSA"), out-of-network providers, like the Practice, are prohibited from billing patients for their services. 42 U.S.C. §§ 300gg-111, *et seq.* If the providers are not satisfied with a health plans initial offer, the providers' only recourse is to use the independent dispute resolution (IDR) process established by the NSA. And, since many of the Practice's services are governed by the NSA, out-of-network providers have become heavily dependent on an efficient IDR process as their only remedy to obtain fair reimbursement for medical services that are subject to the NSA.

Unfortunately, as outlined in the Practice's initial moving papers, the IDR process has been replete with interruptions due to the Departments failure 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, the Practice brought this lawsuit this Spring to compel the Departments to honor their statutory obligations and filed an 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.

However, since that motion was fully briefed, the Departments have taken extraordinary and *ultra vires* actions by suspending NSA IDR process operations effective August 25, 2023. This suspension directly contravenes the Departments' obligations under the NSA. As a result, the Practice filed a 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 Departments have opposed both motions primarily arguing that: (a) the Practice's claims are moot since, as of October 6, 2023, the Departments have reopened the IDR portal for the initiation of new single and bundled disputes, and (b) that the Department's have complied with their statutory mandate to "establish" an IDR process. (Def. Mem., pp. 14-15). The Departments arguments are misplaced.

But, while, as of October 6, 2023, the Departments resumed processing pending IDR proceedings (those that had been commenced before August 3, 2023), the IDR portal is still suspended indefinitely for IDR proceedings for batched claims. Even so, the Department's contention that the Practice's claims are moot are belied by the Department's tacit admission that they are somehow authorized to open and close the portal at any time, for any reason. Contrarily, the Departments have no authority, under the NSA, or the implementing regulations (45 C.F.R. § 149.510) to suspend IDR operations at all. Thus, for the timeframe no IDR process is operating, 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).

Second, the Departments argue that they have fulfilled their statutory duty by establishing an IDR process, period. Defendants seek to dilute their statutory obligations under the NSA by arguing that they were only required to implement a process to certify IDR entities under § 300gg-

111(c)(4)(A). There is no question that the Departments, based on the admitted facts, have failed to even remotely ensure the timely and efficient provision of IDR claims under § 300gg-111(c)(4)(E) as Congress required.

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

Additionally, because the suspension of federal IDR operations has caused the Practice – and other similarly situated out-of-network providers – irreparable harm, the Court should grant the Practice's motion for preliminary injunction. The IDR process delays, interruptions, 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 and resulting backlog.

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 leave to file a Second Amended Complaint and a preliminary injunction preventing the Departments from suspending IDR process operations.

ARGUMENT

I. The Departments Do Not Have the Authority To Suspend the IDR Portal

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).

The Departments have no authority, under the NSA, or the implementing regulations (45 C.F.R. § 149.510) to suspend IDR operations at all. Yet, on August 25, 2023, that is exactly what they did by suspending *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*. The Departments offer no support – statutory or otherwise – for their belief that they can unilaterally suspend the portal and have acted *ultra vires* in doing so. *See NRDC v. Nat'l Highway Traffic Safety Admin.,* 894 F.3d 95, 111-112 (2d Cir. 2018) ("a decision to reconsider a rule does not simultaneously convey authority to indefinitely delay the existing rule pending that reconsideration.")

Congress further ordered that the IDR process runs in a timely and efficient manner. 42 U.S.C. § 300gg-111(c)(4)(E). The Departments unilateral suspension of the IDR portal flies in the face of these constitutional mandates and only creates additional backlog to the process through the Departments indefinite suspensions to the IDR portal.[1] *See Litvin v. Chertoff*, 586 F. Supp. 2d 9, 11 (D. Mass. 2008) (notwithstanding the absence of a fixed deadline, the government had a non-discretionary statutory obligation to process the naturalization application, which it could not avoid through unreasonable delay.)

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." 2023 U.S. Dist. LEXIS 149393 (E.D. Tex. Aug. 24, 2023).

[1] The Departments have suspended the IDR portal at least three times since the NSA's enactment. *See TMA III*, 2023 U.S. Dist. LEXIS 149393, *53 (acknowledging the Departments pause on IDR proceedings in response to the vacatur decisions in *TMA I* and *TMA II*.)

This explanation, though, makes little sense given that nothing in that court's decision requires suspension of federal IDR operations. In *TMA III*, when discussing the remedy of vacatur, the Court commented that the Departments did not sufficiently demonstrate that a pause – when the Court vacated the rules in *TMA I* and *TMA II* – was so disruptive that the Court should bypass the default rule of vacatur. *See TMA III*, 2023 U.S. Dist. LEXIS 149393, at *53. In fact, the Court went on to suggest the opposite commenting that "for patient cost-sharing, the Departments can exercise their enforcement discretion to allow insurers to continue using their existing QPAs until new QPAs are calculated consistent with the Act." *Id*. at *52; *see also Nat'l Highway Traffic Safety Admin.,* 894 F.3d at 112 ("[A]n agency literally has no power to act unless and until Congress confers power upon it.")

Put simply, in *TMA III*, the issue of the Departments authority to suspend the IDR portal was not before the Court. Rather, the same concerns over the Departments *ultra vires* actions stated in *TMA III* remain here: that the Court is left to guess "how long any claimed disruption would last, how many IDR proceedings would be halted or delayed, and the cost of vacatur." *TMA III*, 2023 U.S. Dist. LEXIS 149393, at *53-54. Accordingly, neither the NSA nor the Texas Court's decision authorize the Departments to suspend the IDR portal.

And, while on October 6, 2023, the Defendants directed certified IDR entities to proceed with new single and bundled disputes, the Departments admittedly can close the portal at any time they see fit to do so. 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 during the pause.

For the timeframe no IDR process was operating, 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). 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. The Department's Partial Reopening of the IDR Portal Does Not Moot the Practice's Claims

Contrary to Defendants' contentions, Plaintiff's claims have not become moot by the partial reopening of the portal, which still excludes at least two categories of claims. "The test for mootness . . . is a stringent one" and the Departments "[m]ere voluntary cessation of allegedly illegal conduct does not moot a case" because defendants would still be be "free to return to [their] old ways." *United States v. Concentrated Phosphate Export Ass'n*, 393 U.S. 199, 203, 89 S. Ct. 361, 21 L. Ed. 2d 344 (1968). The Departments track record of opening and closing the IDR portal alone proves that this claim is not moot.

Instead, subsequent events "must make it absolutely clear that the allegedly wrongful behavior [cannot] reasonably be expected to recur." Here, the Departments track record of opening and closing the IDR portal, and belief that they have the unfettered ability to suspend IDR operations at any time, proves that this issue is likely a recurring one. Because it is likely that the Departments will suspend the portal for some indefinite period of time in the future, the Departments have failed to show that it would be impossible for a court to grant any effectual relief to the prevailing party. *See Knox v. Serv. Emps. Int'l Union, Local 1000*, 567 U.S. 298, 307 (2012).

This is further true for batched claims, the submission of which remain blocked on the NSA portal today. *See* Def. Mem. pp. 10-11. 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.

The Departments have not even attempted to argue that that their unlawful suspension of the IDR could not reasonably be expected to recur and, in fact, they believe they have unfettered access to suspend the portal as they see fit. *See DiMartile v. Cuomo*, 834 Fed. Appx. 677, 679 (2d Cir. 2021) (citing *Friends of the Earth, Inc. v. Laidlaw Env. Servs. (TOC), Inc.*, 528 U.S. 167, 189, 120 S. Ct. 693, 145 L. Ed. 2d 610 (2000)). 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).

III. 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. In light of the fact that the Departments have partially reopened the IDR, and their belief that they can subsequently suspend the IDR portal at any time, the Practice has demonstrated grounds for an injunction to prevent the Departments from suspending the portal in the future.

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, from August 25, 2023 through October 6, 2023, the Departments suspended NSA IDR process operations. This suspension currently remains in effect for new (post-August 3, 2023) batched claims[2] 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. Out-of-network providers are prohibited under the No Surprises Act from billing or collecting directly from patients and, 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

[2] The suspension also remains in effect for air ambulance disputes. *See* Def. Mem. p. 20.

sudden drop in revenues has 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. These problems have become far more drastic since the suspension. 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); *see also Semmes Motor Co. v. Ford Motor Co*., 429 F.2d 1197 (2d Cir. 1970); *Samele v. Zucker*, 324 F. Supp3d 313, 333 (E.D.N.Y. 2018) ("Loss of medical care constitutes irreparable harm").

Moreover, despite the Department's partial reopening of the portal, their belief that they can unilaterally shut down the portal at any time, without authority, requires an injunction to prevent the future likelihood of irreparable harm.

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
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