UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION, AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Civ. Action No. 1:21-cv-03231

PLAINTIFFS' MOTION FOR STAY PENDING JUDICIAL REVIEW, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Pursuant to 5 U.S.C. § 705, Plaintiffs American Medical Association, American Hospital Association, Renown Health, UMass Memorial Health Care, Inc., Stuart M. Squires, M.D., and Victor F. Kubit, M.D., hereby move for a stay pending judicial review of specific and limited portions of an interim final rule titled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021). In the alternative, pursuant to Federal Rule of Civil Procedure 56, Plaintiffs move for summary judgment in their favor, provided Defendants consent to summary judgment proceedings on a mutually acceptable expedited schedule.[1]

Plaintiffs seek relief by March 1, 2022—the approximate date arbitrations under the rule are scheduled to begin—in order to prevent irreparable harm to Plaintiffs Renown Health, UMass Memorial Health, Drs. Squires and Kubit, as well as the other members of Plaintiffs American Medical Association and American Hospital Association. In support of this motion, Plaintiffs submit the accompanying Memorandum of Points and Authorities and the Declarations of Bethany Sexton, Exhibit A ("Sexton Decl."), Catherine M. Rossi, Exhibit B ("Rossi Decl."), and Stuart M. Squires, M.D., Exhibit C ("Squires Decl."). A proposed order is attached.

In accordance with LCvR 7.1(m), undersigned counsel have conferred with counsel for Defendants. To date, the parties have been unable to resolve the underlying dispute that forms the basis for this motion, and Defendants oppose this motion.

[1] Because this case involves "purely legal questions," and there are no material facts or record evidence in dispute, *United States v. Philip Morris USA, Inc.*, 327 F. Supp. 2d 13, 17 (D.D.C. 2004), summary judgment is appropriate, provided Defendants consent to summary judgment proceedings on a mutually acceptable expedited schedule, *see Morris v. District of Columbia*, 38 F. Supp. 3d 57, 62 & n.1 (D.D.C. 2014) (converting a motion for preliminary injunction to a motion for summary judgment with the consent of the parties and citing *Curtis 1000, Inc. v. Suess*, 24 F.3d 941, 945 (7th Cir. 1994) ("The general point is that when the eventual outcome on the merits is plain at the preliminary injunction stage, the judge should, after due notice to the parties, merge the stages and enter a final judgment.")).

Further, under LCvR 65.1(d), Plaintiffs are entitled to a hearing on this motion within 21 days of its filing. Due to the holidays, however, Plaintiffs would be amenable to a hearing during the first week of January or at another date convenient to the Court that will allow it to render a decision on this motion before March 1, 2022.

Respectfully submitted,

/s James E. Tysse

Dated: December 9, 2021

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR STAY PENDING JUDICIAL REVIEW, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

Congress passed the No Surprises Act, Pub. L. 116-260, to protect patients from surprise medical bills and remove them from the middle of payment disputes between commercial health insurers ("insurers") and medical care providers ("providers"). The No Surprises Act (the "Act") accomplishes this by establishing an independent dispute resolution ("IDR") process in which an independent arbitrator settles payment disputes between insurers and providers based on its review of six mandatory statutory factors that the arbitrator "shall" consider. 42 U.S.C. § 300gg-111(c)(5)(C). The IDR process in general, and the enumerated factors in particular, reflect Congress's intentionally balanced approach to ensuring fair payment for healthcare services. For years, Plaintiffs American Medical Association ("AMA") and American Hospital Association ("AHA")—the nation's leading member associations of physicians and hospitals, respectively—strongly supported protecting patients from "surprise billing," and they welcomed Congress's solution.

In direct conflict with the Act's text and design, Defendants the United States Department of Health and Human Services ("HHS"), Department of Labor, Department of the Treasury, and Office of Personnel Management (collectively, the "Departments") issued an interim final rule (the "September Rule") that barely resembles the IDR process that Congress created. *See* "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021). Instead of Congress's balanced approach, the September Rule places a heavy thumb on the scale in favor of just one of the factors that Congress directed the independent arbitrator to consider. Specifically, the September Rule requires arbitrators to "presume" that one factor—the Qualifying Payment Amount ("QPA")—reflects the appropriate payment rate. The Departments are wrong to call this the "best interpretation" of the statute. 86 Fed. Reg. at 55,996. In fact, the September Rule directly conflicts with the Act because "Congress carefully avoided attaching any particular

weights to the various factors that must be taken into account," *Public Service Co. of Indiana, Inc. v. ICC*, 749 F.2d 753, 763 (D.C. Cir. 1984), and it surely did not assign any one statutory factor presumptive weight. Every tool of statutory construction—from text to structure to purpose to legislative history—demonstrates just how far the Departments have overreached.

Congress gave the independent arbitrator discretion to weigh the statutorily mandated factors in order to reach a fair resolution of each payment dispute. As the Act's principal architects recently explained, "Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process"—yet the September Rule "strays from the No Surprises Act in favor of an approach that Congress did not enact in the final law." Letter from Chairman Neal and Ranking Member Brady of the House Ways and Means Committee to Department Secretaries, (Oct. 4, 2021) ("Neal and Brady Letter"), https://www.gnyha.org/wp-content/uploads/2021/10/2021.10.04-REN-KB-Surprise-Billing-Letter80.pdf. The Departments' reading of the No Surprises Act distorts this bicameral, bipartisan compromise and undermines the Act's purpose of protecting patients.

Plaintiffs Renown Health, UMass Memorial Health Care, Inc. ("UMass Memorial Health"), Stuart M. Squires, M.D., Victor F. Kubit, M.D., the other provider members of the AMA and AHA, and the patients that they all care for will suffer severe and irreparable harm as a result of the September's Rule illegal presumption. Most directly, out-of-network healthcare providers will suffer irreparable harm because the September Rule's presumption in favor of the QPA will prevent fair and adequate compensation for their healthcare services, and they cannot recover underpayments through damages suits. HHS Secretary Xavier Becerra recently admitted as much, telling healthcare providers that they would "have to tighten their belt[s]" under the Departments' new rules. Michael McAuliff, *Doctors Are Mad About Surprise Billing Rules. Becerra Says Stop*

Gouging Patients, NPR (Nov. 22, 2021) ("NPR Becerra Interview"), https://www.npr.org/sections/health-shots/2021/11/22/1057985191/becerra-defends-hhs-rules-aimed-at-reining-in-surprise-medical-bills. In-network providers will face a similar threat, as insurers demand cuts in payment rates to match the rates they expect to receive through the IDR process—and threaten cancellation of contracts if the providers do not agree. In fact, one insurer recently demanded that a provider accede to a "significant reduction in your contracted rate" based on the "clarity" provided in the September Rule. Letter from Mark Werner, Blue Cross Blue Shield of North Carolina, to Provider (Nov. 5, 2021) ("BCBS Letter"), https://tinyurl.com/y3dfvtts.

The attached declarations demonstrate that these injuries more than "clear the irreparable-harm threshold." *Whitman-Walker Clinic, Inc. v. United States Dep't of Health & Human Servs.*, 485 F. Supp. 3d 1, 57 (D.D.C. 2020). Plaintiffs Renown Health and UMass Memorial Health explain that the QPA-presumption will have "devastating" effects on their non-profit hospitals and the low-income and rural communities they serve. Sexton Decl. ¶ 26; Rossi Decl. ¶ 30. As it is, these hospitals offer a range of vital healthcare services that already operate at a loss. The September Rule will further starve those services of the resources needed to keep them going at the same levels. *See* Sexton Decl. ¶ 28 (identifying trauma, mental health services, Medicaid, indigent women and children's care, and the children's hospital pediatric subspecialties as those that would face potential reductions); Rossi Decl. ¶ 30 (identifying community-based mobile medical services for indigent families and youth, food insecurity assistance care, and pediatric asthma intervention for low-income youth as services that would face potential reductions). The unlawful September Rule will thus stand in the way of these hospitals' missions of improving the health of all members of their communities, including poor and underserved patients. *See* Sexton

Decl. ¶ 27; Rossi Decl. ¶ 29. Plaintiff Dr. Squires further explains that the QPA presumption will consistently undercompensate his and co-Plaintiff Dr. Kubit's anesthesiology practice in rural North Carolina when it provides out-of-network medical services. Squires Decl. ¶ 10. He also anticipates an in-network insurer, Blue Cross Blue Shield of North Carolina, will use the QPA-presumption as leverage to demand in-network payment rates far below the value of the practice's services. *Id.* at ¶¶ 12-13, 18-19. If consistently undercompensated, Drs. Squires' and Kubit's practice may be forced to reduce its hours and terminate contracts with local hospitals. *Id.* at ¶ 21. As a small practice, it may ultimately be forced to close, depriving the patients in their rural area of much-needed medical services. *Id.* at ¶ 22.

Most troublingly, patients will suffer from the September Rule. With fewer insurance and provider choices, the Rule will seriously reduce patients' access to healthcare. Rather than deny these effects, the Departments explicitly admitted during rulemaking that "undercompensation could threaten the viability of these providers [and] facilities," which, "in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care." 86 Fed. Reg. at 56,044. Yet the Departments issued the September Rule anyway. Congress enacted the No Surprises Act to protect patients—not to harm them in this manner.

Because these aspects of the September Rule are manifestly contrary to law and will irreparably harm Plaintiffs and their members, this Court should stay those provisions of the September Rule requiring arbitrators to employ a presumption in favor of the QPA, or, in the alternative, grant summary judgment in Plaintiffs' favor.

BACKGROUND

I. Congress Enacts A Bipartisan, Bicameral Compromise To Address Surprise Medical Billing

On December 27, 2020, Congress enacted the No Surprises Act, "a bipartisan, bicameral deal . . . to protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers." Press Release, House Ways & Means Comm., *Congressional Committee Leaders Announce Surprise Billing Agreement* (Dec. 11, 2020), https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement.[2] Prior to the No Surprises Act, when a patient received care from an out-of-network provider, the provider submitted a bill to the patient's insurer, and the insurer determined how much to pay the provider. The outstanding balance—the difference between what the provider billed and what the insurer paid—was the patient's responsibility. To collect that balance, providers traditionally sent patients "balance bills," sometimes called "surprise bills" because patients often received them when they had no choice in their care, such as in the case of emergency care or care provided by an ancillary healthcare provider (such as an out-of-network clinical lab).

To protect patients from such "surprise bills," the No Surprises Act restricts out-of-network providers' ability to bill patients in excess of what the patient would have paid had she been treated by an in-network provider. 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A). The Act does not,

[2] The Act, which was passed as part of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 tit. I, div. BB, made parallel amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. These Departments, along with the Office of Personnel Management ("OPM") (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the September Rule.

however, expect providers to absorb underpayments. The Act instead provides a process by which providers can seek fair and reasonable payment from insurers. Insurers will continue to send the provider an initial payment or notice of denial of payment, but if a provider believes it to be an underpayment, the provider may initiate a 30-day period of open negotiation with the insurer. *See Id.* § 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K), (c)(1)(A). If the insurer and provider are unable to reach agreement during that 30-day period, either party may initiate binding arbitration before an independent dispute resolution ("IDR") arbitrator, who determines the fair payment amount. *Id.* § 300gg-111(a)(3)(K), (c)(1)(B).

In IDR arbitration, each party must submit their best and final offer, and the independent arbitrator must select one of the offers. 42 U.S.C. § 300gg-111(c)(5)(A)(i), (c)(5)(B)(i)(I). The Act thus establishes a "baseball-style" process designed to encourage the parties to reach a pre-arbitration compromise or, failing that, to make only reasonable, well-supported offers. *See* Matt Mullarkey, *For the Love of the Game: A Historical Analysis and Defense of Final Offer Arbitration in Major League Baseball*, 9 Va. Sports & Ent. L.J. 234, 245 (2010) (explaining that baseball-style arbitration encourages reasonable offers because, if one party's offer is unreasonable, the arbitrator will select the other party's offer even if it is too high or low).

The Act explicitly sets forth several mandatory factors that the arbitrator "shall" consider in deciding which offer to select (the "Subparagraph C Factors"). 42 U.S.C. § 300gg-111(c)(5)(C) ("In determining which offer is the payment to be applied pursuant to this paragraph, the certified [arbitrator] . . . shall consider" six different factors.); *see id.* § 300gg-111(c)(5)(A) ("[T]he certified [arbitrator] shall[,] taking into account the considerations in subparagraph (C), select one of the offers[.]"). Specifically, in a section titled "Considerations in determination," Congress instructs that, "[i]n determining which offer is the payment to be applied," the arbitrator "shall consider":

> (I) the qualifying payment amounts [QPAs] . . . for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; *and*
>
> (II) subject to subparagraph D, information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

42 U.S.C. § 300gg-111(c)(5)(C)(i) (emphasis added). As incorporated in subsection II above, "clause (ii)" lists the following five factors that the arbitrator "shall" consider:

> (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.

Id. § 300gg-111(c)(5)(C)(ii). The arbitrator also must consider any information she requests from the parties, *id.* § 300gg-111(c)(5)(C)(i)(II), as well as any additional information submitted by either party relating to its offer, *id.* § 300gg-111(c)(5)(C)(ii). Congress further specified three factors that the arbitrator "shall not consider": (1) usual and customary charges, (2) the amount the provider would have billed for the item or service if the Act's billing provisions did not apply, and (3) the amount a public payer (like Medicare) would have paid. *Id.* § 300gg-111(c)(5)(D). Finally, Congress required the independent arbitrator to have "sufficient medical, legal, and other

expertise" to be able to assess all the Subparagraph C Factors and come to a conclusion as to the best offer based on those factors. *Id.* § 300gg-111(c)(4)(A).

Calculated by the insurer, the QPA is generally the median of the contracted rates recognized by an insurer for the same or similar services in the same geographic region. 42 U.S.C. § 300gg-111(a)(3)(E)(i); *see also id.* § 300gg-111(a)(2)(B). Initially, Congress considered adopting proposals that would have made the QPA the presumptive benchmark in the arbitrator's selection. *See* Neal and Brady Letter ("Multiple proposals that ultimately did not become law relied on the median in-network rate [effectively, the QPA] as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate."). But Congress ultimately rejected this approach, prescribing no particular weight or presumption for any one factor. Instead, Congress mandated that the arbitrator "shall" consider *all* of the enumerated factors, leaving it to the independent arbitrator's discretion and expertise to decide how much weight to give each factor in a particular case.

II. The Departments Publish The September Rule As An Interim Final Rule

More than nine months after Congress passed the No Surprises Act, the Departments published the September Rule, an interim final rule that became effective on October 7, 2021. *See* 86 Fed. Reg. 55,980. As relevant here, the Departments purported to implement provisions related to the arbitrator's payment determination—even though the Act's provision governing payment determinations does not delegate any substantive authority to the Departments. Specifically, the Departments imposed a novel "presumption" that one of the factors—the QPA—"is [the] appropriate" payment rate, and that (with rare exception) the arbitrator "*must* select the offer closest to the QPA[.]" 86 Fed. Reg. at 55,995 (emphasis added). Despite the Act's language that IDR arbitrators "shall" consider all of the Subparagraph C Factors, under the September Rule, the arbitrator may consider the non-QPA factors only to the extent a party provides "credible

information" that "clearly demonstrates" that the QPA is "materially different" from the appropriate payment rate. 45 C.F.R. § 149.510(b)(4)(ii)(A); *see id.* § 149.510(a)(2)(v) (defining "credible information" as "information that upon *critical analysis* is worthy of belief and is trustworthy" (emphasis added)); *id.* § 149.510(a)(2)(viii) (defining "material difference" to mean "a *substantial* likelihood that [an IDR arbitrator] . . . would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate" (emphasis added)).

The September Rule discourages consideration of the non-QPA factors in additional ways. For instance, the September Rule does not require the parties to submit, or the arbitrator to obtain, information related to any other statutorily mandated factor at all. *See* 45 C.F.R. § 149.510(b)(4)(i)(A). Indeed, the Departments warn arbitrators that certain Subparagraph C Factors that Congress chose—such as the "level of training [and] experience" of the provider and the acuity of the patient or complexity of the service, 42 U.S.C. §§ 300gg-111(c)(5)(C)(ii)(I), (III)—should rarely trump the QPA, based on the Departments' belief that specific statutory language must bow to the Act's general "goals." *See* 86 Fed. Reg. at 55,997. In addition, the September Rule places a special burden on arbitrators who deviate from the QPA. If the arbitrator does not select the offer closest to the QPA, she must provide a "detailed explanation" of why she found the QPA 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 [arbitrator] 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; *see* 45 C.F.R. § 149.510(c)(4)(vi). The Rule contains no such requirement if the arbitrator selects the offer closest to the QPA.

The QPA will typically undervalue the services that physicians and hospitals provide, in large part due to the methods Defendants chose for calculating the QPA.[3] This is why Secretary Becerra recently informed healthcare providers that they—and not insurers—would "have to tighten their belt[s]" under the Departments' new rules. *See* NPR Becerra Interview. Indeed, the Departments have admitted that an intended effect of making the QPA the presumptive factor is to limit "higher out-of-network rates" paid to providers. *E.g.*, 86 Fed. Reg. at 55,996 (noting that the September Rule will limit "higher out-of-network rates").

The Departments were given a year—until December 27, 2021—to stand up the IDR process. *See* 42 U.S.C. § 300gg-111(c)(2)(A). The Departments nonetheless decided to publish the Rule as an interim final rule at the end of September 2021, without first considering public notice and comment. The Departments claimed that "it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until a full public notice and comment process has been completed[.]" 86 Fed. Reg. at 56,043.

Although the September Rule is already in effect, the Departments invited the public to submit any comments by December 6, 2021. The Departments, however, did not commit to a date by which they would issue a final rule, and multiple recent reports have suggested that the Departments are unlikely to change the September Rule following notice and comment. *E.g.*, Sara

[3] Specifically, in an interim final rule issued in July 2021, the Departments concluded that the median contracted rate—on which the QPA is based—should be calculated by (1) using each contract, rather than the number of claims actually paid at a contracted rate, as a data point; (2) excluding single case agreements; (3) ignoring certain elements of contracted rates that would increase the median contracted rate, including risk-sharing, bonus, and incentive payments; and (4) defining the geographic region to include, in some instances, rates in other states. *See* 45 C.F.R. § 149.140(b)(2)(iv); "Requirements Related to Surprise Billing; Part I," 86 Fed. Reg. 36,872, 36,889 (July 13, 2021). The end result is that providers will usually receive lower payments under a regime controlled by the QPA versus one in which no single Subparagraph C Factor takes precedence. The QPA will particularly undervalue medical services where insurers have historically underpaid providers or have not made good-faith efforts to enter network agreements.

Hansard, *Labor Official Defends Embattled Surprise Billing Rule*, Bloomberg Law (Nov. 10, 2021), https://news.bloomberglaw.com/employee-benefits/labor-official-defends-embattled-surprise-billing-rule ("'Obviously we did take an approach in the interim final rule that wasn't an accident. We've been thinking about this issue a lot, and it was a deliberate decision,' Ali Khawar, assistant secretary of the DOL's Employee Benefits Security Administration, said[.]"); NPR Becerra Interview (including similar quotes from Secretary Becerra and observing that "[r]ules that are this far along tend to go into effect with little or no changes").

III. The AMA, AHA, And Plaintiff Providers

The American Medical Association is the largest professional association of physicians, residents, and medical students in the United States. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. The American Hospital Association represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. Founded in 1898, the AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters. Both the AMA and AHA strongly support Congress's goal of protecting patients from "surprise billing." For years, the AMA and AHA consistently advocated for a solution to surprise billing that would shield patients from unexpected medical bills, while enabling providers and insurers to determine fair payment among themselves.[4]

Plaintiff Renown Health is an integrated healthcare system based in Reno, Nevada. It is northern Nevada's largest locally governed, not-for-profit healthcare network. It includes four

[4] *See, e.g.*, Letter from AMA to Chairman Neal and Ranking Member Brady on Surprise Medical Billing (Feb. 7, 2019), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTER

hospitals, 100 sites for primary, urgent, and specialty care; telehealth; and an integrated, provider-sponsored health insurance plan and accountable care organization that serves more than 150,000 members across northern Nevada. It provides the region's only Level II Trauma Center, serving over one million people and 100,000 square miles, from Sacramento to Salt Lake City. Renown also provides the region's first and only children's emergency room, which was opened in 2009. This broad reach allows Renown Health to provide desperately needed health and medical services to those living in remote, rural communities. Indeed, for rural Nevada and regions in Northeastern California, Renown is the safety-net provider for patients with chronic conditions and other serious health conditions. Given the vast health disparities that Nevada residents experience, including high mortality rates for chronic conditions such as heart disease, cancer, chronic respiratory disease, and mental health, Renown has set out to combat Nevada's history of ranking near the bottom of overall health rankings in the United States.

Plaintiff UMass Memorial Health is the largest healthcare system in Central and Western Massachusetts. It is a nonprofit network that makes healthcare accessible for all, regardless of ability to pay. In 1997, the creation of UMass Memorial Health was authorized by state legislation that approved combining the nonprofit Memorial Hospital with the public University of Massachusetts Medical Center. While allowing the combination of these entities into a new private, nonprofit system, the legislation also mandated that UMass Memorial Health permanently fulfill a unique, three-part public mission: (1) to provide highly specialized clinical services unavailable elsewhere in Central Massachusetts, (2) to provide free care to indigent patients, and

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S%2F2019-2-7-Surprise-Billing-Ways-and-Means-Signon.pdf; Letter from AHA to Chairman Neal on Surprise Medical Billing (Dec. 13, 2020), https://www.aha.org/system/files/media/file/2020/12/AHA-Letter-No-Surprises-Act_12-13-20.pdf.

(3) to support the Commonwealth's only public medical school. Consistent with that mission, UMass Memorial Health serves some of the most vulnerable patients and communities in Massachusetts.

UMass Memorial Health includes four hospitals: UMass Memorial Medical Center (Worcester), UMass Memorial Health – HealthAlliance-Clinton Hospital (Fitchburg, Clinton and Leominster), UMass Memorial Health – Marlborough Hospital (Marlborough), and UMass Memorial Health – Harrington Hospital (Southbridge). UMass Memorial Health also includes the only designated Level I Trauma Center for adults in Central Massachusetts and the region's only Level III Neonatal Intensive Care Unit, which provides expert care for ill or premature newborns. In addition to its fully equipped medical centers, UMass Memorial Health also includes a home health and hospice program, and community-based physician practices. UMass Memorial Health also has invested in a range of health-related joint ventures in the Central Massachusetts region, including an affiliation with CareWell Urgent Care to provide regional urgent care services and a joint venture with Shields Health Care to establish the Surgery Center in Shrewsbury, Massachusetts where UMass Memorial Medical Group physicians and other local physicians provide high-quality, low-cost outpatient surgery services. UMass Memorial Health also includes Community Healthlink, the region's largest comprehensive provider of behavioral health, substance use disorder, and homelessness services.

Plaintiffs Stuart M. Squires, M.D., and Victor F. Kubit, M.D., are licensed physicians and practicing anesthesiologists who practice with Cumberland Anesthesia Associates in Fayetteville, NC. Dr. Squires also serves as the practice's president. Both Drs. Squires and Kubit are members in good standing of the AMA. Dr. Squires has practiced at Cumberland for over 21 years, and Dr. Kubit for 20 years. Cumberland provides anesthesia services at several local hospitals, including

Cape Fear Valley Medical Center in Fayetteville, NC; Betsy Johnson Hospital in Dunn, NC; and Central Harnett Hospital in Lillington, NC. Cumberland provides its services in connection with a full range of medical procedures, including a substantial amount of obstetrics services. Their practice treats all patients without regard to their insured status or ability to pay.

ARGUMENT

This Court should stay the specific and limited provisions of the September Rule that require IDR arbitrators to presumptively favor the QPA. *See* 5 U.S.C. § 705. Motions to stay agency action are reviewed under the same standard as requests for preliminary injunctive relief. *See Cuomo v. U.S. Nuclear Regulatory Comm'n*, 772 F.2d 972, 974 (D.C. Cir. 1985); *Bauer v. DeVos*, 325 F. Supp. 3d 74, 105 (D.D.C. 2018). The Court has discretion to grant a preliminary injunction if (1) Plaintiffs are "likely to succeed on the merits," (2) Plaintiffs are "likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [Plaintiffs'] favor," and (4) the provision of interim relief "is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011).

Courts in this Circuit continue to assess the preliminary injunction factors "on a sliding scale, whereby a strong showing on one factor could make up for a weaker showing on another." *NAACP v. Trump*, 321 F. Supp. 3d 143, 146 (D.D.C. 2018) (internal quotation marks omitted) (quoting *Cigar Ass'n of Am. v. FDA*, 317 F. Supp. 3d 555, 560 (D.D.C. 2018)); *Alabama Ass'n of Realtors v. United States Dep't of Health & Hum. Servs.*, No. 20-CV-3377 (DLF), 2021 WL 1946376, at *1 (D.D.C. May 14, 2021) (under sliding scale approach, Plaintiff must show at least "a serious legal question on the merits"); *see Archdiocese of Wash. v. Washington Metro. Area Transit Auth.*, 897 F.3d 314, 334 (D.C. Cir. 2018) (reserving question of "whether the 'sliding scale' approach remains valid after" *Winter*). Whether a plaintiff has "established a likelihood of

success on the merits" nonetheless remains the "most important factor." *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014); *see Electronic Priv. Info. Ctr. v. FTC*, 844 F. Supp. 2d 98, 101 (D.D.C. 2012) ("The likelihood of success requirement is the most important of [the preliminary injunction] factors."), *aff'd*, No. 12-5054, 2012 WL 1155661 (D.C. Cir. Mar. 5, 2012). Because Plaintiffs have an overwhelming likelihood of success on the merits, they are entitled to a stay regardless of whether the sliding scale approach applies.

In the alternative, this Court should grant summary judgment under Federal Rule of Civil Procedure 56 for the reasons explained below. A court may grant a motion for summary judgment if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Because this case presents "purely legal issues," *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 116 (D.D.C. 2004), and because those issues should be resolved in Plaintiffs' favor, summary judgment is appropriate here, provided Defendants consent to summary judgment proceedings on a mutually acceptable expedited schedule. *See generally Curtis 1000, Inc. v. Suess*, 24 F.3d 941, 945 (7th Cir. 1994) ("The general point is that when the eventual outcome on the merits is plain at the preliminary injunction stage, the judge should, after due notice to the parties, merge the stages and enter a final judgment.").

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A reviewing court must "set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Grossmont Hosp. Corp. v. Burwell*, 797 F.3d 1079, 1085 (D.C. Cir. 2015) (internal quotation marks and citation omitted); *see* 5 U.S.C. § 706(2)(A). "An agency Order that is at odds with the requirements of the applicable statute cannot survive judicial review." *United Parcel Serv., Inc. v. Postal Regul. Comm'n*, 955 F.3d 1038, 1050 (D.C. Cir. 2020); *see Atlantic City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) ("In the absence of statutory authorization for its act, an agency's action is plainly contrary to law and

cannot stand." (internal quotation marks and citation omitted)). Considering the "traditional tools of statutory construction," including "the provision's text, context, legislative history, and purpose," *American Fuel & Petrochemical Mfrs. v. EPA*, 3 F.4th 373, 380 (D.C. Cir. 2021), the September Rule is contrary to the unambiguous terms of the No Surprises Act.

A. The Departments Acted Contrary To Law And In Excess Of Their Statutory Authority By Mandating A Presumption In Favor Of The QPA

1. The September Rule Conflicts With The No Surprises Act's Text And Design

The September Rule unlawfully conflicts with the No Surprises Act's unambiguous text and design in numerous ways.

First, the September Rule conflicts with the Act's direction that, in deciding which offer to select, the arbitrator shall consider all six statutory factors in every case. Congress twice instructed the arbitrator that she "shall" consider *all* the Subparagraph C Factors in determining which offer is the best. The Act first mandates that "the certified [arbitrator] *shall* . . . select one of the offers" after "taking into account the considerations specified in subparagraph (C)." 42 U.S.C. § 300gg-111(c)(5)(A) (emphasis added). The Act then reiterates that "[i]n determining which offer is the payment to be applied pursuant to this paragraph, the certified [arbitrator] . . . *shall* consider" the Subparagraph C Factors. *Id.* § 300gg-111(c)(5)(C) (emphasis added). Where, as here, a statute "comes in terms of the mandatory 'shall,'" it "creates an obligation impervious to judicial"—or agency—"discretion." *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Similarly, "[t]he statute's use of the word 'and' between the [factors] provides clear indication that *all* [six] factors are to be considered" by the arbitrator when determining the appropriate payment rate. *Wedelstedt v. Wiley*, 477 F.3d 1160, 1165-66 (10th Cir. 2007) (emphasis added); *see United States v. Palomar-Santiago*, 141 S. Ct. 1615, 1620-21 (2021) ("The requirements are connected by the conjunctive 'and,' meaning defendants must meet all

three."); *Levine v. Apker*, 455 F.3d 71, 81 (2d Cir. 2006) ("Significantly, Congress used the word 'and' rather than 'or' to unify its five concerns. All of the listed factors must therefore be considered."). What is more, the title of the relevant subsection is "Considerations in determination." 42 U.S.C. § 300gg-111(c)(5)(C). Not only does this title say nothing about a favored or presumptive consideration, but its plain text instructs that all of the factors listed therein are "considerations" for the arbitrator's payment determination. *See Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) ("[T]he title of a statute and the heading of a section are tools available for the resolution of a doubt about the meaning of a statute." (internal quotation marks and citation omitted)).

In the September Rule, however, the Departments dictated that the arbitrator must ignore the non-QPA factors unless a party first meets a heightened standard—*i.e.*, the party must "clearly demonstrate[]" the QPA is "materially different" from the appropriate payment rate. 45 C.F.R. § 149.510(b)(4)(ii)(A). Indeed, the Rule makes clear that, despite Congress's decision to require arbitrators to consider all six factors, the Departments believe that certain non-QPA factors should rarely "necessitate an out-of-network rate higher than the offer closest to the QPA." 86 Fed. Reg. at 55,997. Relying on the example of "the simple repair of a superficial wound," the Departments explain that they believe the training or experience of a provider should almost never necessitate a rate higher than the QPA. *Id.* But contrary to the Departments' assertion, the "simple" repair of such wounds is often not so simple. Their position fails to take account of added complications, such as the fact that patients with "simple" wounds may often have extenuating circumstances such as substance use or psychiatric disorders that complicate a repair, or that homeless patients are less likely to have the ability to keep such a wound clean and uninfected, creating a host of related medical issues. A provider's training and experience in managing those patients matters,

and managing them requires greater resources and time. In addition, patients often require emergency care for numerous reasons other than superficial wounds—such as for pulmonary embolisms, gunshot wounds, ectopic pregnancies, and strokes—where treatment by experienced providers matters as well. More fundamentally, the Departments have no authority to discard Congress's judgment that training and experience are important considerations in determining the appropriate payment rate, even if they disagree with it. *Cf.* 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(I) (arbitrator "shall" consider "[t]he level of training [and] experience . . . of the provider").

Moreover, the Rule explicitly instructs the arbitrator to consider the evidence related to the non-QPA factors with skepticism. *See* 45 C.F.R. § 149.510(a)(2)(v) (defining "credible information" as "information that upon *critical analysis* is worthy of belief and is trustworthy" (emphasis added)). That is true even though the September Rule affirmatively *forbids* the arbitrator from scrutinizing the QPA, commanding her to take the insurer's proffered QPA as given. *See* 86 Fed. Reg. at 55,996 ("[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly."). As such, some statutory factors may be cast aside before they are even considered if they do not meet the Rule's high "critical analysis" standard. The QPA, on the other hand, must always be considered, even if an arbitrator is dubious about its accuracy. To be clear: Plaintiffs have always assumed that parties would submit credible evidence and that arbitrators would take credibility into account when analyzing each of the statutorily mandated factors. Plaintiffs' objection is that the September Rule sets up a skeptical, one-sided evidentiary burden that is found nowhere in the statute and makes it more difficult for the arbitrator to fairly consider all six statutory factors as Congress intended.

These features of the September Rule are contrary to law. "A statutorily mandated factor, by definition, is an important aspect of any issue" under consideration. *United Parcel Serv.*, 955

F.3d at 1050-51. An agency is therefore not "free to ignore any [such] factor entirely," or to instruct another entity to do so. *Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 344 (D.C. Cir. 2019). Nor can an agency alter a statutorily imposed burden of proof, as the Departments do here. *See Public Service Co. of Indiana, Inc.*, 749 F.2d at 765-66. Accordingly, the September Rule violates Congress's unambiguous command for the arbitrator to independently consider *all* of the statutory factors, in every case, in deciding which offer to select.

Second, the September Rule conflicts with the No Surprises Act by treating "the QPA [as] the presumptive factor" in selecting a payment offer. 86 Fed. Reg. at 55,996. By inventing a "presumption that the QPA is the appropriate payment amount"—a requirement found nowhere in the Act—the Departments have violated Congress's decision to prescribe factors for the arbitrator's consideration without giving any one factor controlling weight. Where, as here, Congress has "carefully avoided attaching any particular weights to the various concerns that must be taken into account," an agency cannot "select . . . one [statutorily mandated] factor as controlling." *Public Service Co. of Indiana, Inc.*, 749 F.2d at 763; *see id.* at 765 ("One statutory factor cannot be isolated out of context, or blindly exalted at the expense of others that are at least co-equal in importance."). "To treat one of the . . . statutory factors in such a dramatically different fashion distorts the judgment Congress" made not to give presumptive weight to any particular factor. *American Corn Growers Ass'n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002); *see Trowell v. Beeler*, 135 F. App'x 590, 594-96 (4th Cir. 2005) (concluding that an agency abused its discretion in "ced[ing] veto power" to one statutorily mandated factors over all others).

Defendants have distorted Congress's design by "bifurcat[ing] the [arbitrator's] determination of the appropriate" payment rate, when it is clear "the [Subparagraph C] factors were meant to be considered together." *American Corn Growers*, 291 F.3d, at 6. Well-established

D.C. Circuit precedent squarely forecloses this approach. In *American Corn Growers*, the court of appeals partially vacated the EPA's Haze Rule because it "extract[ed]" one of five factors mandated by a statute (the Clean Air Act) and thereby "bifurcate[d]" the consideration of the factors. *Id.* Specifically, the EPA instructed states to treat one statutorily mandated factor differently (*i.e.*, on an area-wide basis) from their treatment of the remaining four factors (*i.e.*, on a source-by-source basis)—thus ensuring that the five factors could not be considered together, as Congress intended. The D.C. Circuit held that this "splitting of the statutory factors is consistent with neither the text nor the structure of the statute." *Id.* So too here. The Departments' splitting of the Subsection C factors—whereby the arbitrator must "presume" that one factor is correct, and consider the other factors only if they first meet a heightened credibility showing—also must be rejected.

A review of the full statute cinches the conclusion that the Departments' presumption is contrary to law. Congress passed the No Surprises Act as part of the Consolidated Appropriations Act, 2021. Elsewhere in that Act, Congress expressly created a "presumption." *See, e.g.*, Consolidated Appropriations Act, 2021, Section 226 (15 U.S.C. § 1116), "Rebuttable Presumption of Irreparable Harm" ("A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection[.]"). When Congress creates a presumption in one part of an Act, but "omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Collins v. Yellen*, 141 S. Ct. 1761, 1782 (2021) (internal quotation marks and citation omitted)). Had Congress wished to make any one of the Subparagraph C Factors presumptively correct, it knew how to do so.

Third, the September Rule unlawfully constrains the discretion Congress gave to the arbitrator to weigh the Subparagraph C factors. An agency acts contrary to law when it "constrains authority Congress conferred on" a different entity. *American Corn Growers*, 291 F.3d at 9; *see Texas v. EPA*, 829 F.3d 405, 426-28 (5th Cir. 2016) (concluding that the EPA had to "defer to Texas's [reasonable progress] goals so long as the Texas goals compl[ied] with the [Clean Air] Act" because the Act limited the EPA "to a deferential role"). Hence, in *American Corn Growers*, the D.C. Circuit held that the EPA's Haze Rule was contrary to the Clean Air Act because the Haze Rule "tie[d] the states' hands" by requiring them to assess one of the five statutorily mandated factors in a particular manner. This instruction contravened the statute's "provisions giving the states broad authority over [such] determinations." *American Corn Growers*, 291 F.3d at 8.

The September Rule similarly arrogates to the Departments discretion that Congress gave the arbitrator to determine how best to weight the Subparagraph C Factors in a given case. Congress specifically required that IDR arbitrators have "sufficient medical, legal, and other expertise" to competently assess the Subparagraph C Factors and render a payment determination in the exercise of their discretion. 42 U.S.C. § 300gg-111(c)(4)(A). By contrast, Congress gave Defendants no substantive role with respect to the arbitrator's "[p]ayment determination." *Id.* § 300gg-111(c)(5). This is in distinct contrast to the active role the Act gives the Departments in other provisions. *Compare id.* § 300gg-111(c)(1)(B), (2)(A), (4)(F), *with id.* § 300gg-111(c)(5). Given this clear textual division of labor, the Departments cannot now "tie the [arbitrators'] hands" with their invented presumption. *American Corn Growers*, 291 F.3d at 8.

2. The September Rule Conflicts With The Statute's History And Purpose

Even when the statute's plain meaning is clear from its terms, legislative history can help "confirm [a court's] reading of the text." *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 643 (D.C. Cir. 2021); *see Planned Parenthood Fed'n of Am., Inc. v. Heckler*, 712 F.2d 650, 656–57 (D.C.

Cir. 1983) ("Even when the statute's plain meaning is clear from its terms, legislative history can be equally illuminating." (internal quotation marks omitted)). Here, the No Surprises Act's legislative history further demonstrates that Congress meant what it said when it required an independent arbitrator—not the Departments—to consider all of the statutory factors, without a presumption in favor of any single one.

The No Surprises Act was the result of "a long-fought and negotiated bipartisan and bicameral compromise to protect patients by ending surprise billing." 166 Cong. Rec. H7290, H7291 (Dec. 21, 2020). Specifically, "[t]he IDR process was subject to extensive Congressional consideration for nearly two years prior to the enactment of the No Surprises Act." Neal and Brady Letter. At the end of that process, all of the House and Senate Committee Chairmen and Ranking Members who considered different legislation on "surprise billing" issued a joint press release announcing their compromise. In it, these legislators stated:

> When choosing between the two offers the arbiter is required to consider the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, and any other information submitted by the parties.

Press Release, House Ways & Means Comm., *Congressional Committee Leaders Announce Surprise Billing Agreement* (Dec. 11, 2020), https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement; *see* Press Release, *Senator Murray Announces Bipartisan Deal to Protect Patients, End Surprise Medical Bills* (Dec. 11, 2020), https://www.murray.senate.gov/senator-murray-announces-bipartisan-deal-to-protect-patients-end-surprise-medical-bills/ (same).

Notably, some of these legislators originally favored legislation that looked much more like the presumption-based approach the Departments imposed in the September Rule. Many

"proposals that ultimately did not become law relied on the median in-network rate as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate." Neal and Brady Letter. For example, the Lower Health Care Costs Act provided that, with certain exceptions, "[a] group health plan or health insurance issuer offering group or individual health insurance coverage *shall pay providers*, including facilities and practitioners, furnishing [certain] services[,] . . . *the median in-network rate* for such services." Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019) (emphases added); *see also, e.g.*, Ban Surprise Billing Act, H.R. 5800, 116th Cong. § 2(a) (2020); No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019). But that was *not* the compromise that Congress reached. Instead, by "provid[ing] for an IDR process overseen by an independent and neutral arbiter who must consider a number of factors equally in deciding whether to select the provider or payer's offer," Congress "deliberately crafted the law to avoid any one factor tipping the scales during the IDR process." Neal and Brady Letter.

The September Rule also conflicts with Congress's purpose. "Despite the careful balance Congress designed for the IDR process," the September Rule "strays from the No Surprises Act in favor of an approach that Congress did not enact in the final law," and which "essentially tips the scale for the median contracted rate being the default appropriate payment amount." Neal and Brady Letter. It thus "affronts the provisions enacted into law" by "bias[ing] the IDR entity toward one factor (a median rate) as opposed to evaluating all factors equally as Congress intended." *Id.* A recent letter from 150 bipartisan Members of Congress made the same point: the September Rule's presumption-based approach for determining payment rates "do[es] not reflect the way the law was written, do[es] not reflect a policy that could have passed Congress, and do[es] not create a balanced process to settle payment disputes." Letter from Members of Congress to Departments

Secretaries (Nov. 5, 2021), https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf. Stated simply, the Departments exceeded their statutory authority by imposing a presumption that Congress explicitly rejected.

3. The Departments' Asserted Justifications Cannot Salvage Their Unlawful Presumption

In the September Rule, the Departments defended their decision to treat the QPA in a dramatically different fashion from the other factors by raising the following heretofore unknown canons of construction: (1) "[t]he statutory text lists the QPA as the first factor," (2) the other factors "are described in a separate paragraph" and are "subject to a prohibition on considering certain factors," and (3) the statute "sets out detailed rules for calculating the QPA" and requires the QPA to be used in determining patient cost-sharing. 86 Fed. Reg. at 55,996. The agencies claimed that these three features rendered their reading "the best interpretation" of the statute. *Id.* It is not. Because it is a "foundational principle of administrative law" that judicial review of agency action is limited to "the grounds that the agency invoked when it took the action," *Michigan v. EPA*, 576 U.S. 743, 758 (2015), and because these arguments are unpersuasive in light of the plain text of the statute, the Departments' interpretation of the No Surprises Act fails on its own terms.

As an initial matter, it is important to emphasize that Defendants' interpretation is in no way based on the text of the relevant statutory provisions. Rather, their so-called "best interpretation" is based entirely on contextual and structural features, such as the order in which the factors were listed, where those factors were located in the statute, and *other* provisions of the Act. But as Chief Justice Roberts has cautioned, "[r]eliance on context and structure in statutory interpretation is 'a subtle business, calling for great wariness lest what professes to be mere

rendering becomes creation and attempted interpretation of legislation becomes legislation itself.'" *King v. Burwell*, 576 U.S. 473, 497-98 (2015) (quoting *Palmer v. Massachusetts*, 308 U.S. 79, 83 (1939)). Just as the Chief Justice predicted, the Departments' reliance on these contextual and structural features replaces the text of the No Surprises Act with an entirely new piece of legislation.

First, in every list of factors, one factor must be first. But that unremarkable fact has never implied that the first factor should enjoy privileged status or, on the other hand, that the last should receive inferior status. The Departments offered no authority for the proposition that the mere arrangement of statutory factors reflects congressional prioritization. On the contrary, "[n]o accepted canon of statutory interpretation permits 'placement' to trump text, especially where, as here, the text is clear and our reading of it is fully supported by the legislative history." *Padilla v. Rumsfeld*, 352 F.3d 695, 721 (2d Cir. 2003), *rev'd on other grounds by Rumsfeld v. Padilla*, 542 U.S. 426 (2004).

Second, although the non-QPA factors are listed in a separate paragraph from the QPA, that does not change the fact that all of the factors are textually set forth as separate "considerations for determination." 42 U.S.C. § 300gg-111(c)(5)(C). This would be true regardless of the Act's paragraph placement, but it is particularly true because the non-QPA factors are expressly *incorporated in the same paragraph* as the QPA factor. *See id*. § 300gg-111(c)(5)(C)(i) (listing all the factors the arbitrator shall consider "[i]n determining which offer is the payment to be applied pursuant to *this paragraph*" (emphasis added)). The Departments' attempt to minimize the non-QPA statutory factors because they were incorporated by reference, rather than listed directly, is precisely the kind of form-over-substance reasoning that courts have rejected.

What is more, that paragraph structure merely indicates Congress's intent that the non-QPA factors be considered *independently* of the QPA—not dependently as the September Rule treats them. *See VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1313 (Fed. Cir. 2014) (noting that where two factors are "listed separately in [a] statute . . . , even when both factors point in the same direction[,] . . . they continue to be separate, individual factors which must be weighed"). Indeed, where, as here, a statute mandates consideration of a factor, the factor must be independently considered even if it "has arguably [already been] considered" elsewhere. *United Parcel Serv.*, 955 F.3d at 1042. In *United Parcel Services*, the D.C. Circuit thus held that the Postal Regulatory Commission "must consider all costs uniquely or disproportionately associated with competitive products . . . even if [the Commission] has already accounted for those costs under [a different statutory provision]," and remanded the case for the Commission to do so. 955 F.3d at 1051.

Third, the Departments make far too much of the fact that the non-QPA factors may be subject to certain statutory prohibitions. Because the QPA is a set number submitted by the insurer to the arbitrator, the prohibited factors will be largely irrelevant to the QPA. There is thus little to divine from the Departments' claim that the prohibited factors do not apply to the QPA. In fact, despite the Departments' claim to the contrary, the prohibited factors are likewise irrelevant to the *non*-QPA factors. It is nonsensical to say that an arbitrator "shall not consider" certain *quantitative* factors (such as "usual and customary charges" or Medicare rates) when evaluating the *qualitative* Subparagraph C factors (such as a patient's "acuity" or a doctor's "experience" or an insurer's "good faith efforts" to enter a network agreement with a provider). 42 U.S.C. § 300gg-111(c)(5)(C)(i)-(ii). In reality, the prohibited factors are far more likely to come into play in connection with an arbitrator's consideration of "information . . . submitted by either party" or

requested by the arbitrator. *Id.* § 300gg-111(c)(5)(B), (C)(ii). And if anything, the Act's explication of certain prohibited factors demonstrates that Congress purposely specified exactly what it wanted (and did not want) the arbitrator to consider. That the Department now uses those prohibited factors to prop up its atextual presumption reveals the frailty of its interpretation.

Fourth, it is no surprise that the Act goes into detail about how to calculate the QPA, but not other factors like a provider's experience or a patient's acuity. The QPA is a new concept, created entirely by the Act itself. The other factors exist independent of the Act. That Congress wanted "an accurate and clear calculation of the QPA" is not a sign that the QPA is more "integral to . . . the certified [arbitrator]'s determination of the out-of-network rate." 86 Fed. Reg. at 55,996. All it shows is that Congress needed a few more words to explain a new statutory concept than to list straightforward, pre-existing concepts like a provider's level of training or market share.

Finally, the Departments rely on a range of "policy considerations," such as "increas[ing] the predictability of IDR outcomes," "encourag[ing] parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs," and "aid[ing] in reducing prices that *may* have been inflated due to the practice of surprise billing prior to the No Surprises Act." 86 Fed. Reg. at 55,996 (emphasis added). But "[d]isagreeing with Congress's expressly codified policy choices isn't a luxury administrative agencies enjoy." *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016). The Departments may not like the considered compromise Congress reached, but when Congress speaks clearly, "'the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Id.* (quoting *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984)); s*ee Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 325 (2014) (an "agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

B. The Departments' Interpretation Of The Act's Payment Determination Provision Is Owed No Deference.

The Departments may argue that their interpretation of the Act's "Payment determination" provision is owed deference under *Chevron*, 467 U.S. 837. It is not.[5]

First, the Departments' interpretation is contrary to the Act's plain and unambiguous meaning. A court will not defer to an agency's interpretation when, after employing the "'traditional tools of statutory construction,'" it determines that "Congress has directly spoken to the precise question at issue." *American Fuel & Petrochemical Mfrs.*, 3 F.4th at 380 (quoting *Chevron*, 467 U.S. at 843 n.9). Here, the Departments do not claim that the Act is ambiguous; they instead claim that theirs is the "best interpretation" of the Act. 86 Fed. Reg. at 55,996. But the Act includes a detailed listing of the factors an arbitrator "shall" and "shall not" consider in making a payment determination, and it delegates to the arbitrator the authority to weigh those factors and make that determination. The Act therefore unambiguously speaks to the direct question at issue: what factors the arbitrator should consider when determining which offer to select.

[5] This is especially true in light of recent statements from Supreme Court justices casting doubt on the underpinnings of the *Chevron* doctrine. *See, e.g.*, *Pereira v. Sessions*, 138 S. Ct. 2105, 2121 (2018) (Kennedy, J., concurring) ("It seems necessary and appropriate to reconsider, in an appropriate case, the premises that underlie *Chevron* and how courts have implemented that decision."); *Michigan*, 576 U.S. at 760 (Thomas, J., concurring) ("I write separately to note that [the agency's] request for deference raises serious questions about the constitutionality of our broader practice of deferring to agency interpretations of federal statutes."); *Gutierrez–Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring) ("[T]he fact is *Chevron* . . . permit[s] executive bureaucracies to swallow huge amounts of core judicial and legislative power and concentrate federal power in a way that seems more than a little difficult to square with the Constitution of the framers' design. Maybe the time has come to face the behemoth."). Plaintiffs reserve the right to challenge the continuing vitality of *Chevron* should this Court conclude that Defendants are likely to prevail based on such deference.

In the September Rule, Defendants also did not claim that their invented presumption was based on either a "gap" Congress left them to fill or an express delegation regarding arbitrator payment considerations—and thus cannot do so now.[6] *See Michigan*, 576 U.S. at 758. In any event, Congress does not create a "gap" to fill whenever it omits "thou shalt not" terms—that is, terms that expressly bar Defendants from imposing their invented presumption on the arbitrator. *American Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995). To suggest "that *Chevron* step two is implicated any time a statute does not expressly negate the existence of a claimed administrative power . . . is both flatly unfaithful to the principles of administrative law . . . , and refuted by precedent." *Railway Labor Executives' Ass'n v. National Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*); *see also Aid Ass'n for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) ("In this case, the Postal Service's position seems to be that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency. We reject this position as entirely untenable under well-established case law.").

Nor does the Act expressly delegate any authority to the Departments to direct the arbitrator how to determine appropriate payment rates. Congress deliberately assigned the Departments implementation roles elsewhere in the Act. For instance, the Act directs that the "Secretary [of Health and Human Services,] in consultation with the Secretary of Labor and Secretary of the

[6] Indeed, the interim final rule does not "manifest[] its engagement in the kind of interpretive exercise to which review under *Chevron* generally applies." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 22 (D.C. Cir. 2019) (quoting *SoundExchange, Inc. v. Copyright Royalty Bd.*, 904 F.3d 41, 54 (D.C. Cir. 2018)). As noted, the Departments merely assert that their interpretation is the "best" one based on contextual and structural features. They do not: (1) invoke *Chevron* by name or echo its language; (2) contend that the Act is ambiguous; or (3) consider the "statutory purpose, applicable prior decisions, and the relevant legislative history." *SoundExchange, Inc.*, 904 F.3d at 54.

Treasury, shall establish a process to certify . . . [IDR] entities under this paragraph." 42 U.S.C. § 300gg-111(c)(4)(A). Likewise, the Act provides that, in addition to four statutorily mandated criteria, the Departments "shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity." *Id.* § 300gg-111(c)(3)(A). Congress thus specifically delegated authority to the Departments to supplement statutorily mandated criteria found elsewhere in the Act. Yet Congress did not do the same in prescribing the Subparagraph C Factors. *See id.* § 300gg-111(c)(5)(A) ("Not later than 30 days after the date of selection of the certified IDR entity . . . the certified IDR entity shall" "taking into account the [Subparagraph C Factors]" select one of the offers.). That choice was "intentional[]." *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (citation omitted)).[7]

[7] The Departments cannot rely on the Act's delegation—located in paragraph (2), not under paragraph (5)'s "Payment determination"—to "establish by regulation one independent dispute resolution process." *See* 42 U.S.C. § 300gg-111(c)(2). By using the word "establish," the paragraph (2) delegation gives the Departments the task of "set[ting] up" the IDR process in the first instance, not of giving the arbitrator substantive instructions with respect to her payment determination. *See* Oxford English Dictionary (defining "establish" as "To set up on a secure or permanent basis; to found (a government, an institution; in modern use often, a house of business)"); American Heritage Dictionary of the English Language (defining "establish" as "To cause (an institution, for example) to come into existence or begin operating; found; set up"). And even if the Act's delegation to "establish" an independent dispute resolution process were broader than to simply stand up the new arbitration system, the presence of more specific delegations throughout the Act defeats any possible contention that this paragraph (2) delegation permits the Departments to impose a presumption for payment determinations. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) ("[T]he [general/specific] canon has full application as well to statutes such as the one here, in which a general authorization and a more limited, specific authorization exist side-by-side. There the canon avoids not contradiction but the superfluity of a specific provision that is swallowed by the general one.").

Second, *Chevron* deference is not due when "[a] regulation is 'procedurally defective'—that is[,] where the agency errs by failing to follow the correct procedures in issuing the regulation." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001)); *see New Hampshire Hosp. Ass'n v. Azar*, 887 F.3d 62, 76 (1st Cir. 2018) (refusing to apply *Chevron* deference under *Encino Motorcars* because "the adoption of a substantive policy in a preamble added to a regulation after notice and comment is procedurally improper"). The September Rule is "procedurally defective" because the Departments failed to provide notice and opportunity for public comment before publishing the September Rule.

The APA requires federal agencies to provide such notice and comment, unless they "for good cause" find that such procedures "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). HHS Secretary Becerra in fact "guarantee[d]" that before HHS took any action on the Act, it would "take the comments necessary, hear from all the stakeholders to make sure what we're doing is based on the facts, the science, *and the law*." Health and Human Services Department Fiscal Year 2022 Budget Request before the House Appropriations Sub-Committee (Apr. 15, 2021), https://www.c-span.org/video/?c4980111/userclip-becerra-statements-health-human-services-budget-request (at minute 49:06) (emphasis added). The Departments did not keep this promise. As a result, the Departments were deprived of the "expertise and input" of the parties most likely to be affected by the Rule. *National Tour Brokers Ass'n v. United States*, 591 F.2d 896, 902 (D.C. Cir. 1978).

The Departments cannot satisfy the high bar necessary to establish "good cause" here. *See Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754 (D.C. Cir. 2001) ("[T]he 'good cause' exception is to be narrowly construed and only reluctantly countenanced. The exception is not an

escape clause; its use should be limited to emergency situations." (internal citations and quotation marks omitted)). With respect to the IDR process, Congress gave the Departments a full year to act. 42 U.S.C. § 300gg-111(c)(2). The Departments cannot claim exigency simply because they waited nine months to actually do so. In any event, when the Departments issued the September Rule, Congress's deadline for establishing IDR regulations—December 27, 2021—was still three months away, and the first arbitrations were not set to begin until two months thereafter. Had the Departments promulgated the September Rule as a proposed rule and sought comment, they easily could have finalized that rule with sufficient time for the IDR process to begin in approximately March 2022.

In setting a deadline for final IDR regulations of December 27, 2021, Congress indicated that there would be sufficient time to establish the IDR process if final rules were not issued until then. In the September Rule, the Departments acknowledged this statutory deadline, but countered that "this timeframe would not provide sufficient time for the regulated entities to implement the requirements." 86 Fed. Reg. at 56,044. Here again, the Departments have blatantly overridden Congress's judgments, citing nothing more than a perceived need to provide guidance to insurers and providers in advance of January 1, 2022. But "good cause to suspend notice and comment must be supported by more than the bare need to have regulations." *National Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980); *see also United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009) ("A desire to provide immediate guidance, without more, does not suffice for good cause." (citation omitted)). Accordingly, "*Chevron* deference is not warranted" because Defendants failed "to follow the correct procedures in issuing the regulation," and had no "good cause" for doing so. *Encino Motorcars*, 579 U.S. at 220-21.

Third, even if the No Surprises Act left some ambiguity or a gap to fill, the Departments' interpretation would be "unreasonable" in light of Congress's detailed list of factors for the arbitrator to consider (and not to consider). That list leaves no room for supplementation by the Departments. When the Departments "replaced those [multiple factors] with [a presumption] of [their] own choosing, [they] went well beyond the 'bounds of [their] statutory authority.'" *Utility Air Regulatory Grp.*, 573 U.S. at 325. Indeed, "the need to rewrite clear provisions of the statute" by inventing an extra-statutory presumption "should have alerted [the Departments] that [they] had taken a wrong interpretive turn." *Id.* at 328. The September Rule could not survive *Chevron* Step Two, if it could ever get that far.

II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM ABSENT A STAY

The September Rule's presumption in favor of the QPA will irreparably harm Plaintiffs Renown Health, UMass Memorial Health, Dr. Squires, Dr. Kubit, and the other members of the AMA and AHA.

First, the September Rule will irreparably harm Plaintiff providers and the AMA's and AHA's other members when they are forced to accept unfairly low reimbursement rates as a result of the Departments' unlawful presumption. Plaintiffs' economic losses from an unfair and unlawful arbitration system will be unrecoverable from insurers because the statute expressly precludes judicial review of final and binding IDR decisions. *See* 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II). Plaintiffs will also be unable to recover damages from Defendants, who enjoy sovereign immunity. 5 U.S.C. § 702 (providing for relief "other than money damages"). This renders Plaintiffs' harms "per se" irreparable. *See Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (unrecoverable harms are "per se" irreparable); *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (similar); *see also Whitman-Walker Clinic, Inc.*, 485 F. Supp. at 64-65 ("'[W]here economic loss will be unrecoverable, such as in a case against a

Government defendant where sovereign immunity will bar recovery, economic loss can be irreparable' even if it would not wipe the business out." (quoting *Everglades Harvesting & Hauling, Inc. v. Scalia*, 427 F. Supp. 3d 101, 115 (D.D.C. 2019), and citing additional cases)). In addition to being "beyond remediation," these losses are irreparable because they are "certain and great" for the reasons detailed in the Rossi, Sexton, and Squires Declarations and summarized below. *Whitman-Walker Clinic, Inc.*, 485 F. Supp. 3d at 56 (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006), and *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

Second, the September Rule is *already* irreparably harming, and threatens to further harm, Plaintiff providers and the AMA and AHA's members, because it is *already* incentivizing insurers to reduce payment rates under their contracts. Because the Rule's presumption in favor of the QPA allows insurers to pay out-of-network providers at unfairly low rates, insurers can leverage the Rule to demand that in-network providers accept commensurately low rates, threatening to cancel in-network agreements if providers do not capitulate.

In fact, little more than a month after the September Rule's publication, an insurer sought to exploit the Departments' misinterpretation of the Act, to the detriment of its in-network providers and their patients. *See* BCBS Letter. Specifically, Blue Cross Blue Shield of North Carolina recently sent a letter to certain in-network providers demanding that they agree to reduced in-network rates in light of the September Rule's presumption in favor of the QPA as the appropriate payment rate. The letter states that "[w]hile the exact, final QPAs are not yet available . . . the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." *Id.* It goes on to demand "an immediate reduction in rates" to be followed by negotiation of final rates "in light of the QPA amounts established in accordance

with the upcoming Rules." *Id.* If the provider does not agree to reduce its rates, Blue Cross Blue Shield of North Carolina will terminate its contract, thereby leaving patients with more limited coverage options than they had prior to the September Rule. *Id.* ("If we are unable to establish in-network rates more in line with a reasonable, market rate, our plan is to terminate agreements where the resulting out-of-network QPA would reduce medical expenses to the benefit of our customers' overall premiums.").

The attached declarations demonstrate that the September Rule's harms are "both certain and great; . . . actual and not theoretical and of such imminence that there is a clear and present need for equitable relief." *Olu-Cole v. Haynes Pub. Charter Sch.*, 930 F.3d 519, 529 (D.C. Cir. 2019) (citations omitted). The declaration submitted by Plaintiff Renown Health makes clear that, based on its experience with a similar regime under Nevada law, arbitrations will begin in March 2022 and they will occur frequently. *See* Sexton Decl. ¶¶ 22-25. The declaration explains the serious consequences that will occur as a result of the September Rule. It states: "This interim final rule would deliver a crippling blow to Renown's overall reimbursement for hospital services, which we have modeled to be a minimum of 10% reduction in net reimbursement. This drop in reimbursement would drive our otherwise positive system-wide margin into an untenable net loss." *Id*. at ¶ 26. It also explains that "[i]nsurers will likely forego negotiating longer term contracts at reasonable market rates (or will effectively do so by making unreasonable demands to arbitrarily drive reimbursement rates to below cost levels), let agreements with our hospitals lapse, and rely on this arbitration process that greatly favors them via the QPA-presumption." *Id*. at ¶ 23. In fact, Renown notes that on December 2, 2021, one such insurer "explicitly stated [it would] no longer contract for emergency services with Renown" because of the September Rule. *Id*. at ¶ 24.

As a result of these "crippling" losses, Renown explains, it will be "even more difficult to provide the same treatments to those patients who turn to us for their healthcare needs, many of whom are the most vulnerable in our communities, be they children or those from rural parts of our state." *Id.* at ¶¶ 26, 27; *cf. Minney v. U.S. Office of Personnel Mgmt.*, 130 F. Supp. 3d 225, 235 (D.D.C. 2015) ("The harm at issue here is irreparable in the truest sense. . . . The lapse of medical coverage caused by OPM's failure to provide adequate advance notice is devastating for a man who is arguably more susceptible than sighted individuals to grievous physical injury. This Court is not alone in finding that a loss of this magnitude meets the litmus test for irreparable injury."). Potential services that may be targeted for cuts include trauma, Medicaid, indigent women and children's care, mental health services, and Renown's children's hospital pediatric subspecialties. *Id.* at ¶ 28. As Renown's declarant explained: "I am gravely concerned that the negative financial implications of the QPA-presumption to Renown would leave these already-underfunded and over-burdened services with no alternative but to scale back services." *Id.* This, in turn, will frustrate Renown Health's mission to "make a genuine difference in the health and well-being of the people and communities [it] serve[s]." *Id.* at ¶ 29.

So too for Plaintiff UMass Memorial Health. Like Renown Health, its declaration states that the QPA-presumption "will strain UMass Memorial Health's resources, make it more difficult for our providers to treat our patients, and thereby frustrate our non-profit health system's statutorily-imposed mission." Rossi Decl. ¶ 22. Specifically, based on her long experience with Blue Cross Blue Shield and recent incidents with another insurer, UMass Memorial Health's declarant is "confident that national and local insurers in the Massachusetts market will soon similarly threaten to terminate their provider contracts if providers are unwilling to accept substantial rate reductions." *Id.* at ¶ 25. As a result, UMass Memorial Health will receive

approximately "30% less than it otherwise would," *id*. at ¶ 27, which is particularly damaging for a hospital that has had an average annual operating margin (1.26%) that is *half* of what experts recommend for non-profit hospitals (2.5%), *id*. at ¶¶ 19, 28. Unsurprisingly, "UMass Memorial would lose access to the resources necessary to subsidize already-underfunded services like community-based mobile medical services for indigent families and youth, food insecurity assistance care, and pediatric asthma intervention for low-income youth[.]" *Id*. at ¶ 30.

Likewise, Plaintiff Dr. Squires, an anesthesiologist who practices with Plaintiff Dr. Kubit in rural North Carolina, will suffer irreparable harm as a result of the September Rule. Based on his experience negotiating with insurers as president of his anesthesiology practice, Cumberland Anesthesia Associates, as well as his understanding of the September Rule's presumption in favor of the QPA, Dr. Squires is "very concerned that the IDR arbitration process will routinely result in payments that are below the fair value of the out-of-network services" provided by Cumberland. Squires Decl. ¶ 9. Dr. Squires explains that the cost of anesthesia provider salaries, including for both doctors and nurses, increases substantially each year, largely due to a shortage of qualified providers in the rural area in which he practices. *Id.* at ¶ 10. A QPA tied to a 2019 lodestar and increased each year by only the consumer price index will thus "fail to adequately reflect the actual annual salaries necessary to attract talented anesthesia providers to our area." *Id.* Accordingly, he explains that the QPA-presumption will typically result in below-fair-value payments for Cumberland's out-of-network services, which Cumberland provides "every day" because it treats "all patients . . . regardless of their insured status or ability to pay." *Id.* at ¶ 8. In addition, Dr. Squires expects that the September Rule will lead to undercompensation from in-network insurers, like Blue Cross Blue Shield of North Carolina, that will feel "empowered" by the QPA-presumption to demand "in-network payment rates that are far below the value of our services."

Id. at ¶ 12. Such consistently below-fair-value payments will force Cumberland to make changes to its services, such as reducing the hours or days in which it provides anesthesia services, forcing local patients "to wait longer for surgeries or drive more than an hour to a larger city, like Raleigh, NC" for medical care. *Id.* at ¶ 11. Ultimately, Dr. Squires believes such consistent underpayments could drive small practices like Cumberland out of business, depriving local residents of much-needed medical care. *Id.* at ¶ 22.

"These harms from the forced diversion of resources are similar to those recognized as irreparable harm in other suits," *District of Columbia v. USDA*, 444 F. Supp. 3d 1, 42 (D.D.C. 2020), and they far exceed the showing required here. Courts in this circuit have repeatedly recognized that the effects Renown Health, UMass Memorial Health, and Dr. Squires describe constitute irreparable harm. *E.g.*, *Whitman-Walker Clinic, Inc.*, 485 F. Supp. 3d at 58 ("Because of the significant financial and operational harms the health-provider Plaintiffs will suffer on account of the 2020 Rule—and the consequent, well-established threat to their ability to deliver timely and effective care to their patients—the Court finds that their asserted injuries clear the irreparable-harm threshold."); *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224 (D.D.C. 2014) ("Plaintiffs, moreover, are not for-profit entities facing the loss of profit; rather, they are non-profits for whom lost funds would mean reducing hospital services to children, many of whom are Medicaid-eligible. . . . While this harm would not drive plaintiffs out of business, it is different in kind from economic loss suffered by a for-profit entity."); *see also League of Women Voters v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (finding irreparable harm when challenged action "ma[de] it more difficult for [organizations] to accomplish their primary mission"). As in those cases, the September Rule will irreparably harm both non-profit hospitals and anesthesiologists by "perceptibly impair[ing]" their "ability to provide services." *Whitman-Walker Clinic, Inc.*, 485 F.

Supp. 3d at 56 (quoting *Food & Water Watch*, 808 F.3d 905, 919 (D.C. Cir. 2020)). What is more, "[t]he Court also [should] not turn a blind eye to the reality that here, 'economic loss' is not simply 'loss of profit'; rather, it means 'reducing [health-care] services' to patients, many of whom are indigent." *Id.* at 59 (quoting *Texas Children's Hosp.*, 76 F. Supp. 3d at 243-44) (alteration in original). All in all, "the health-provider Plaintiffs' unrecoverable future harm is of such a degree, severity, and 'imminence that there is a clear and present need for equitable relief to prevent' it." *Id.* (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

Finally, the Plaintiff hospitals describe another type of well-recognized irreparable harm that they will suffer as a result of the Departments' unlawful QPA-presumption. As noted in the Sexton and Rossi Declarations, the presumption will cause Plaintiffs and their members significant reputational harm. Both hospitals, for example, explain that their relationships with the patients and communities they serve will suffer greatly if they are forced by pervasive underpayments to either reduce some medical services or if they refuse the underpayments and thereby face termination of their contracts by insurers. *See* Sexton Decl. ¶ 29; Rossi Decl. ¶ 31. They further explain how important their reputations and relationships are to their institutions, and how both will be "irredeemably damaged" if the Rule remains in effect. *See* Sexton Decl. ¶ 29; Rossi Decl. ¶ 31. "Courts have recognized that such [reputational] harm . . . can constitute irreparable harm sufficient to qualify for a preliminary injunction." *Everglades Harvesting*, 427 F. Supp. 3d at 116. Accordingly, even setting aside the massive economic and mission-related harms described above and in the attached declarations, Plaintiffs have amply demonstrated irreparable harm as a result of the September Rule.

To prevent this litany of irreparable harms, the Rule should be stayed.

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST STRONGLY FAVOR A STAY PENDING JUDICIAL REVIEW

When a stay of agency action is sought against the government, harm to the opposing party and the public interest merge into a single inquiry "because the government's interest *is* the public interest." *Pursuing Am.'s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). The Court thus weighs the harm to the movants absent a stay against the impact of a stay on the government and the public interest. *Id.*

Here, the harms to movants and their patients far outweigh any potential harm to the government. The government "cannot suffer harm from [a stay] that merely ends an unlawful practice or reads a statute as required[.]" *R.I.L-R v. Johnson*, 80 F. Supp. 3d 164, 191 (D.D.C. 2015) (citation omitted); *see also League of Women Voters*, 838 F.3d at 12 ("There is generally no public interest in the perpetuation of unlawful agency action." (collecting cases)). Rather, "there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *Id.* (internal quotation marks omitted).

If that were not enough, a limited stay of the unlawful portions of the September Rule will not interfere with the IDR process because the government's "interpretation" is not necessary for successful arbitrations under the Act. The Act already describes in detail the considerations the arbitrator should take into account in determining which offer to accept. There is thus no need for Defendants to promulgate *any* rule with respect to the arbitrator's payment selection; Congress already gave the arbitrator all the direction she needs to select an offer. *See Public Service Co. of Indiana, Inc.*, 749 F.2d at 763 ("The *Staggers Act itself* sets certain standards that must be followed by the ICC and state commissions alike.").

Even if there were a need for Defendants to promulgate a rule with respect to the arbitrator's payment selection, staying the specific and limited portions of the interim final rule is

not likely to delay arbitration decisions. While the Departments dawdled in issuing their Rule, the ensuing comment period closed on December 6, 2021. *See* 86 Fed. Reg. 55,980. Thus, if they deem it necessary, the Departments would have more than enough time to publish updated final rules that conform to the Act before the first expected arbitration decisions are due in March 2022.

The public interest, meanwhile, weighs heavily in favor of a stay. Critically, the September Rule will irreparably harm the patients served by Renown Health, UMass Memorial Health, Drs. Squire and Kubit, and the other members of the AMA and AHA. As the letter from Blue Cross of North Carolina makes clear, the Rule emboldens insurers to narrow their networks and threaten to "terminate" those providers who refuse to accept unfairly low compensation rates. Other insurers are likely to take similar action. *See* Sexton Decl. ¶¶ 22-25; Rossi Decl. ¶ 25; Squires Decl. ¶¶ 17-19. The insurers' actions will reduce the number of doctors and hospitals that are "in-network," and thereby reduce choices and access to in-network care for patients. As explained in the attached declarations, consistent underpayments to providers will also prompt them to take measures to reduce their expected losses, such as by limiting medical services.

Finally, "[t]here is clearly a robust public interest in safeguarding prompt access to health care." *Whitman-Walker Clinic, Inc.*, 485 F. Supp. at 61; *see New York v. DHS*, 969 F.3d 42, 87-88 (2d Cir. 2020) (finding that public interest favored preliminary injunction where agency action would likely result in worse health outcomes); *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018) (similar). As even the Departments themselves recognize, undercompensating providers "could lead to participants, beneficiaries and enrollees not receiving needed medical care[.]" 86 Fed. Reg. at 56,044. Accordingly, the public interest will be served by staying the September Rule, leaving the arbitrators to abide by Congress's clear and detailed instructions rather than the Departments' atextual presumption.

CONCLUSION

For the foregoing reasons, this Court should issue as soon as possible, and before March 1, 2022, a stay pending judicial review of the provisions of the September Rule that require IDR entities to employ a presumption in favor of the offer closest to the QPA, or in the alternative, grant summary judgment in Plaintiffs' favor.

Respectfully submitted,

/s James E. Tysse

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STATUTORY AND REGULATORY ADDENDUM

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Statute

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42 U.S.C. § 300gg-111. Preventing Surprise Medical Bills

***

(c) Determination of out-of-network rates to be paid by health plans; independent dispute resolution process

***

(5) Payment determination

(A) In general

Not later than 30 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the certified IDR entity shall—

(i) taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such item or service determined under this subsection for purposes of subsection (a)(1) or (b)(1), as applicable; and

(ii) notify the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination of the offer selected under clause (i).

(B) Submission of offers

Not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination—

(i) shall each submit to the certified IDR entity with respect to such determination—

(I) an offer for a payment amount for such item or service furnished by such provider or facility; and

(II) such information as requested by the certified IDR entity relating to such offer; and

(ii) may each submit to the certified IDR entity with respect to such determination any information relating to such offer submitted by either party, including information relating to any circumstance described in subparagraph (C)(ii).

(C) Considerations in determination

(i) In general

In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider—

(I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and

(II) subject to subparagraph (D), information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

(ii) Additional circumstances

For purposes of clause (i)(II), the circumstances described in this clause are, with respect to a qualified IDR item or service of a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer of group or individual health insurance coverage the following:

(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 1395aaa of this title).

(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.

(D) Prohibition on consideration of certain factors

In determining which offer is the payment to be applied with respect to qualified IDR items and services furnished by a provider or facility, the certified IDR entity with respect to a determination shall not consider usual and customary charges, the amount that would have been billed by such provider or facility with respect to such items and services had the provisions of section 300gg-131 or section 300gg-132 of this title (as applicable) not applied, or the payment or reimbursement rate for such items and services furnished by such provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act, under the Medicaid program under title XIX of such Act, under the Children's Health Insurance Program under title XXI of such Act, under the TRICARE program under chapter 55 of Title 10, or under chapter 17 of Title 38.

***

45 C.F.R. § 149.510. Independent Dispute Resolution Process

(a) Scope and definitions—

***

(2) Definitions

***

(v) Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

***

(viii) Material difference means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

***

(c) Federal IDR process following initiation—

***

(4) Payment determination for a qualified IDR item or service—

(i) Submission of offers. Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(1) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(2) Information requested by the certified IDR entity relating to the offer.

(3) The following additional information, as applicable—

(i) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has

fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(ii) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(iii) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(iv) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) Payment determination and notification. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

***

(iii) Considerations in determination. In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(1) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

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

(3) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(4) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(5) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, 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.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

***

(vi) Written decision.

(A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION, AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.* *Defendants*.	Civ. Action No. _____

DECLARATION OF BETHANY SEXTON
IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Bethany Sexton, state as follows under the pains and penalty of perjury.

Personal Experience and Educational Background

1. I am Chief Transformation Officer at Renown Health, the parent company of Regional Medical Center ("Renown Hospitals"), a Plaintiff in this action. I have been employed by Renown Health for seven (7) years.
2. As a member of Renown Health's executive team, my responsibilities include oversight of payer contracting, value-based care, including Renown's clinically integrated network, Western Clinical Alliance, Renown Accountable Care, and Renown Direct Contracting Entity. Additionally, I serve as a member of our population health services organization executive team.
3. Prior to my current role at Renown Health, I worked as a health care leader for more than ten (10) years, including as Vice President of Strategic Initiatives, Vice President and Administrator for the Department of Medicine, and Vice President of Revenue Cycle.

4. I hold an undergraduate degree from the Western Washington University in Business Administration, and a Masters of Business Administration from the University of Nevada, Reno.

5. The information set forth in this affidavit is based on my personal knowledge.

Renown Health and the Population It Serves

6. Renown Health is an integrated healthcare system based in Reno, NV. It is northern Nevada's largest locally governed, not-for-profit healthcare network.

7. Formerly known as the Washoe Health System, Renown Health was founded as a clinic in 1862 during a smallpox outbreak. That clinic became the area's first hospital when Nevada became a state in 1864. Over the next century, Washoe Health System would establish pediatric, cardiac, and cancer centers in northern Nevada.

8. Today, Renown Health includes four hospitals, 100 sites for primary, urgent, and specialty care; telehealth; an integrated, provider-sponsored health insurance plan and accountable care organization that serves more than 150,000 members across northern Nevada.

9. Renown Health has more than 6,000 employees and 1,500 physician-providers. According to the National Research Corporation, in 2018, Renown Health was responsible for an additional 6,790 indirect jobs and had a $2.4 billion overall economic impact for the region it serves.

10. Renown Health, through Renown Hospitals, provides the region's only Level II Trauma Center, serving over 1 million people and 100,000 square miles from Sacramento to Salt Lake City. This broad reach allows Renown Health to provide desperately-needed health and medical services to those living in remote, rural communities.

11. Renown Health provides over two-thirds of the hospital care for Northern Nevada's Medicaid population. Renown Hospitals' payer mix is approximately 19% Medicaid, 40% Medicare, and 31% private insurance. Government-payer reimbursement is well below Renown Hospitals' cost, so Renown must rely on private insurance reimbursement to offset those losses.

12. Renown Hospitals also provide the area's first and only children's emergency room, which was opened in 2009, and is the region's only Children's Miracle Network Hospital.

13. Since 2014, Renown has participated in a Medicare Shared Savings Program ACO through the CMS Innovation Center. These efforts have delivered over $12 million in savings, which have been shared with CMS and reinvested in care delivery programs across the health network along with shared savings to community provider partners.

14. In 2020, Renown Health established Western Clinical Alliance, a clinically-integrated network focused on improving patient outcomes and lowering the overall cost of care. Along with partnering with community physicians, Renown Health is affiliated with the University of Nevada, Reno School of Medicine, establishing Nevada's first fully integrated health system.

15. For rural Nevada and regions in Northeastern California, Renown is the safety-net provider for patients with chronic conditions and other serious health conditions. Given the vast health disparities that Nevada's residents experience, including high mortality rates for chronic conditions such as heart disease, cancer, chronic respiratory disease and mental health, Renown has shifted to care for the overall population's health and has set out to combat Nevada's history of ranking near the bottom of overall health rankings in the United States.

16. Renown Health is a member of the American Hospital Association, a Plaintiff in this action.

17. Renown Health recently submitted comments to the Departments in connection with their Interim Final Rule, entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("IFR").

The Impact of the IFR's Unlawful Presumption on Renown Health

18. Under current Nevada law, Renown is subject to arbitration for determining rates paid by non-contracted payers for emergency services. *See* Nevada Assembly Bill 469. Since January 2020, when the relevant Nevada law went into effect, Renown has participated in fifty-nine (59) such arbitrations, either subject to the state Office of Community Health Affairs (OCHA) or independent arbitration processes set forth in Nevada law. Given this frequency of arbitrations over the past two years (*i.e.*, on average, more than one every other week), I am confident that Renown will be engaged in similar arbitrations under the federal No Surprises Act as soon as March 2022. In fact, I anticipate Renown Health would continue to see increased frequency of cases moving to arbitration due to the presumption included in the interim final rule titled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021), which incentivizes insurers to enter such arbitrations rather than maintain contracts for services. Renown Hospitals expect that payors will immediately demand arbitrations under this Rule because the "presumed" amount would be significantly lower than Renown's current reimbursement rates.

19. Absent the QPA-presumption, Renown Hospitals would have many factors outlined by Congress in the No Surprises Act in its favor. For example, Renown Hospitals' level of training, experience, and quality outcomes measurements are high relative to others in the

region (*e.g.*, Renown Hospitals was recently selected as Nevada's Number 1 rated hospital by U.S. News and World Report). Similarly, Renown Hospitals are the premier teaching sites in the region, as evidenced by its recent 50-year affiliation agreement with the University of Nevada, Reno Medical School. These factors, and others favorable to Renown Hospitals, are significantly undermined by the QPA-presumption adopted by the Departments.

20. To be clear: Renown Health fully supports protecting patients from surprise billing and removing them from the middle of payment disputes between commercial health insurers and medical care providers—provided that insurers are prohibited from unilaterally determining out-of-network rates and providers and insurers are equally incentivized to negotiate reasonable reimbursement rates. However, any rate-setting that too strongly favors insurers and/or does not take into account the unique patient population of a provider or sets out-of-network rates below a provider's contracted rates will have severe consequences for patients and providers.

21. While the sustainability of our programs and organization are at stake, Renown will be forced to closely evaluate in which cases we will elect to participate in the IDR process at all, despite having a favorable case under the non-QPA factors. Our experience under Nevada state law demonstrates that arbitration is costly; the administrative, legal, and other cost-burden represents more than 25% of the disputed amounts. I also am aware that, under the No Surprises Act, the losing party must pay for the cost of the arbitrator, *see* 42 U.S.C. § 300gg-111(c)(5)(F)(i), which the federal government has estimated to be approximately $400, *see* 86 Fed. Reg. 55,980, 56057 ("The fees charged by IDR entities in New York ranged from $300 to $600. In Texas, the state contracted with individual attorneys to

provide IDR entities. In Texas, fixed fees ranged from $270 to $6,000. Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately $400."). In our experience, those arbitration costs are much higher. For five of our cases alone, we have paid a total of $265,000 in arbitration fees. These arbitration costs, which do not include substantial outside legal fees and internal resource demands, coupled with the far lower likelihood of success under the QPA-presumption, strongly disincentives Renown's participation in the arbitration process at all, which further undermines the ability of Renown to maintain viable contracted rates with payers.

22. In addition, I am aware that some insurance providers are already leveraging this interim final rule in an attempt to lower rates because they believe they may pay reduced amounts as out-of-network providers under the rule's presumption in favor of the QPA. For example, I have reviewed a letter from Blue Cross Blue Shield NC to its providers stating that "the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." I am also aware that this letter demanded "an immediate reduction in rates" to be followed by negotiation of final rates "in light of the QPA amounts established in accordance with the upcoming Rules."

23. I have seen through Renown's experience with the Nevada law that insurers have taken a similarly aggressive stance towards us, with demands for under-market rates that are well below our costs, in order to force cases to arbitration. Insurers have a far greater motivation to pursue arbitration and the potential for even further reduced reimbursement, whereas emergency services providers such as Renown are obligated by EMTALA to provide services and bear the associated costs regardless of appropriate reimbursement. I believe this clear bias toward insurers will likely incentivize payers to consider non-contracted

status as a negotiating and long-term tactic. Insurers will likely forego negotiating longer term contracts at reasonable market rates (or will effectively do so by making unreasonable demands to arbitrarily drive reimbursement rates to below cost levels), let agreements with our hospitals lapse, and rely on this arbitration process that greatly favors them via the QPA-presumption.

24. This was most recently confirmed by a large national commercial insurer in a negotiation on December 2nd, 2021, whereby that insurer explicitly stated its intent to no longer contract for emergency services with Renown due to protections afforded by developments in the law.

25. Similarly, earlier this fall, another non-contracted insurer, Prominence refused to contract with Renown Health for emergency services. During negotiations, Renown contended that if it were required to accept rates from private third-party insurances equivalent to Prominence's offer for all of its acute and professional services, this would result in turning a viable entity into one that could not continue operating. Renown further explained that without the payments from private third-party insurances at contracted rates rather than Medicare rates, Renown Health would be unable to provide the same services that it provides to the uninsured and underinsured community in Northern Nevada.

26. The presumption that the "Qualifying Payment Amount" reflects the appropriate payment rate will have a significant and devastating impact to both Renown's financial viability, as well as our ability to serve the healthcare needs of our community. By substantially lowering reimbursement rates to levels that will no longer adequately offset the deficit experienced by Renown as a result of providing a majority of the government-sponsored and indigent care in our community, resources will be further strained, and our ability to

retain the breadth of comprehensive services required to serve all patients will be severely compromised. The healthcare landscape continues to face unprecedented challenges, including burgeoning insurance plan payment reductions and denials, labor and supply chain shortages, and higher acuity needs of our patients. All of these factors, coupled with payer-mix shifts reducing the privately-insured population and increasing the Medicaid and indigent population, have driven a diminishing bottom-line for Renown. This interim final rule would deliver a crippling blow to Renown's overall reimbursement for hospital services, which we have modeled to be a minimum of 10% reduction in net reimbursement. This drop in reimbursement would drive our otherwise positive system-wide margin into an untenable net loss.

27. As we have experienced with the Nevada statute, the impact of the "no surprises" arbitration rules will significantly increase the administrative burdens Renown already faces and further harm its financial position, which in turn will make it even more difficult to provide the same treatments to those patients who turn to us for their healthcare needs, many of whom are the most vulnerable in our communities, be they children or those from rural parts of our state. This severely undermines Renown Health's mission to "make a genuine difference in the health and well-being of the people and communities we serve," Our Story, Our Mission, Renown Health, *available at* https://www.renown.org/about/our-story-and-mission/,

28. Many of our region's most important services, such as trauma, Medicaid, and indigent women and children's care, and our children's hospital pediatric subspecialties, are made available primarily through Renown Health. As the region's only not-for-profit health system, we have been committed to providing as much local access to these critical and

comprehensive services as possible. I am gravely concerned that the negative financial implications of the QPA-presumption to Renown would leave these already-underfunded and over-burdened services with no alternative but to scale back services. Other services, such as mental health services so critical to serving our fragile Medicare and Medicaid populations, would also face potential reductions as a result of reduced health system revenues.

29. The effects of the QPA-presumption will not only undermine Renown Health's ability to maintain the wide breadth of comprehensive care we provide to our community, but it will likely impact our community's most vulnerable populations the most as resources go unfunded. Renown Health has built its reputation and goodwill on "making a genuine difference in the health and well-being of the people we serve." *Id.* If Renown is unable to provide the same level of services due to the deleterious financial implications of the QPA-presumption and/or is no longer an in-network provider for parts of the community for the same reason, our reputation and status with patients and existing community members will be irredeemably damaged.

30. Renown Hospitals will not be able to recoup its severe financial losses resulting from the unlawful features of the IFR, including and especially if it is forced to participate in an independent dispute resolution process that applies the IFR's presumption. It is my understanding that The No Surprises Act, Pub. L. 116-260, provides that an arbitrator's decision is generally not subject to judicial review. *See* 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II). Likewise, it is my understanding that the Administrative Procedure Act waives sovereign immunity for federal agencies only in actions "seeking relief other than money damages." 5 U.S.C. § 702. Accordingly, the losses that Renown Hospitals

will suffer as a result of the illegal presumption applied under the IFR cannot be recouped in court and are irreparable.

Signed under penalty of perjury on this 6th day of December, 2021.

Bethany Sexton
Chief Transformation Officer, Renown Health

Exhibit B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION, AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.* *Defendants.*	Civ. Action No. _____

DECLARATION OF CATHERINE M. ROSSI
IN SUPPORT OF PLAINTIFFS' MOTION FOR STAY PENDING JUDICIAL REVIEW, OR IN THE ALTERNATIVE, A PRELIMINARY INJUNCTION

I, Catherine M. Rossi, state as follows under the pains and penalty of perjury.

Personal Experience and Educational Background

1. I am Vice President of Health System Contracting at UMass Memorial Health Care, Inc. ("UMass Memorial Health"), a Plaintiff in this action. I have been employed by UMass Memorial Health for twenty-two (22) years.
2. My responsibilities at UMass Memorial Health include leading Managed Care Contracting, Provider Relations, and Managed Care Operations for the largest health care delivery system in Central and Western Massachusetts, which includes a tertiary academic medical center, housing a Level 1 trauma center, Neonatal Intensive Care Unit, Solid Organ & Bone Marrow Transplant programs, and the region's only electronic Intensive Care Unit (eICU); three community hospitals, 1,800 physician network, specialty pharmacy, and full complement of behavioral health, substance use disorder and ancillary services.
3. Prior to working at UMass Memorial Health, I managed integrated delivery system and ancillary provider contracts for Tufts Health Plan.

4. I have a Bachelor's Degree in Economics from the University of Massachusetts Amherst.

5. The information set forth in this affidavit is based on my personal knowledge and information provided by my colleagues at UMass Memorial Health.

UMass Memorial Health and the Population It Serves

6. UMass Memorial Health is the largest healthcare system in Central and Western Massachusetts. It is a non-profit healthcare system that provides healthcare accessible for all, regardless of ability to pay.

7. UMass Memorial Health is the clinical partner of UMass Chan Medical School (f/k/a University of Massachusetts Medical School), which is the Commonwealth's first and only public medical school.

8. The creation of UMass Memorial Health was authorized by state legislation in 1997 that approved the merger of the nonprofit Memorial Hospital and the public University of Massachusetts Medical Center. While allowing the merger of these entities into a new private, nonprofit system, the legislation also mandated that UMass Memorial Health permanently fulfill a unique, three-part public mission: (1) to provide highly specialized clinical services unavailable elsewhere in Central Massachusetts, (2) to provide free care to indigent patients, and (3) to support the Commonwealth's only public medical school. (*See* Chapter 163 of the Acts of 1997). Consistent with that mission, UMass Memorial Health is the primary provider of highly specialized clinical services across Central Massachusetts, and it provides substantial annual support payments to the Commonwealth's public UMass Chan Medical School.

9. In addition to this statutory mission, UMass Memorial Health's Mission Statement is: "UMass Memorial Health is committed to improving the health of the people of our diverse

communities of Central Massachusetts through culturally sensitive excellence in clinical care, service, teaching and research." *See* Mission, Vision, and Values, UMass Memorial Health, *available at* https://www.ummhealth.org/about-us/mission-vision-and-values.

10. UMass Memorial Health also has a "Community Benefits Program," the mission of which is to improve "the health status of all those it serves and to address the health problems of the poor and other medically underserved populations." *See* Community Benefits Program, UMass Memorial Health, *available at* https://www.ummhealth.org/about-us/community-benefits-program. Through this Community Benefits Program, UMass Memorial Health provides residents of Central Massachusetts with vital programs such as mobile medical and dental care, senior services, youth programs, and more. *See id.*

11. UMass Memorial Health includes four hospitals: UMass Memorial Medical Center (Worcester), UMass Memorial Health – HealthAlliance-Clinton Hospital (Fitchburg, Clinton and Leominster), UMass Memorial Health – Marlborough Hospital (Marlborough), and UMass Memorial Health - Harrington Hospital (Southbridge).

12. In addition to its fully equipped medical centers, UMass Memorial Health also includes a home health and hospice program, and community-based physician practices. UMass Memorial Health also has invested in a range of health related joint ventures in the Central Massachusetts region, including an affiliation with CareWell Urgent Care to provide regional urgent care services and a joint venture with Shields Health Care to establish The Surgery Center in Shrewsbury, Massachusetts where UMass Memorial Medical Group physicians and other local physicians provide high-quality, low-cost outpatient surgery services. UMass Memorial Health also has invested in joint ventures with Shields Health Care to offer lower-cost imaging and Quest Diagnostics to offer lower-cost outpatient

laboratory services. UMass Memorial Health also includes Community Healthlink, the region's largest comprehensive provider of behavioral health, substance use disorder and homelessness services.

13. UMass Memorial Health has over 1,800 active or affiliated medical staff, 3,166 registered nurses, and more than 16,000 employees in over 22 communities. Its team includes specialists who are nationally acclaimed for their expertise and leadership in areas such as heart and vascular care, orthopedics, cancer, diabetes, surgery, newborn intensive care, children's services, women's services, and emergency medicine and trauma.

14. UMass Memorial Health also includes the only designated Level I Trauma Center for adults in Central Massachusetts and the region's only Level III Neonatal Intensive Care Unit, which provides expert care for ill or premature newborns.

15. In 2019 alone, UMass Memorial Health had more than 220,000 emergency department visits and more than 1.5 million outpatient visits.

16. UMass Memorial has been a pioneer in telemedicine, operating a telestroke program which has enabled community hospital emergency physicians and first responders to diagnose and transfer stroke patients for life-saving treatment. It also operates the region's only electronic Intensive Care Unit (eICU), staffed with intensivists at its flagship Academic Medical Center, allowing critical care patients to remain in lower cost community hospitals with 24/7 remote monitoring, coordinating care in concert with on-site clinicians.

17. In 2021, UMass Memorial launched a new Hospital at Home acute care model pursuant to the Center for Medicare and Medicaid Services (CMS) Hospital Without Walls program.

18. UMass Memorial Health serves some of the most vulnerable patients and communities in Massachusetts. It treats over 50% of inpatient Medicaid cases in Central Massachusetts.

Each of its hospitals is designated by the Commonwealth of Massachusetts as "High Public Payer," a label assigned only to hospitals for which 63% or more of gross patient service revenue is attributed to government payers, and each is located in a city or town that is lower-income than the state median. The City of Worcester, where UMass Memorial Medical Center is located, is the second largest city in Massachusetts and, per the U.S. Census, had a median annual household income of $48,139 for 2015-2019, compared to the statewide median annual household income of $81,215. By race and ethnicity, the city of Worcester's 2020 U.S. Census population is 49% White, 25% Hispanic or Latino, 14% Black or African American, and 7% Asian, compared to statewide demographics of 68% White, 13% Hispanic, 7% Black and 7% Asian.

19. UMass Memorial Health relies upon fair and appropriate payment rates from commercial insurers to counterbalance financial losses associated with serving MassHealth patients and implementing its statutorily-mandated mission. Even with appropriate commercial rates, given its high public payor mix and statutory obligations, UMass Memorial Health is financially challenged. In twenty-five (25) years since its founding in 1997, UMass Memorial Health has had a negative operating margin in seven (7) of those years and in years in which it has had a positive operating margin it averaged only 2.28%. Over the course of these 25 years, UMass Memorial Health's overall average operating margin has been only 1.26% per year.

20. UMass Memorial Health is a member of the American Hospital Association, a Plaintiff in this action.

21. UMass Memorial Health recently submitted comments in connection with the Interim Final Rule, entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("IFR").

The Impact of the IFR's Unlawful Presumption on UMass Memorial Health

22. The presumption in favor of the Qualified Payment Amount ("QPA") included in the interim final rule titled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021), will strain UMass Memorial Health's resources, make it more difficult for our providers to treat our patients, and thereby frustrate our non-profit health system's statutorily-imposed mission.

23. To be clear: UMass Memorial fully supports prohibiting "surprise billing," provided that insurers are prohibited from unilaterally determining out-of-network rates and providers and insurers are equally incentivized to negotiate reasonable reimbursement rates. However, any rate setting that too strongly favors insurers and/or does not take into account the unique patient population of a provider or sets out-of-network rates below a provider's in-network contracted rates will have severe consequences for patients and providers.

24. I am aware that some insurance providers are already leveraging this interim final rule in an attempt to lower rates because they believe that they can pay reduced amounts to out-of-network providers under the rule's presumption in favor of the QPA. For example, I have reviewed a letter from Blue Cross Blue Shield NC to its providers stating that "the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." I am also aware that this letter demanded "an immediate reduction in rates" to be followed by negotiation of final rates "in light of the QPA amounts established in accordance with the upcoming Rules."

25. Based on my 22 years of experience at UMass Memorial, I am confident that national and local insurers in the Massachusetts market will soon similarly threaten to terminate their provider contracts if providers are unwilling to accept substantial rate reductions. *First*, given the structure of the Blue Cross Blue Shield (BCBS) Association, Blue Cross Blue Shield of Massachusetts and other BCBS plans are known to apply similar approaches to contracting, often relying on BCBS Association rules as a defense for their tactics. *Second*, in 2015, a commercial insurer administering an indemnity insurance plan for Commonwealth of Massachusetts state employees refused to negotiate rates as a result of a state law (MGL c32A, Sect. 20) prohibiting balance billing beyond deductibles and copayments. This law had the effect of permitting the insurer to unilaterally determine provider rates with no recourse for providers other than to refuse to accept patients enrolled with this plan. The insurer's inpatient hospital rates were priced below Medicare rates for a commercial population, and physician rates were priced approximately 45% below their direct competitors, which offered HMO and PPO products for the same book of business, since the legislation was specific to the Commonwealth Indemnity plan. Like Blue Cross Blue Shield North Carolina more recently, this insurer was prepared to leverage the incentives created under state law to unilaterally set reimbursement rates below cost and fair market value, which would have had severe financial effects on UMass Memorial Health and forced it to terminate its contract with the insurer. This situation was resolved at the eleventh-hour through the intervention of the Governor's office and local legislators and the insurer ultimately agreed to negotiate market competitive rates. Given this recent history, however, I am confident that insurers will apply a similar strategy, only now using the Interim Final Rule as their leverage.

26. As in 2015, there is simply a point at which an insurers' demands to reduce reimbursement rates will become so financially costly to UMass Memorial Health that it will have to accept those severe economic losses (and alter its services accordingly) or terminate its contracts with these insurers altogether. These outcomes would cause an array of irreparable financial, operational, and reputational harm to UMass Memorial Hospital and create access issues for patients.

27. Most directly, when forced to accept out-of-network reimbursement rates based on a presumptive QPA rate, UMass Memorial Health is likely to receive upwards of thirty percent (30%) less than it otherwise would receive. Being forced to accept commercial reimbursement rates that low will severely strain our resources and exacerbate the losses already incurred as a result of the cost gap under governmental programs.

28. Although precise numbers vary based on the characteristics of individual non-profit hospitals, experts recommend that nonprofit hospitals achieve an operating margin of no less than 2.5 percent annually in order to be able to reinvest in critical assets such as capital and workforce to benefit the patients they serve. *E.g.*, Alex Kacik, *Operating margins stabilize, but not-for-profit hospitals still vulnerable*, Modern Healthcare (Apr. 26, 2019), https://www.modernhealthcare.com/providers/operating-margins-stabilize-not-profit-hospitals-still-vulnerable; Christopher Cheney, *Mission and Growth: Intersections for Nonprofit and For-Profit Health Systems*, Healthleaders Media (Sept. 4, 2019), https://www.healthleadersmedia.com/clinical-care/mission-and-growth-intersections-nonprofit-and-profit-health-systems. Due to its costly, statutorily-mandated mission and high public payor patient mix, UMass Memorial Health rarely achieves this target. However, this margin target does not account for the additional burden

Disproportionate Share Hospitals bear with respect to subsidizing free care and underinsured patients. Reductions in commercial insurance reimbursements associated with implementation of the Interim Final Rule will severely impede the ability of UMass Memorial Health to satisfy each prong of its statutorily-mandated mission.

29. To make matters worse, UMass Memorial Health is under severe strains because of COVID-19, not only because of cancelled elective services (which we anticipate we will eventually recover), but also due to increased costs associated with increased acuity of patients and new infection control protocols, staffing and supplies, and now vaccine administration (all of which are here to stay). Our Academic Medical Center is over capacity with bed shortages for both medical/surgical and critical care patients, while our community hospitals are currently at capacity but having difficulty staffing for an increased and volatile census. UMass Memorial is struggling with a staffing crisis and is paying a premium for overtime and temporary help. While we received Federal Relief Funds, these funds were insufficient to fully cover the incremental cost increases, resulting in a shortfall of more than $20,000,000 in 2020. The losses expected from the Interim Final Rule will severely exacerbate those existing pandemic-related strains. As a general matter, then, the Interim Final Rule is a serious obstacle to fulfilling UMass Memorial Health's mission of "improving the health of the people of our diverse communities."

30. As a result of the QPA-presumption and its financial impacts, UMass Memorial will face difficult decisions regarding continuing to provide certain high-cost services and community-based programs, as well as other vital health services in low-income neighborhoods. For example, as a result of the QPA presumption, UMass Memorial would lose access to the resources necessary to subsidize already-underfunded services like

community-based mobile medical services for indigent families and youth, food insecurity assistance care, and pediatric asthma intervention for low-income youth in coordination with community partners. These "Community Benefit Programs" and other low-income health services already operate in the red, and the financial impact of the QPA-presumption will have a devastating effect on our ability to fund them going forward. In addition, if UMass Memorial Health's insurance contracts are terminated altogether because the health system cannot accept insurers' demanded cuts in reimbursement rates or insurers do not offer participation since they can rely on the QPA-presumption to force lower rates, large numbers of residents of Central Massachusetts will lose access to UMass Memorial Health for non-emergent services. These newly out-of-network patients could be redirected by the insurers to higher-cost hospitals in Boston, adding a range of new burdens on them and the region's self-funded employers.

31. All of these consequences of the QPA-presumption will not only adversely impact UMass Memorial Health's ability to fulfill its mission of providing care to the Central Massachusetts community, but also will cause significant reputational harm to our non-profit institution. UMass Memorial Health has built its reputation and goodwill within the Central Massachusetts community on its ability to "make outstanding care accessible for all, regardless of ability to pay." About Us, UMass Memorial Health, *available at* https://www.ummhealth.org/umass-memorial-health/about-us. Indeed, as our website says, "UMass Memorial Health is the health and wellness partner of the people of Central Massachusetts. Through pain and pandemics, our commitment to our communities never wanes. We use knowledge and innovation to create breakthrough medicine. To create jobs. To make life better for those we serve." *Id.* If UMass Memorial Health is no longer an in-

network provider for the Central Massachusetts community, and thus patients can no longer obtain the same care at UMass Memorial Health, then our reputation with former patients and existing community members will be irredeemably damaged.

32. UMass Memorial Health will not be able to recoup its financial losses resulting from the unlawful features of the IFR, including and especially if it is forced to participate in an independent dispute resolution process that applies the IFR's illegal presumption. It is my understanding that The No Surprises Act, Pub. L. 116-260, provides that an arbitrator's decision is generally not subject to judicial review. *See* 42 U.S.C. Id. § 300gg-111(c)(5)(E)(i)(II). Likewise, it is my understanding that the Administrative Procedure Act waives sovereign immunity for federal agencies only in actions "seeking relief other than money damages." 5 U.S.C. § 702. Accordingly, the losses that UMass Memorial Health (and the Central Massachusetts community) will suffer as a result of the illegal presumption applied under the IFR cannot be recouped in court and are irreparable.

Signed under penalty of perjury on this 6th day of December, 2021.

Catherine M. Rossi
Vice President, Health System Contracting
UMass Memorial Health Care, Inc.

Exhibit C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION, AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Civ. Action No. _____

DECLARATION OF STUART M. SQUIRES, M.D.

I, Stuart M. Squires, M.D., hereby declare as follows:

1. I am a licensed physician and practicing anesthesiologist. I hold a Bachelor of Science from Elizabeth City State University and a Doctor of Medicine from The Brody School of Medicine at East Carolina University. I completed my residency at Emory University.

2. This declaration is based on my personal knowledge.

3. Along with my colleague, Dr. Victor F. Kubit, M.D. (who is also a plaintiff in this case), I practice anesthesia with Cumberland Anesthesia Associates in Fayetteville, NC. Both Dr. Kubit and I are members in good standing of the American Medical Association.

4. I have practiced at Cumberland for over 21 years, and Dr. Kubit for 20 years. Fayetteville is in a rural part of the state where most people have modest incomes, and Cumberland's patients are no different. Cumberland provides anesthesia services at several local hospitals, including Cape Fear Valley Medical Center in Fayetteville, NC; Betsy Johnson Hospital in Dunn, NC; and Central Harnett Hospital in Lillington, NC. Cumberland provides its services

in connection with a full range of medical procedures, including a substantial amount of obstetrics services.

5. In addition to practicing anesthesiology with Cumberland, I serve as the practice's president. My responsibilities include negotiating contractual payment rates with insurance companies.

6. I am familiar with the interim final rule titled "Requirements Related to Surprise Billing; Part II," issued in September 2021 ("September Rule"), insofar as it establishes a presumption that, during the independent dispute resolution process ("IDR") created by the No Surprises Act, Pub. L. 116-260, the Qualifying Payment Amount ("QPA") reflects the appropriate payment amount for out-of-network healthcare services. I understand that Dr. Kubit submitted comments via Regulations.gov opposing the September Rule because its presumption in favor of the QPA as the appropriate out-of-network rate will result in unfair payments to physicians and could reduce patients' access to needed care.

7. The QPA corresponds to the median of contracted rates for the same or similar services in a particular region. Consequently, for any given case, it will not necessarily reflect the additional factors that bear on the value of services that Congress required IDR arbitrators to consider, including physician training and experience, quality and outcomes measurements, the acuity of the patient, complexity of the procedures, the market share held by the insurer, and additional relevant information. Under the September Rule, these additional factors may not be taken into account during an arbitration to determine a payment amount unless a party provides "credible information" that "clearly demonstrates" that the QPA "materially differ[s]" from the appropriate payment rate. As a result, arbitrators must presume that the offer closest to the QPA is

the appropriate payment rate, even though the QPA often will not account for many of the factors that bear on the value of services in a particular case.

8. Cumberland provides out-of-network care to patients every day. That is because we treat all patients, and provide them with excellent service, regardless of their insured status or ability to pay. Because we will not send balance bills to patients under the No Surprises Act, we expect to participate in the IDR arbitration process on a regular basis beginning as early as March 2022.

9. Even before the September Rule, insurers with whom we did not have in-network contracts tried to pressure us to accept lower out-of-network payment rates than we receive for our in-network services. Based on this experience, as well as my understanding of the September Rule's presumption in favor of the QPA, I am very concerned that the IDR arbitration process will routinely result in payments that are below the fair value of the out-of-network services Cumberland provides.

10. There are a number of reasons why I expect the QPA, which is based on a median contracted rate, to undervalue the cost of our services. For one, the cost of anesthesia provider salaries, including both doctors and nurses, increases substantially each year, especially in rural areas such as our own where there is a shortage of providers. As a result, a QPA tied to a 2019 lodestar and increased each year by only the consumer price index will fail to adequately reflect the actual annual salaries necessary to attract talented anesthesia providers to our area. Second, our practice employs Certified Registered Nurse Anesthetists ("CRNAs"), which allows us to more efficiently and cost-effectively meet our patients' needs. Most anesthesia practices in our area, however, employ only physicians. As a result, negotiated payment rates with insurers in our area rarely reflect the cost of CRNAs. I anticipate that the median contract rate will fail to capture

unique situations like ours in which an anesthesia provider pays the salaries and benefits of CRNAs. Finally, I was glad to see that the No Surprises Act planned to account for an insurer's market share, as I believed it would allow the IDR arbitrator an opportunity to consider the impact of the mix of insurers in an area. But if arbitrators are not permitted to regularly account for this fact, I anticipate that we will be consistently undercompensated for our services.

11. Consistently below-fair-value payments will ultimately force Cumberland to make changes to our services so that we are adequately paid to cover our ongoing costs. For example, we may have to reduce the hours or days of the week during which we will provide anesthesia services. As a consequence, patients will have to wait longer for surgeries or drive more than an hour to a larger city, like Raleigh, NC, for needed medical care.

12. In addition, Cumberland is an in-network provider with Blue Cross Blue Shield of North Carolina ("Blue Cross"). Even though we are in-network, the September Rule's establishment of the QPA as the presumptive out-of-network payment rate appears to have empowered Blue Cross to demand that we accept in-network payment rates that are far below the value of our services.

13. To take one example, since the September Rule was published, Blue Cross has halted all conversations about how to compensate Cumberland for its obligation to reimburse Harnett Health, a hospital system in North Carolina, for services rendered for Cumberland by Harnett Health's CRNAs.

14. CRNAs are advanced practice registered nurses who administer anesthesia under the supervision of an anesthesiologist. Because a single physician can supervise up to four CRNAs at a time, Cumberland has relied on CRNAs as a cost-effective means of providing a substantial portion of our anesthesia services.

15. In February 2021, Cumberland entered into an employee lease agreement with Harnett Health. Under this contract, Cumberland agreed to reimburse Harnett Health for the salaries and benefits of five CRNAs in order to utilize the CRNAs' services and maintain a good working relationship with Harnett Health.

16. CRNA salaries are approximately $190,000 per year base salary, not including bonus or overtime expenses. Because Cumberland employs five CRNAs under its contract with Harnett Health, Cumberland's cost for CRNAs is expected to be at least $1,500,000 for 2021.

17. Employing CRNAs, and thus paying their salaries and benefits, is much costlier to Cumberland than if Cumberland were not responsible for those employee expenses. We therefore factored these additional costs into the payment rate we requested during good-faith negotiations with Blue Cross earlier this year. Based on conversations with Blue Cross early this year, we understood that Blue Cross would agree to pay a fair rate that reflects our changed cost structure incorporating the CRNAs.

18. However, shortly after the September Rule was issued, Blue Cross discontinued those negotiations. A Blue Cross representative stated in a November 19, 2021, email to Cumberland that she had been advised to "halt" negotiations "due to pricing changes that are forthcoming." The representative said that she would try to get approval to continue negotiations with Cumberland, but, to date, Blue Cross has not done so.

19. Based on that email and Blue Cross's refusal to continue negotiations since issuance of the September Rule, I believe that Blue Cross plans to lower payment rates in light of the QPA presumption and that the forthcoming "pricing changes" described in the Blue Cross representative's November 19, 2021, email will correspond to the QPA. As discussed, most anesthesia practices in the area employ only physicians, so their negotiated payment rates do not

reflect the value of CRNA services. I therefore anticipate that the QPA will not accurately reflect situations like ours, where an anesthesia provider pays the salaries and benefits of CRNAs. Moreover, because I anticipate that the salaries of qualified CRNAs will rise significantly each year, I expect that an increase in the median contract rate based on the consumer price index will be inadequate to compensate us for the actual cost of CRNAs' salaries.

20. This is unsustainable for Cumberland. Cumberland simply cannot finance the large gap between the actual cost of the services it provides and the payment rates that I fear Blue Cross will demand in light of the September Rule.

21. If Blue Cross refuses to adequately pay us for the services we render our patients, such as the cost of employing CRNAs, I am very concerned that it will affect the level of care we can provide our patients. Although Cumberland is still assessing the measures we will take, if the QPA becomes the de facto rate for anesthesia services, Cumberland is unlikely to be able to finance its operations under its existing arrangement with Harnett Health. As described above, we would at the very least have to reduce our services, and ultimately we might have to terminate our contract with Harnett Health as this would no longer be a sustainable business model. In turn, that would reduce the level of care that we can provide to our patients.

22. Overall, if insurers demand lower rates each time we engage in a rate negotiation (which we do every few years and in special circumstances), using the threat of IDR arbitration and the QPA presumption as a club, I believe the ultimate effect will be to drive small anesthesia practices like Cumberland out of business.

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

Executed this 8th day of December 2021, in Fayetteville, NC.

Stuart M. Squires, M.D.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION, AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Civ. Action No. 1:21-cv-03231

[PROPOSED] ORDER

This matter is before the Court on Plaintiffs' Motion for a Stay Pending Judicial Review, or in the Alternative, for Summary Judgment. Upon consideration of the Motion, it is hereby

ORDERED that the Motion is GRANTED; and it is further

ORDERED that the following provisions of the Code of Federal Regulations are [stayed and will not become effective pending conclusion of the review proceedings under 5 U.S.C. § 705] / [held unlawful and set aside under 5 U.S.C. § 706 and Federal Rule of Civil Procedure 56]:

(1) 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).

(2) 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(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)(iv); and 26 C.F.R. § 54.9816-8T(c)(4)(vi)(B).

(3) 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)(iv); and 29 C.F.R. § 2590.716-8(c)(4)(vi)(B).

Dated: _____, _____

_____

United States District Judge