UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

DR. DANIEL HALLER and LONG ISLAND SURGICAL PLLC,

Plaintiff,

- against -

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue SW, Washington, DC 20201, et al.,

Defendants.

Case No. 21-cv-7208-AMD-AYS

ORDER TO SHOW CAUSE

Upon the Declaration of Dr. Daniel Haller, sworn to on March 25, 2022, and Plaintiffs' Memorandum of Law in Support of Their Motion for a Temporary Restraining Order and Preliminary Injunction, the Plaintiffs, Dr. Daniel Haller and Long Island Surgical PLLC ("Plaintiffs") hereby move by Order to Show Cause against Defendants, the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Office of Personnel Management, Xavier Becerra in his official capacity as the Secretary of Health and Human Services, Janet Yellen in her official capacity as the Secretary of the Treasury, Martin J. Walsh in his official capacity as the Secretary of Labor, and Kiran Ahuja in her official capacity as the Director of the Office of Personnel Management (collectively "Defendants"), for a Preliminary Injunction pursuant to Federal Rule of Civil Procedure 65, for the reasons that (1) provisions of the No Surprises Act, Pub. L. 116-260 (the "Act"), specifically 42 U.S.C. § 300gg-111(c), 42 U.S.C. § 300gg-131 and 42 U.S.C. §300gg-132, are illegal and unconstitutional, and that an injunction should be issued prohibiting the implementation, enforcement, or otherwise carrying out these provisions of the Act, and (2) pursuant to the Administrative Procedure Act, specific provisions of the interim final rule implementing the Act, entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) should be vacated, specifically, 45 C.F.R. § 149.510(a)(2)(v); 45 C.F.R. § 149.510(a)(2)(viii); the second and third sentences of 45 C.F.R. § 149.510(c)(4)(ii)(A); the final sentence of 45 C.F.R. § 149.510(c)(4)(iii)(C); 45 C.F.R. § 149.510(c)(4)(iv); and 45 C.F.R. § 149. 510(c)(4)(vi)(B); 26 C.F.R. § 54.9816-8T(a)(2)(v); 26 C.F.R. § 54.9816-8T(a)(2)(viii); the second and third sentences of 26 C.F.R. § 54.9816-8T(a)(2)(viii); the second and third sentences of 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A); the final sentence of 26 C.F.R. § 54.9816-8T(c)(4)(iii)(C); 26 C.F.R.; § 54.9816-8T(c)(4)(vi)(B); 29 C.F.R. § 2590.716-8(a)(2)(v); 29 C.F.R. § 2590.716-8(a)(2)(viii); the second and third sentences of 29 C.F.R. § 2590.716-8(c)(4)(ii)(A); the final sentence of 29 C.F.R. § 2590.716-8(c)(4)(iii)(C); 29 C.F.R. § 2590.716-8(c)(4)(ii)(A); and 29 C.F.R. § 2590.716-8(c)(4)(vi)(B) (the "Rule"), and the Court having reviewed the Complaint, supporting Declaration, and the papers submitted therewith,

IT IS HEREBY ORDERED that

- 1. Plaintiffs' *ex parte* application for a temporary restraining order and order to show cause why Defendants should not be preliminarily enjoined from implementing, enforcing, or otherwise carrying out the specific provisions of the Act and the Rule set forth above, is GRANTED;
- 2. Sufficient reason having been shown therefore, pending the hearing of the Plaintiffs' application for a preliminary injunction, pursuant to Rule 65 of the Federal Rules of Civil Procedure, Defendants ARE TEMPORARILY RESTRAINED from implementing, enforcing, or otherwise carrying out the specific provisions of the Act and the Rule set forth above;

- 3. Defendants show cause on the _____day of ______, 2022 at _____.m. or as soon thereafter as counsel can be heard, in Courtroom _______ in the United States District Court for the Eastern District of New York, 225 Cadman Plaza East, Brooklyn, New York, why an Order pursuant to Federal Rule of Civil Procedure 65 should not be entered granting Plaintiffs a preliminary injunction enjoining Defendants, during the pendency of this action, from implementing, enforcing, or otherwise carrying out the specific provisions of the Act and the Rule set forth above; and
- 4. Plaintiffs' counsel shall serve a copy of this order on the Defendants by personal delivery or electronic communication on or before the day of , 2022;
- Defendants shall respond by submitting opposition papers on or before the _____ day of _____, 2022;
- 6. Plaintiffs shall submit their reply papers on or before the _____ day of _____, 2022.

Dated: this ____ day of _____, 2022

SO ORDERED:

Hon. Ann M. Donnelly, U.S.D.J.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

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- against -

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Defendants.

Case No. 21-cv-7208-AMD-AYS

DECLARATION OF DR. DANIEL HALLER IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Dr. Daniel Haller, hereby declares pursuant to 28 U.S.C. § 1746:

1. I am a Plaintiff in this action, and I am the President and 100% owner of Plaintiff Long Island Surgical PLLC ("Long Island Surgical"). I respectfully submit this Declaration in support of Plaintiffs' motion for a preliminary injunction prohibiting enforcement of the federal No Surprises Act, Pub. L. 116-260 (the "Act") and the regulations implementing the Act, and for a temporary restraining order prohibiting their enforcement while the motion is being heard and determined.

2. This declaration is made upon my personal knowledge of the facts and circumstances set forth herein.

3. I earned my medical degree in 2006 from the Technion – Israel Institute of Technology, Faculty of Medicine. I completed my residency in general surgery at Maimonides Medical Center, and my fellowship in surgical critical care at North Shore-Long Island Jewish Health System. I am board-certified in both general surgery and surgical critical care by the American Board of Surgery. I am a fellow of the American College of Surgeons and an Adjunct Clinical Associate Professor of Surgery, teaching both students and residents.

4. I specialize in general surgery and acute care surgery, which includes general surgery, trauma and critical care surgery. Among other things, as an acute care surgeon I perform a wide range of services and procedures for urgent medical conditions when patients require either short or long-term treatment for a severe illness or injury in addition to services provided during their recovery period. Critical care deals with the sickest patients in the hospital and requires 24 hour a day attention to meet their medical needs. During the first wave of COVID-19 in March of 2020 we managed two intensive care units in two different hospitals, taking care of over 40 patients a day, while risking our lives during a time of extreme uncertainty on how to safely care for our patients, ourselves and our families.

5. Long Island Surgical is a general and acute care surgical private practice in Rockville Centre, New York. We provide individualized and high-quality services to each patient, whether a consult, surgery, and/or follow up. Patients receive their provider's cell phone number with 24 hour, seven-days-a-week access to discuss their clinical needs. Long Island Surgical employs six physicians who have over forty combined years of clinical experience. The practice offers traditional, laparoscopic, and robotic services to best meet the needs of each patient. Additionally, our surgeons offer their time and effort to ensure the best possible patient outcomes. Our surgeons engage in high quality peer review and performance improvements meetings to ensure high quality patient care. Our surgeons are affiliated with hospitals in Long Island, including Mercy Hospital, Mount Sinai South Nassau, and St. Joseph Hospital, and cooperate with many other doctors and specialists.

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6. I and the other surgeons at Long Island Surgical perform approximately 2,700 emergency consultations and surgical procedures each year for patients admitted to hospitals through their emergency departments.

7. Around 78% of the patients that I and Long Island Surgical treat each year are covered by health insurance plans with whom we have no contractual relationship. We are therefore "out-of-network" providers with respect to these insurers.

Effects of The Federal No Surprises Act

8. A large majority of the out-of-network services I and my colleagues at Long Island Surgical provide are subject to the balance billing prohibition for patients with health insurance covered by the Act. The Act applies to most emergency services, including those provided in hospital emergency rooms, inpatient settings and urgent care centers that are licensed to provide emergency care. Other out-of-network services that I and Long Island Surgical provide are nonemergency medical services in which I or one of my colleagues is out-of-network, but the facility in which we are providing services is in-network for our patient. The Act also broadly defines covered non-emergency services to include treatment, equipment and devices, and preoperative and postoperative services, all services that I and Long Island Surgical often render. Under the Act, patients cannot consent to being balanced billed for either emergency services or many other services I and my Long Island Surgical colleagues provide, despite the fact that, because of our reputation, patients often seek us out for their emergency care.

9. Since January 1, 2022, when the Act went into effect, I and the other providers at Long Island Surgical have provided out-of-network services subject to reimbursement through the

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Act's independent dispute resolution ("IDR") process, and we will continue to provide out-ofnetwork services that are subject to reimbursement through that process.

10. I expect that the rates I and my Long Island Surgical colleagues submit to outof-network health plans will generally not be the amount closest to the qualifying payment amount ("QP A") under the Act. I therefore do not expect that the issue of a reasonable reimbursement rate for out-of-network services provided by me and the other Long Island Surgical providers can in most cases be resolved solely by reference to the QPA. My level of training, and the level of training of my colleagues, all of whom are fellowship-trained, is well above-average, and the surgical services we provide are often highly complex due to the acuity of the patients. Therefore, the QP A will often be well below the true median contracted rate as paid in the marketplace because the QPA fails to account for the severity of the patient's condition(s) or the difficulty of the treatment(s). We at Long Island Surgical often operate on the most acute and sickest patients at the hospitals where we practice, and during all hours of the day, including nights, weekends, and holidays.

11. Upon information and belief, now that the Act is in effect, providers will need to first find out the patient's insurance status and then submit the out-of-network bill directly to the health plan. Health plans must respond within 30 days, advising the provider of the applicable innetwork amount for that claim, generally based on the median in-network rate the plan pays for the service. The health plan will send an initial payment or notice of denial to the provider and send the consumer a notice that it has processed the claim. Either side has 30 days to initiate a 30-day "open negotiation" period. If the parties cannot agree by the last day of the open negotiation period, either party may initiate the IDR process within four business days after the close of the open negotiation period. The parties may jointly select an IDR arbitration service provider or a

service provider will be selected for them, within 6 business days following the notice of IDR initiation. In IDR arbitration, each party must submit their best and final offer, and the independent arbitrator must select one of the offers, a so-called "baseball-style" process in which the IDR entity can only pick from one of two competing offers without modification. While the time deadlines in the act might seem like a good idea, they are unrealistic and will be difficult to keep track of and adhere to, especially since in our experience, the insurance companies do not have dedicated personnel to negotiate claims or even answer questions that providers may have in a timely fashion.

12. As required by the Act, I and my colleagues at Long Island Surgical would engage in open negotiation with out-of-network insurers for a reasonable out-of-network reimbursement rate. However, as discussed above, because the rules implementing the Act default to the QPA, the bargaining power of the health plans has dramatically increased. Therefore, as a result of the Act, negotiation alone is less likely to resolve rate disputes. If negotiation does not succeed, I and my colleagues will work with Long Island Surgical administrative staff to submit claims under the Act's IDR process. An IDR arbitrator will then determine the reimbursement rate that Long Island Surgical receives, defaulting to the QPA.

13. Based on my experience with the New York State Emergency Medical Services and Surprise Bill Act (the "New York Act"), I expect that Long Island Surgical will have to participate in tens of thousands, of IDRs under the Act in the coming years.

14. In that regard, Long Island Surgical must navigate the new IDR program and the administrative burdens and costs associated with the program. We have started the process of hiring additional administrative staff to deal with the impending IDR arbitrations should the Act continue to go into effect without the Court's intervention. This problem is acute because, as discussed above, the deadlines provided for under the Act are strict.

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15. We must compete with other independent practices to hire individuals who are proficient with the new regulations and procedures of the Act, and who are in short supply, thereby making staffing difficult and expensive. Our current administrative staff numbers nine, and we anticipate needing to hire at least six to ten more professionals. It will therefore take up an enormous amount of my and Long Island Surgical staff's time and effort to properly prepare to meet the Act's requirements, and more importantly, to receive fair compensation for services provided. As one example of severe underpayment, Long Island Surgical received \$238 for a hernia repair surgery, which thus far has taken up two years of challenges and appeals.

16. Another aspect of the Act's effects on our practice is that physicians are now required to make available to each patient who is enrolled in a health plan a disclosure regarding the Act's protections against balance billing. Typically, when dealing with an out-of-network patient, the patient completes an assignment of benefits form ("AOB") requiring his or her health insurance provider to pay the provider directly. In our experience, even with a signed AOB from the patient, the insurer still chooses to send payment checks to the patient as reimbursement instead of directly to the provider, causing additional burden on the practice and staff to obtain any payment at all for those services. In addition, the AOB should allow the provider, such as my colleagues and me, with the opportunity to negotiate directly with the out-of-network insurer in a more efficient manner and increases the bargaining position of the provider with respect to the insurer. I estimate that as many as 99% of Long Island Surgical's out-of-network patients provide AOBs when requested. However, patients are becoming increasingly reluctant to sign an AOB with Long Island Surgical because they know that, under the Act, they cannot in any case be billed for any outstanding balance. Should this trend continue and grow, the lack of AOBs will severely

limit our ability to negotiate directly with out-of-network insurers, further eroding our bargaining position.

17. Similarly, the Act also requires disclosure to certain patients seeking nonemergency surgery as to how much in theory they would be billed for the procedure if their outof-network provider does not pay the unnegotiated bill in full. This disclosure is required notwithstanding that (a) the out-of-network non-emergency patient will in most cases have out-ofnetwork benefits, (b) we are likely negotiating with the out-of-network insurer to obtain coverage for the procedure at an agreed upon rate, and (c) the patient will likely end up paying little if anything additional out-of-pocket. It has been our experience recently that this mandated disclosure is scaring off out-of-network, non-emergency surgical patients and causing them to seek in-network providers, who may be less qualified or have worse clinical outcomes, but who do not have to make a similar disclosure, when the disclosure in any event does not reflect the reality of what that patient will in fact pay for our services. Patients therefore elect and pay for increased coverage that allows them to utilize the services of out-of-network providers, but are now being unnecessarily dissuaded from exercising their contracted rights. This will cause me and my colleagues to lose out-of-network, non-emergency surgical patients at a rate that will be difficult to calculate.

18. I declare under penalty of perjury that the foregoing is, to my knowledge and understanding, true and correct.

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Dr. Daniel Haller

Sworn to before me on this

2 <u>4</u> day of March, 2022

Notary Public

DAVID REICH Notary Public, State of New York Registration No. 02RE4989171 Qualified in Queens County Commission Expires February 15, 2026

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Defendants.

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PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

This is an action seeking a declaration that the No Surprises Act, Pub. L. 116-260 (the "Act"), is unconstitutional and for an injunction prohibiting its enforcement and, pursuant to the Administrative Procedure Act, setting aside specific provisions of an interim final rule promulgated by the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management (collectively, the "Departments") in violation of the authority given to them by the Act. The regulations were adopted on September 30, 2021, and the requirements of the Act generally went into effect on January 1, 2022.

This memorandum of law, and the accompanying Declaration of Plaintiff Dr. Daniel Haller ("Haller Decl."), are submitted in support of the plaintiffs' motion for a preliminary injunction prohibiting enforcement of specific provisions of the Act (as set forth in the Complaint) and the regulations and for a temporary restraining order prohibiting their enforcement while the motion is being heard and determined.

SUMMARY OF ARGUMENT

Physicians are entitled under New York State law to be paid fairly for the critical services they provide to their patients. They are also entitled under State law to have the amount of their compensation determined by courts and juries based on the reasonable value of the services rendered. The Act and its implementing regulations deprive New York physicians of these rights.

The Act limits payments to "out-of-network" physicians to an amount established through the market power of self-interested insurance companies negotiating with "in-network" physicians and forces out-of-network physicians to participate in mandatory binding arbitration that, while referred to as an "independent dispute resolution process" (the "IDR"), is, in reality, not independent at all, since it is designed to end in a result controlled by the insurers. Worse, the out-of-network physicians are barred from seeking judicial review of that determination or presenting their claims to a jury, as

is their constitutional right. And where the process results in a fee determination that is less than the reasonable value of the out-of-network physicians' services (as it invariably will), the physicians are prohibited by the Act from seeking to recover the balance from their patients.

Congress lacks the authority to require that state common law claims—such as out-of-network physicians' claims for the reasonable value of services they render—be determined by administrative tribunals created by Congress. The Seventh Amendment to the United States Constitution guarantees to out-of-network physicians the right to a jury trial for those claims. Therefore, the Act exceeds Congress' authority and violates the Seventh Amendment. Further, by allowing insurers to define the standard by which the IDR will determine out-of-network physicians' claims for the reasonable value of their services, and by precluding the physicians from billing patients for the amounts insurers refuse to pay, the Act deprives those physicians of property without due process of law and is therefore unconstitutional under the Fifth and Fourteenth Amendments.

But even if the Act is constitutional, the rules promulgated by the Departments to implement the Act are *ultra vires* and illegal. The regulations go beyond the Act. They require that fee determinations made by the IDR be based on the amounts that health insurers pay to their participating providers (as opposed to any independent legal or fact-based standard). The Act makes no such provision, and, as at least one federal court has already held recently in striking down those regulations, the Departments were not entitled to enact rules that altered the Act by supplying terms that Congress omitted.

Physicians are as concerned as other Americans about the increasing cost of health care. But they are adamantly opposed to legislation that benefits insurers at the expense of the physicians who actually provide that care. Plaintiffs are physicians who are affected by the Act and the regulations. They will be irreparably harmed if they are forced to participate in the IDR process mandated by Act and the regulations. For the reasons that follow, Plaintiffs are entitled to a preliminary injunction prohibiting enforcement of the regulations and the offending provisions of the Act pending the determination of this action, and a temporary restraining order enjoining the Act and the regulations pending the Court's determination of the preliminary injunction motion.

STATEMENT OF FACTS

A. <u>The Plaintiffs</u>

Plaintiff Dr. Haller earned his medical degree from the Technion – Israel Institute of Technology, Faculty of Medicine, completed his residency in general surgery at Maimonides Medical Center, and his fellowship in surgical critical care at North Shore-Long Island Jewish Health System. (Haller Decl. at ¶ 3). Dr. Haller is board-certified in both surgery and surgical critical care by the American Board of Surgery. (*Id.*). He is President and 100% owner of Plaintiff Long Island Surgical PLLC ("Long Island Surgical"), a general and acute care surgical private practice in Rockville Centre, New York employing six physicians who have over forty combined years of clinical experience. (*Id.* at ¶¶ 1, 5). Notably, during the first wave of COVID-19 in March of 2020 Long Island Surgical managed two intensive care units in two different hospitals, treating over 40 patients a day. (*Id.* at ¶ 4).

Dr. Haller and the other surgeons of Long Island Surgical perform approximately 2,700 emergency consultations and surgical procedures each year on patients admitted to hospitals through their emergency departments. (Docket No. 1, Complaint at ¶ 12; Haller Decl. at ¶ 6). Approximately 78 percent of the patients that Dr. Haller and Long Island Surgical treat each year are covered by health plans with whom Dr. Haller and Long Island Surgical have no contractual relationship. (Complaint at ¶ 13; Haller Decl. at ¶ 7). With respect to those patients, Dr. Haller and Long Island Surgical are nonparticipating, or out-of-network, providers within the meaning of the Act whose fees will be determined by the Act and the procedures established under the Act and its implementing regulations. (Complaint at ¶ 13).

B. <u>The Act and the Rule</u>

The Act was passed on December 27, 2020, as part of the Consolidated Appropriations Act of 2021. Its requirements generally go into effect on January 1, 2022. (Complaint at ¶ 2).

The Act restricts the amount that out-of-network physicians are entitled to be paid for their services by patients and by insurers and delegates to an administrative tribunal the authority to determine the physicians' state common law claims. (Complaint at \P 3). It deprives physicians of jury trials by requiring out-of-network physicians to adjudicate their claims against insurers in an "independent dispute resolution" process that is not actually independent, since the insurers define the standard by which the physicians' claims are determined, through negotiations with in-network physicians who lack market power and who, in any case, do not represent out-of-network physicians. (Complaint at \P 3). And it prohibits physicians from recovering the balance of the reasonable value of their services from their patients by providing that an out-of-network provider "shall not bill, and shall not hold [the patient] liable" for any amount beyond what the patient's insurer pays the physician. 42 U.S.C. §§ 300gg-131(a), 300gg-132(a). (Complaint at \P 33).

The Act also disregards a New York physician's right under State law to be paid the reasonable value of his or her services. Under the Act, the fee for an out-of-network physician's services is determined in accordance with, *inter alia*, an IDR established by the Act, *i.e.*, by arbitration, when the physician and the insurer cannot agree upon the fee. 42 U.S.C. § 300gg(a)(3)(H). (Complaint at ¶ 35). The IDR is a "baseball-style" arbitration in which the provider and insurer each submit their best and final offers for the amount each considers to be reasonable payment. (Complaint at ¶ 36). Once an arbitrator is selected, the provider and the insurer have ten days to submit (1) an offer for a payment amount, (2) any information requested by the arbitrator, and (3) any other information the party wishes the arbitrator to consider, including information relating to statutory factors the arbitrator must consider. 42 U.S.C. §§ 300gg-111(c)(5)(B), 300gg-111(c)(5)(C)(ii). (*Id*.).

The arbitrator then reviews the offers and "shall ... select one of the offers" after "taking into account the considerations in subparagraph (C)," which includes the qualifying payment amount ("QPA") defined as the "median of the contracted rates recognized by the" insurer as of January 31, 2019 in the same insurance market for "the same or similar item or service" provided by a provider "in the same or similar specialty and ... geographic region," increased by inflation over the base year (*see* 42 U.S.C. § 300gg-111(a)(3)(E)(i))—for the applicable year for comparable services that are furnished in the same geographic region. Subparagraph (C) also includes additional information that is submitted, including, *inter alia*, the level of training, experience, and quality and outcomes measurements of the physician, as well as the acuity of the individual receiving the service or the complexity of furnishing such service. 42 U.S.C. § 300gg-111(c)(5)(A) and (C)(i), (ii). (Complaint at ¶¶ 37-38).

The Act requires that the arbitrator consider each of these factors in determining which offer to select and leaves it to the discretion and expertise of the arbitrator to decide how much weight to give each factor based on the facts and circumstances of a particular case. (Complaint at ¶ 41). The Act does not give presumptive weight to any single factor. The determination made in the IDR is binding on the parties and is not subject to judicial review except in cases of fraud, bias, misconduct or where the arbitrator exceeded his or her authority. 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II). (Complaint at ¶ 40).

Congress did not authorize the Departments to determine how the statutory factors should be considered. Nevertheless, the Departments adopted an interim final rule entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) (the "Rule"). (Complaint at \P 4).¹ The Rule purports to implement provisions of the Act related to the rate at which physicians

¹ The Complaint (at pp. 17-18) sets forth the specific provisions of the Rule that Plaintiffs seek to vacate in this action.

must be paid by insurers. (Complaint at \P 5). But various parts of the Rule effectively ignore the factors that the Act requires be used in setting the payment rate and, instead, creates a presumption in favor of just one of these factors—the QPA—which is determined solely by the insurers. (Id.). Specifically, the Rule provides that the arbitrator "*must* presume that the OPA is [the] appropriate" out-of-network rate and "*must* select the offer closest to the [OPA]" unless the physician "clearly demonstrates" that the OPA is "materially different from the appropriate out-of-network rate." 45 C.F.R. § 149.510(c)(4)(ii)(A); 86 Fed. Reg. at 55,995 (emphasis added). (Complaint at ¶¶ 43-44). Pursuant to the Rule, the arbitrator then need not consider any factor beyond the QPA. 86 Fed. Reg. at 55,997-55,998 (entity "must consider" Congress's other five mandated factors only "to the extent credible information is submitted by a party") (Complaint at ¶ 45). There is, however, no such limitation in the Act. The Rule defines "credible information" as "information that upon critical analysis is worthy of belief and is trustworthy." 45 C.F.R. § 149.510(a)(2)(v); 86 Fed. Reg. at 56,100. (Complaint at ¶ 46). There is, again, no such requirement in the Act. The Rule also affirmatively forbids the arbitrator from scrutinizing the QPA. It states, "it is not the role of the certified IDR entity to determine whether the OPA has been calculated by the [insurer] correctly[.]" See 86 Fed. Reg. at 55,996. (Complaint at \P 47). Once again, there is no such requirement in the Act.

The Rule further provides that if the arbitrator does not choose the offer closest to the QPA, he or she must provide a "detailed explanation" as to why the QPA was found to be materially different from the appropriate rate, including a description of "the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate." 86 Fed. Reg. at 56,000. (Complaint at ¶ 44).

This action is one of several actions pending in federal courts around the Nation seeking to

invalidate the parts of the Rule at issue here. In *Texas Medical Ass'n v. U.S. Dep't of Health and Human Services*, a case brought by a physician trade association and a physician who is a "nonparticipating provider" for certain medical services, the United States District Court for the Eastern District of Texas recently vacated the Rule on substantially the same grounds as are urged by Plaintiffs here. *See* Case No. 21-cv-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022) (Memorandum Opinion and Order, Docket No. 113 and Final Judgment, Docket No. 114).

Specifically, the court in *Texas Medical Ass'n* found, among other things, that:

- The Act "is unambiguous," and provides that arbitrators deciding which offer to select "shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii)," citing 42 U.S.C. § 300gg-111(c)(5)(C)(i) (2022 WL 542879 at *7);
- "Nothing in the Act . . . instructs arbitrators to weigh any one factor or circumstance more heavily than the others" (*Id.* at * 8);
- "Nor does the Act impose a 'rebuttable presumption' that the offer closest to the QPA should be chosen—or suggest anywhere that the other factors or information is less important than the QPA" (*Id.*);
- "The Rule thus places its thumb on the scale for the QPA, requiring arbitrators to presume the correctness of the QPA and then imposing a heightened burden on the remaining statutory factors to overcome that presumption" (*Id.*);
- "If Congress had wanted to restrict arbitrators' discretion and limit how they could consider the other factors, it would have said so—especially here, where Congress described the arbitration process in meticulous detail" (*Id.*);
- "[T]he Rule adds several key words not in the statute. The Act instructs arbitrators to 'consider' the QPA and the five other factors in deciding which offer to accept. § 300gg-111(c)(5)(C). That's it. The Rule, in contrast, requires arbitrators to 'select the offer closest to the [QPA]' and deviate from that number only if 'credible information' 'clearly demonstrates' that the QPA is 'materially different from the appropriate out-of-network rate.' 45 CFR § 149.510(c)(4)(ii). The Rule thus impermissibly 'rewrite[s] statutory language by ascribing additional, material terms'" (*Id.* at * 9); and
- "[T]he Rule treats the QPA—an insurer-determined number—as the default payment amount and imposes on any provider attempting to show otherwise a heightened burden of proof that appears nowhere in the statute. This is why the Departments themselves repeatedly touted the Rule as establishing a 'rebuttable presumption' in favor of the QPA when they presented the Rule for public viewing" (*Id.*).

In granting summary judgment to the plaintiffs, the court in Texas Medical Ass'n held that

"[b]ecause the Rule 'rewrites clear statutory terms,' it must be 'h[e]ld unlawful and set aside' on this

basis alone." *Id.* (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014)); 5 U.S.C. § 706(2)(A). As a result, the court vacated the relevant provisions of the Rule altogether, rejecting the Departments' request that the holding apply only to the named plaintiffs. *Id.* at *15.

C. <u>New York State Law</u>

Under New York law, a physician who treats a patient is entitled to be paid for his or her services. Where there is an agreement between the physician and the patient about the physician's fee, the physician is entitled to be paid the agreed upon fee. (Complaint at \P 23). If the patient is covered by an insurer and the physician has contracted with the insurer to treat the patient for a particular fee, or for a fee to be determined in accordance with a particular formula, *i.e.*, the physician is "in network," the physician is entitled under New York law to be paid the fee agreed upon and customarily agrees to waive recovery of the balance of the fee from the patient. (Complaint at \P 24).

When the patient is covered by an insurer and the physician does not have an agreement with that insurer, *i.e.*, the physician is "out-of-network" or "nonparticipating," and the patient assigns to the physician his or her right to benefits, the physician is entitled under New York law to be paid by the insurer the amount required by the insurer's contract with the patient, and the patient must pay the balance of the amount due pursuant to the agreement between the physician and the patient. (Complaint at ¶ 25). When a patient requires emergency services and has not agreed with the physician on the physician's fee, and may not have even spoken with the physician before the services are rendered, the physician is entitled under New York law to be paid for the services rendered based on an implied contract with the patient. (Complaint at ¶ 26). The amount of the fee under an implied contract is determined under New York common law in *quantum meruit*, based on the reasonable value of the services provided. (Complaint at ¶ 27).

In October 2014, the New York State Legislature adopted the New York State Emergency Medical Services and Surprise Bill Act (the "New York Act"). (Complaint at ¶ 29). The New York Act applies when the patient is covered by an insurer regulated by the State, the physician is an outof-network provider, and the patient has assigned his or her benefits to the physician. N.Y. Financial Services Law § 605(a). (*Id.*). The New York Act prohibits an out-of-network physician from billing a patient who receives emergency care (and certain post-stabilization care) for the balance of the physician's fee that the patient's insurer will not pay, but, as under common law, the physician remains entitled under the New York Act to recover the "usual and customary cost of the service," N.Y. Financial Services Law § 604(f). (Complaint at ¶ 30). As a result, under current New York law (including the New York Act), out-of-network physicians providing services to patients who require emergency services and have not agreed with the physician on the physician's fee are entitled to be paid the reasonable value of the services. (Complaint at ¶ 31). The Act deprives these physicians, including Plaintiffs here, of this right under New York law.

ARGUMENT

I. <u>The Act is Illegal and Unconstitutional</u>

Under New York law, where a physician does not have an express contractual relationship with a patient about the physician's fee, the physician is entitled to recover the reasonable value of his or her services by bringing a claim for *quantum meruit*. *See McGuire v. Hughes*, 207 N.Y. 516, 521 (1913); *Ruppert v. Bowen*, 871 F.2d 1172, 1178 (2d Cir. 1989); *see also Long Island Jewish Medical Center v. Budhu*, 20 Misc.3d 131(A), *1, 867 N.Y.S.2d 17 (App. Term 2008); *Huntington Hosp. v. Abrandt*, 4 Misc.3d 1, *3, 779 N.Y.S.2d 891, 892 (App. Term 2004); *United Healthcare Servs., Inc. v. Asprinio*, 16 N.Y.S.3d 139, 49 Misc. 3d 985, 993 (Sup. Ct. Westchester Cnty. 2015).

The Act deprives the out-of-network physician of that right by requiring the physician to adjudicate his or her claim against an insurer through an IDR established by the Act and by prohibiting the physician altogether from collecting from the patient any amount above the amount found to be the insurer's responsibility. 42 U.S.C. § 300gg-131(a). The Act thus effectively requires out-of-

network physicians, such as the Plaintiffs here, to arbitrate their state-created right to be paid on a *quantum meruit* basis. Congress lacks the authority to do that. It cannot force physicians to submit these claims to mandatory binding arbitration, without recourse to a jury, and doing so violates the physicians' right to a jury trial guaranteed by the Seventh Amendment. The Act also violates the out-of-network physicians' rights to due process of law under the Fifth and Fourteenth Amendments by permitting the insurer to define the standard by which the dispute will be adjudicated. In addition, the Act takes the out-of-network physician's property without just compensation by depriving the physician of the right to collect from the patient the amount that the insurer is not required to pay. As detailed below, the relevant provisions of the Act at issue must be set aside as unconstitutional.

A. Congress Lacks Authority to Compel Physicians to Submit State Law Claims to Arbitration

The Supreme Court has held that Congress lacks the authority to require that state law contract claims be heard before a tribunal not established under Article III of the Constitution. *Northern Pipeline Construction Co. v. Marathon Pipe Line Co.*, 458 U.S. 50 (1982). In *Northern Pipeline*, the tribunal was a bankruptcy court established under Article I of the Constitution. The Court reasoned that while Congress can define the forum for adjudication of a right that Congress has created, it cannot require that rights created by state law be adjudicated by a non-Article III tribunal: "[W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to . . . provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right. . . No comparable justification exists, however, when the right being adjudicated is not of congressional creation." 458 U.S. at 83-84.

Here, the out-of-network physicians' claims for the reasonable value of their services was not created by Congress. It is based on New York State common law. But the Act effectively requires that physicians arbitrate those claims, in direct contravention of *Northern Pipeline*. Specifically, the

Act bars physicians from recovering from patients any amount beyond what is determined by the IDR to be the insurer's responsibility. Because Congress did not create the physicians' New York State *quantum meruit* claims, and the physicians have not consented to submit those claims to arbitration, the Act's mandatory arbitration provision exceeds the authority of Congress and must be set aside.

B. The Act's Requirement that Physicians Submit their Disputes to Arbitration Deprives Physicians of their Right to a Jury Trial Guaranteed by the Seventh Amendment

The Seventh Amendment preserves the right to a jury in "suits at common law, where the value in controversy shall exceed twenty dollars." U.S. Const. Amend. VII. To be sure, "when Congress creates new statutory 'public rights,' it may assign their adjudication to an administrative agency with which a jury trial would be incompatible, without violating the Seventh Amendment's injunction that jury trial is to be 'preserved' in 'suits at common law." *Atlas Roofing Co. v. Occupational Safety & Health Rev. Comm'n*, 430 U.S. 442, 455 (1977). Here, however, the out-of-network physicians' claims for the fair value of their services are not created by Congress. As explained above, it is a state common law right entitled to be brought as a "suit at common law." By prohibiting physicians from bringing that suit and requiring that the physician's claim be adjudicated through the IDR, the Act deprives physicians of their Seventh Amendment right to a jury trial.

The constitutional right to a trial by jury attaches to an action involving "rights and remedies of the sort traditionally enforced in an action at law, rather than an action in equity or admiralty." *Wm. Passalacqua Builders, Inc. v. Resnick Developers South, Inc.*, 933 F.2d 131, 135 (2d Cir. 1991) (quoting *Pernell v. Southall Realty*, 416 U.S. 363, 375 (1974)). "In determining whether a particular action is one at law or in equity, it is necessary to examine 'both the nature of the issues involved and the remedy sought." *Id.* (citing *Chauffeurs, Teamsters and Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 565 (1990)).

1. A cause of action by physicians to recover the value of services provided without contract is a suit at law.

Suits for monetary relief are suits at law, requiring a trial by jury. See City of Monterey v. Del Monte Dunes at Monterey, Ltd., 526 U.S. 687, 710, 723 (1999) (Kennedy, J. and Scalia, J., concurring). Quantum meruit claims specifically are actions at law. Aniero Concrete Co., Inc. v. New York City Constr. Auth., 2000 WL 863208, *10 (S.D.N.Y. June 27, 2000) ("under New York law the correct characterization of a quasi contract quantum meruit claim is that of an action at law"); Dayton Superior Corp. v. Marjam Supply Co., Inc., 2011 WL 710450, *19 (E.D.N.Y. Feb. 22, 2011) (same); see also Unicorn Crowdfunding, Inc. v. New Street Enterprise, Inc., 507 F. Supp.3d 547, 577 n.22 (S.D.N.Y. 2020) ("New York courts treat actions for quantum meruit or unjust enrichment as actions at law"). Therefore, quantum meruit claims, such as lawsuits by an out-of-network physician against patients with whom the physician has no contract to recover the value of services rendered, require a jury trial. See Athletes and Artists, Inc. v. Millen, 1999 WL 587883, *8 n.16 (S.D.N.Y. Aug. 4, 1999) ("It now seems settled that an action for quantum meruit must be deemed an action at law. Accordingly, A&A's jury demand as to their quantum meruit claim must be honored."); GSGSB, Inc. v. New York Yankees, 1995 WL 507246, *5-6 (S.D.N.Y. Aug. 28, 1995) (collecting cases).

2. By denying physicians the right to a trial de novo after the IDR, the Act and its enabling regulations deprive physicians of their Seventh Amendment right to a jury trial.

Unlike other federal arbitration mandates, the Act does not provide for a trial *de novo* following the arbitration. The Act's requirement that an out-of-network physician's claim for the fair value of his or her services be determined by arbitration therefore violates the physician's Seventh Amendment right to a jury trial.

Arbitration requirements do not violate the Seventh Amendment where they preserve the right to a jury trial. Indeed, in States that have mandated arbitrations, "appeal by trial *de novo* is a

constitutional prerequisite to such mandatory arbitration so as to preserve the right to a jury trial." *West Virginia Investment Management Board v. Variable Annuity Life Ins. Co.*, 241 W.Va. 148, 159 (2018) (noting that various States have court mandated arbitration, but, as Arizona courts have declared: "[t]he right to trial *de novo* is essential to the constitutionality of *compulsory* arbitration, since both the United States and Arizona Constitutions guarantee the right to trial by jury") (emphasis in original) (citing *Valler v. Lee*, 190 Ariz. 391, 949 P.2d 51, 53 (Ariz. Ct. App. 1997)).

For example, in *Perez v. New York City Health and Hospitals Corp.*, 1987 WL 9673 (E.D.N.Y. Apr. 13, 1987), the court held that, because the plaintiff had the right to demand a trial *de novo* following an arbitration, but her attorney failed to timely request one, the arbitration rules did not "impinge on plaintiff's seventh amendment rights, for the core of the right is to have a 'jury ultimately determine the issues of fact if they cannot be settled by the parties or determined as a matter of law." 1987 WL 9673 at *3 (quoting *Seoane v. Ortho Pharmaceuticals, Inc.*, 660 F.2d 146, 149 (5th Cir.1981)). The court reasoned that "[b]y permitting the parties to request a trial *de novo* after the arbitration procedure is completed, the arbitration in the instant case did not deprive plaintiff of her right to a jury trial." *Id. See also Kimbrough v. Holiday Inn*, 478 F.Supp. 566, 571, 573 (E.D. Pa. 1979) (holding that a Department of Justice requirement that civil suits in the District Court for less than \$50,000 had to be arbitrated did not violate the Seventh Amendment, reasoning that after the arbitration, both parties had the right to demand a jury trial).

The critical factor in each of these cases was that the arbitration was preliminary to—*and not a substitute for*—the plaintiff's right to a jury trial. Here, however, the Act contains no such protection. To the contrary, the Act does not permit a jury trial post-arbitration, but, rather, provides for relief from the arbitrator's determination *only* in the same manner as provided by the Federal Arbitration Act. 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II). That means that the determination may be set aside only in cases of fraud, bias, misconduct or where the arbitrator exceeded his or her authority.

9 U.S.C. § 10(a). Importantly, however, the Federal Arbitration Act, unlike the Act at issue here, applies where parties have expressly consented, in advance, to arbitration.

3. Congress lacks the authority to compel arbitration of a private dispute based on a common law claim.

In *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989), the Supreme Court made it clear that Congress cannot deprive a private party of its right to a jury trial for a private contractual dispute: "Congress may devise novel causes of action involving public rights free from the strictures of the Seventh Amendment if it assigns their adjudication to tribunals without statutory authority to employ juries as factfinders. But it lacks the power to strip parties contesting matters of private right of their constitutional right to a trial by jury." 492 U.S. at 51–52. The Court defined the distinction between a "public right" and a "private right," stating that a private right is "the liability of one individual to another under the law." 492 U.S. at 51, n. 8.

Under this definition, an out-of-network physician's right to recover the fair value of the services the physician has rendered to a patient is clearly a private right. Congress cannot require that a private contractual claim be adjudicated without a jury. *See Germain v. Connecticut Nat. Bank*, 988 F.2d 1323, 1331 (2d Cir. 1993) (Chapter 7 trustee's state law causes of action demanding monetary relief and sounding in contract and tort "are paradigmatic private rights" under *Granfinanciera* that were required to be tried by a jury); *McCord v. Papantoniou*, 316 B.R. 113, 122, n.13 (E.D.N.Y. 2004) (claims seeking monetary relief must be tried before a jury because such claims were legal in nature, and thus concerned "paradigmatic private rights" under *Granfinanciera*).

Here, the Act requires the parties to a private billing dispute to submit themselves to final and binding arbitration, to which neither party agreed, and which would otherwise enjoy the right to a jury trial under the Seventh Amendment. Congress has no authority to deny to the physician the right to a jury trial *de novo* on state common law claims.

C. Allowing Insurers to Define the Standard by Which the IDR Determines Out-of-Network Physicians' Claims Deprives Physicians of Property Without Due Process in Violation of the Fifth Amendment

The Due Process Clause of the Fifth Amendment prohibits the United States from depriving persons of property without due process of law. The Fifth Amendment also prohibits the government from taking private property without just compensation. The Act violates both constitutional provisions. Under New York law, physicians have a property right to be paid the reasonable value of the services they render to their patients. The Act deprives them of that right without due process of law. The Act and the Rule also take the physicians' property without just compensation by depriving them of the reasonable value of those services and restricting the amount they can recover for those services to the amount determined in an arbitration in which the other party to the dispute—the insurer—effectively determines the outcome.

1. Physicians have a property right under New York law to be paid the fair value of the services they render to patients.

It has long been established in New York that, absent a contract, a physician "may recover upon an implied agreement to pay for his services *quantum meruit*, when they have been rendered at the request of the patient" or a person authorized to act on behalf of the patient. *McGuire*, 207 N.Y. at 521; *see also Budhu*, 20 Misc.3d at *1 ("The performance by plaintiff and acceptance of the services by defendant gave rise to an inference that an implied contract to pay for the reasonable value of such services existed."); *Abrandt*, 779 N.Y.S.2d at 892 ("an agreement to pay for medical services may be implied" and "[t]he performance and acceptance of services can give rise to an inference of an implied contract to pay for the reasonable value of such services"); *Asprinio*, 49 Misc. 3d at 993 ("it is well recognized that, even in the absence of an express contractual agreement, a physician may recover upon an implied agreement to pay for services *quantum meruit*, when the services have been rendered at the request of the patient").

The common law right to receive payment for medical services applies even when a patient cannot consent to receive the services because of her condition, provided that the services are necessary to prevent serious bodily harm. *See, e.g., Ruppert v. Bowen*, 871 F.2d 1172, 1178 (2d Cir. 1989) ("Under New York law, an incompetent is liable under an implied agreement for the reasonable value of necessities.") (citing *In re Estate of Anderson*, 119 Misc.2d 248, 254, 462 N.Y.S.2d 589 (Surr. Ct. Saratoga Cnty. 1983) (stating that under most circumstances a physician would have a right to payment for necessary treatment provided to a comatose patient unable to consent)).² Thus, the physician is entitled to recover in *quantum meruit* the reasonable value of the services she provided.

This generally applicable common law right of a physician to recover in *quantum meruit* for services rendered at the request of a patient, or when the patient could not consent, but treatment was necessary to prevent serious harm, is codified for certain patients in the New York Act, which Act applies to health insurance policies regulated by the State of New York. N.Y. Financial Services Law § 603(c) (defining "health care plans" subject to the law). It prohibits an out-of-network physician from billing patients who receive emergency care (and certain post-stabilization care) for an amount greater than the out-of-pocket costs the insured would have incurred with a participating physician. N.Y. Financial Services Law § 605(a). Under the statute, just as under the common law, the physician remains entitled to a reasonable fee, which is determined through an independent dispute resolution mechanism that must consider, among other factors, the "usual and customary cost of the service." N.Y. Financial Services Law § 604(f). One court has described the New York Act's approach to determining a reasonable fee as "akin to the common law approach" of determining an appropriate recovery in *quantum meruit. Asprinio*, 49 Misc. 3d at 1001.

² New York courts have adopted four criteria to establish the right to restitution when the patient cannot consent: (i) that the provider of services intended to charge for its services; (ii) that the services were necessary to prevent the person from suffering serious bodily harm or pain; (iii) that the provider of services had no reason to know the recipient of the services would not consent to receiving them, if competent; and (iv) that it was impossible for the recipient to give consent. 22A N.Y. Jur. 2d Contracts § 619; *Estate of Anderson*, 119 Misc.2d at 254.

In contrast, the Act at issue here negates the common law right to recover in *quantum meruit*. It expressly prohibits the IDR from considering the "usual and customary charges" for services provided by the physician or the amount she would have billed had the federal law not existed (*i.e.*, under common law). 42 U.S.C. § 300gg-111(c)(5)(D). Instead, the Act provides that the physician's fee will be determined under the IDR by the QPA, 42 U.S.C. § 300-gg-111(c)(5)(C)(i), which it defines as "the median of the contracted rates recognized by the plan or issuer," § 300gg-111(a)(3)(E)(i), subject to considering five other factors.³

The Rule implementing the Act goes even further. It establishes a *presumption* that the QPA is the appropriate fee, regardless of the other considerations established by the Act. *See* 45 CFR § 149.510(c)(4)(ii); *Texas Medical Ass'n*, 2022 WL 542879 at *9 ("the Rule treats the QPA—an insurer-determined number—as the default payment amount"). Indeed, the Departments themselves "repeatedly touted the Rule as establishing a 'rebuttable presumption' in favor of the QPA" (86 Fed. Reg. at 56,056–61), and have argued that vacating the Rule "would result in higher reimbursement payments to providers." *Texas Medical Ass'n*, 2022 WL 542879 at *9.

Under the Act, therefore, the general standard for determining the payment to physicians, and

³

The five factors as set forth in 42 U.S.C. §300gg-111(c)(5)(C)(ii)(I)-(V) are:

⁽I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).

⁽II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.

⁽III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.

⁽IV) The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.

⁽V) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

under the Rule, the presumptive standard for determining such payment, is not the reasonable value of the services the physicians have rendered under New York law. It is, rather, the median contract rate that the insurers have agreed to pay to other physicians that reflects the insurers' decisions about what to pay based on their market power, not on the amount that would be reasonable and recoverable in *quantum meruit* under common law.

2. The Act unconstitutionally deprives physicians of their right to be paid for the fair value of their services as defined under New York law.

The Act prohibits out-of-network physicians recovering anything for their services other than the amount determined by the IDR, in which the standard of decision is, effectively, the rate determined by insurers in their negotiations with in-network physicians. However, in these negotiations, to which out-of-network physicians are not parties, the insurers have outsized negotiating power and the in-network physicians have no authority, interest, or incentive to act on behalf of out-of-network physicians.

"A fundamental requirement of procedural due process is 'the opportunity to be heard" in a "meaningful time and in a meaningful manner." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). The purpose of due process and an opportunity to be heard in a meaningful manner is "to minimize substantively unfair or mistaken deprivations of property." *Krimstock v. Kelly*, 306 F.3d 40, 52 (2d Cir. 2002) (quoting *Fuentes v. Shevin*, 407 U.S. 67, 80-81 (1972)).

By predetermining the QPA as the presumptive, default amount owed to the out-of-network physicians, and defining that amount based on what an insurer has previously agreed to pay innetwork physicians without any input by the out-of-network physicians, the Act and the Rule effectively deprive the out-of-network physicians a meaningful opportunity during the IDR to challenge the deprivation of their rights to a reasonable fee under New York law, thus depriving out-of-network physicians of procedural due process. *See Kellman v. District Director, U.S. I.N.S.*, 750

F.Supp. 625, 628 n.4 (S.D.N.Y. 1990) ("procedural due process cannot be satisfied merely by the opportunity for a hearing where the result of that hearing is statutorily predetermined"); *accord D'Angelo v. Winter*, 403 Fed.Appx. 181, 182 (9th Cir. 2010) ("A hearing with a predetermined outcome does not satisfy due process."); *Washington v. Kirksey*, 811 F.2d 561, 564 (11th Cir. 1987) ("Due process of law does not allow the state to deprive an individual of property where the state has gone through the mechanics of providing a hearing, but the hearing is totally devoid of a meaningful opportunity to be heard."). Accordingly, the IDR scheme set forth in the Act as implemented by the Rule must be struck down as unconstitutional.

D. The Act Deprives the Physician of Property Without Due Process of Law or Just Compensation

The takings clause of the Fifth Amendment prohibits the United States from taking private property for public use without just compensation. *Armstrong v. United States*, 364 U.S. 40, 49 (1960). Fundamentally, the Fifth Amendment protects valid contract rights. *See Lynch v. United States*, 292 U.S. 571, 579 (1934) ("The Fifth Amendment commands that property be not taken without making just compensation. Valid contracts are property, whether the obligor be a private individual, a municipality, a State or the United States."); *Cienega Gardens v. U.S.*, 331 F.3d 1319, 1334 (Fed. Cir. 2003) (agreements between private parties "give rise to protected property interests, irrespective of whether the subject matter of the contracts is under the government's regulatory jurisdiction").

Cienega Gardens is particularly instructive. There, the plaintiffs were real estate developers who received loans from private lenders to construct low-income housing projects administered by the Department of Housing and Urban Development. 331 F.3d at 1325. HUD provided the participants with mortgage insurance, which facilitated low-interest mortgages, and in return, each participant entered into a regulatory agreement with HUD, which placed restrictions on the owners,

including prohibiting the sale or further mortgage of the property without HUD approval. *Id.* The regulatory agreements and their restrictions were to remain in effect for at least 20 years, at which point the owners would have the option of prepaying the mortgages and thereby dissolving the restrictive agreements with HUD. *Id.* at 1326. Congress became concerned that too many owners would prepay their mortgages and remove their properties from the low-income housing pool. Congress thus enacted an additional statute that, even after twenty years, all housing program participants had to obtain HUD approval in order to prepay their mortgages. *Id.*

The Court of Appeals for the Federal Circuit held the new statute was a taking of the plaintiffs' property interests in violation of the Fifth Amendment that must be compensated. *Id.* at 1338. The court found that "[u]nquestionably, Congress acted for a public purpose (to benefit a certain group of people in need of low-cost housing), but just as clearly, the expense was placed disproportionately on a few private property owners." *Id.* The court held that Congress' objective "in preserving low-income housing—and method—forcing some owners to keep accepting below-market rents—is the kind of expense-shifting to a few persons that amounts to a taking. This is especially clear where, as here, the alternative was for all taxpayers to shoulder the burden." *Id.* at 1338-1339.

Here, the Act prohibits physicians from billing their patients for the reasonable value of their services that it is not paid by the patients' insurer. 42 U.S.C. § 300gg-132. As in *Cienega Gardens*, the Act thus compels physicians to bear the societal burden of the increasing cost of health care, without imposing any corresponding burden on insurers or patients or the general public. *See also Armstrong*, 364 U.S. at 49 ("The Fifth Amendment's guarantee that private property shall not be taken for a public use without just compensation was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole."). Because the Act does not compensate physicians for benefitting insurers and the taxpayer at the expense of physicians, it violates the Fifth Amendment's proscription against taking

private property without just compensation, and it must be struck down on that basis. *Cienega Gardens*, 331 F.3d at 1334 ("abrogation by legislation of clear, unqualified contract rights requires a remedy, even in a highly regulated industry . . . because the contracts embodied the commitments of the contracting parties").

II. The Rule Must be Vacated Where it Exceeds the Authority Congress Granted to the Departments and Conflicts with the Act

Congress legislates and administrative agencies implement the legislation adopted. The Supreme Court has cautioned that "agency power to make rules that affect substantial individual rights and obligations carries with it the responsibility not only to remain consistent with the governing legislation, but also to employ procedures that conform to the law." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974). Thus, "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress," and it is the judiciary that is "the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." *Chevron, U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 and n.9 (1984).

Here, the relevant provisions of the Rule sought to be vacated (Complaint at pp. 17-18) do not conform to the Act. As stated above, the Act defines the factors that must be considered in the IDR. 42 U.S.C. \$ 300 gg-111(c)(5)(C). It does not give any one of those factors priority or otherwise dictate how the arbitrator should weigh the factors, providing instead for the arbitrator to exercise his or her discretion, based on the arbitrator's "medical, legal, and other expertise," in determining the appropriate out-of-network rate considering the facts and circumstances of a particular case. 42 U.S.C. \$ 300 gg-111(c)(4)(A). The Rule conflicts with the statute. It *requires* that the arbitrator in the IDR select the offer closest to the QPA, unless a party "clearly demonstrates that the QPA is materially different from the appropriate out- of-network rate." 86 Fed. Reg. at 55,995. As the Departments explained when issuing the Rule, it creates a "rebuttable presumption" that the amount closest to the QPA is the proper payment amount. *See* 86 Fed. Reg. at 56,060-61.

This implementation contradicts the plain meaning of the Act. The Act instructs the arbitrator to consider *every* Subparagraph C Factor "[i]n determining which offer" to select, not just in determining whether the QPA is materially different from the appropriate out-of-network rate. 42 U.S.C. § 300gg-111(c)(5)(A) ("the certified IDR entity shall . . . taking into account the [Subparagraph C Factors]" select one of the offers). Where the regulations depart from the legislation, the regulations are invalid. *See American Corn Growers Ass'n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002) (where "no weights were assigned" to statutory factors, "treat[ing] one of the five statutory factors in such a dramatically different fashion distorts the judgment Congress directed"). As the court in *Texas Medical Ass'n* ruled, the Act does not "impose a 'rebuttable presumption' that the offer closest to the QPA should be chosen—or suggest anywhere that the other factors or information is less important than the QPA." *Texas Medical Ass'n*, 2022 WL 542879, at *8.

Nor can Defendants defend their "interpretation" of the Act under *Chevron*. Because Congress spoke clearly on the issue relevant here, the Departments' interpretation of the statute is owed no *Chevron* deference. *See id.* (citing *Chevron*, 467 U.S. at 843); *see also Lutwin v. Thompson*, 361 F.3d 146, 156 (2d Cir. 2004) ("Because we find the statutory language to be clear and unambiguous, deference to the Secretary's interpretation under *Chevron* is not appropriate.").

The Departments' attempt to override the language of the Act and upset the balanced approach that Congress required the IDR to follow when making payment determinations is *ultra vires* and contrary to the law passed by Congress. As did the court in *Texas Medical Ass'n*, the Court should vacate those provisions of the Rule requiring the IDR to employ a presumption in favor of the offer closest to the QPA. *See Texas Medical Ass'n*, 2022 WL 542879 at *14-15; Complaint at pp. 17-18.

III. <u>Plaintiffs are Entitled to a Preliminary Injunction</u>

A. <u>Standard for a Preliminary Injunction</u>

Where, as here, the moving party seeks to stay governmental action purportedly taken in the public interest pursuant to a statutory or regulatory scheme, the moving party must show "irreparable injury and a likelihood of success on the merits." *RxUSA Wholesale, Inc. v. Department of Health and Human Servs.*, 467 F.Supp.2d 285, 300 (E.D.N.Y. 2006) (citing *Bery v. City of New York*, 97 F.3d 689, 694 (2d Cir. 1996)). A court "need not find with 'absolute certainty' that Plaintiffs will succeed on the merits of their claims," but rather that Plaintiffs have "more than a fifty-fifty chance of succeeding." *Id.* at 288-89 (citing *Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d Cir.1984) ("A movant ... need only make a showing that the probability of his prevailing is better than fifty percent. There may remain considerable room for doubt.")).

B. <u>Plaintiffs Are Likely to Succeed on the Merits</u>

With respect to the level of persuasion required to satisfy a likelihood to succeed on the merits, courts have distinguished between motions seeking a prohibitory injunction as opposed to those seeking a mandatory injunction. *Averhart v. Annucci*, 2021 WL 2383556, *8 (S.D.N.Y. June 10, 2021). Where, as here, the requested injunction seeks to enjoin government enforcement of a regulation "such an injunction is considered prohibitory rather than mandatory," and the party moving for a preliminary injunction must show a "likelihood of success" on the merits of the case, rather than the more rigorous "clear" or "substantial" likelihood of success on the merits. *Id.* (citing *Mastrovincenzo v. City of New York*, 435 F.3d 78, 89 (2d Cir. 2006)).

Here, for all the reasons discussed above, Plaintiffs' claims under the Seventh, Fifth and Fourteenth Amendments to the United States Constitution are likely to succeed on the merits. Moreover, the District Court in *Texas Medical Ass'n* has already vacated the Rule requiring the IDR to employ a presumption in favor of the offer closest to the QPA, which is a substantial part of the underlying relief sought by Plaintiffs. To be sure, that decision is not binding on this Court, but its thorough and correct analysis is certainly persuasive and indicates a likelihood of success on the merits. *See, e.g., In re Calpine Corp.*, 365 B.R. 401, 409 (S.D.N.Y. 2007) (affirming preliminary injunction and finding a "strong likelihood" that debtors could successfully reorganize when another district court had confirmed that finding in a separate adversary proceeding).

C. <u>Plaintiffs Will be Irreparably Harmed</u>

"Irreparable harm is injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages." *New York Bay Capital, LLC v. Cobalt Holdings, Inc.*, 456 F.Supp.3d 564, 573 (S.D.N.Y. 2020) (quoting *Forest City Daly Hous., Inc. v. Town of North Hempstead*, 175 F.3d 144, 153 (2d Cir.1999)).

It is well established that "an alleged violation of a constitutional right 'triggers a finding of irreparable harm," and "no separate showing of irreparable harm is necessary." *Johnson v. Miles*, 355 Fed.Appx. 444, 446 (2d Cir. 2009) (quoting *Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir.1996) ("The district court therefore properly relied on the presumption of irreparable injury that flows from a violation of constitutional rights.") and *Statharos v. New York City Taxi and Limousine Comm'n*, 198 F.3d 317, 322 (2d Cir.1999)).

Furthermore, "as a matter of law, there is irreparable harm when a party is compelled to arbitrate without having agreed to arbitration because that party is forced to expend time and resources arbitrating an issue that is not arbitrable." *New York Bay Capital, LLC*, 456 F.Supp.3d at 573; *UBS Securities, LLC v. Voegeli*, 405 Fed.Appx. 550, 552 (2d Cir. 2011) (finding "irreparable harm" and "lack of adequate remedy at law" where the moving party may not be legally obligated to arbitrate, and the lack of an injunction would result in it effectively being required to do so).

In addition, "Courts in this district have routinely found that the risk of inconsistencies between arbitrations and a court's ruling establishes irreparable harm." *Gov't Emps. Ins. Co. v. SMK*

Pharmacy Corp., 21-CV-3247 (AMD)(RLM), 2022 WL 541647, *5 (E.D.N.Y. Feb. 23, 2022) (Donnelly, J.) (collecting cases).

For at least three reasons, Plaintiffs will suffer irreparable harm if a temporary restraining order and preliminary injunction staying enforcement of the Act and the Rule are not issued.

First, Plaintiffs' claims alleging Constitutional violations under the Fifth, Seventh and Fourteenth Amendments alone establish irreparable harm as a matter of law.

Second, while large parts of the Rule have already been vacated by the court in *Texas Medical Ass 'n*, that decision did not stay commencements of IDRs under the Act. If an injunction does not issue in this proceeding, Plaintiffs will still be subject to the IDR process provided for in the Act, and will be forced to expend considerable time and resources preparing for, and participating in, that process while the Court is considering whether that process is Constitutional in the first place.

In that regard, Dr. Haller and his colleagues at Long Island Surgical expect that they will have to participate in potentially thousands of IDRs under the Act in the coming years. (Haller Decl. at ¶ 13). Dr. Haller and Long Island Surgical have therefore started the process of hiring as many as nine additional staff members, doubling their administrative staff, to deal with the impending IDR arbitrations should the Act continue to go into effect without the Court's intervention. (Haller Decl. at ¶ 15). They must compete with other independent practices to hire individuals who are proficient with the new regulations and procedures of the Act, and who are in short supply, thereby making staffing difficult and expensive. (*Id.*). It will therefore take up an enormous amount of Plaintiffs' time and effort to properly prepare to meet the Act's requirements should the Court not enjoin implementation of the Act and the Rule.

Finally, the risk of inconsistent judgments is manifest. Plaintiffs could be subject to multiple adverse rulings in the IDR process only to have that entire process and those rulings invalidated as a result of an eventual decision in the instant proceeding striking down the Act and/or the Rule.

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CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request that their motion for a temporary restraining order and a preliminary injunction be granted.

Dated: White Plains, New York March 31, 2022

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