IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

GEORGIA COLLEGE OF EMERGENCY PHYSICIANS and BRETT CANNON, M.D., Plaintiffs, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	CIVIL ACTION NO. 1:21-cv-05267-MHC

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Pursuant to 5 U.S.C. § 705, Plaintiffs Georgia College of Emergency Physicians ("GCEP") and Brett Cannon, M.D., by and through their attorneys, hereby move for a preliminary injunction against Defendants 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[2]—in order to prevent irreparable harm to Plaintiffs GCEP and Brett Cannon, M.D., as well as GCEP's other provider-members. In support of this motion, Plaintiffs submit the following Brief in Support

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[1] Because this case presents "purely legal issues," *Atlanta Indep. Sch. Sys. v. S.F. ex rel. M.F.*, 740 F. Supp. 2d 1335, 1341 (N.D. Ga. 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* Fed. R. Civ. P. 65(a)(2) ("Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing").

[2] The estimated March 1, 2022 arbitration beginning date is based on timing requirements contained in 42 U.S.C. § 300gg-111(a)(1)(C) and 49 C.F.R. § 149.510. Under these provisions, payment must be made within thirty days of claim submission. 42 U.S.C. § 300gg-111(a)(1)(C). Following payment, there is a thirty business day negotiation period. 49 C.F.R. § 149.510(b)(1)(ii). Within four business days of the close of the negotiation period, the parties must initiate the independent dispute resolution process and must select an arbitrator entity within three business days of initiation. 49 C.F.R. §§ 149.510(b)(2)(i) and 149.510(c)(1)(i). Offers must be submitted within ten business days of selection, and the arbitrator has thirty days from the offer deadline to make a final decision. 49 C.F.R. §§ 149.510(c)(4)(i) and 149.510(c)(4)(ii). Based on this timeline, the theoretical earliest an IDR decision could be issued is March 2, 2022.

and accompanying Declarations of Dee William Pettigrew, III, M.D., Exhibit A (“Pettigrew Decl.”) and Plaintiff Brett Cannon, M.D., Exhibit B ("Cannon Decl."). A proposed order is attached.

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BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

This action under the Administrative Procedure Act ("APA") challenges provisions of an interim final rule issued by Defendants in violation of their statutory authority and the APA's notice-and-comment requirement. The rule, entitled "Requirements Related to Surprise Billing; Part II," 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("September IFR"), implements provisions of the federal surprise medical billing law, the No Surprises Act, Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758–890 (2020) (the "Act").

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 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 the arbitrator's review of ***six mandatory statutory factors*** that the arbitrator "***shall***" consider. 42 U.S.C. § 300gg-111(c)(5)(C) (emphasis supplied). Congress carefully avoided attaching any particular weights to the various factors that must be taken into account, and it surely did not assign any one statutory factor presumptive weight. The IDR process in

general—and the enumerated factors in particular—reflects Congress's intentionally balanced approach to ensuring fair payment for healthcare services.

However, in direct conflict with the Act's text and design, Defendants 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 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 thus read into the statute a "rebuttable presumption" that skews IDR results in payors' favor and grants them a windfall they were unable to obtain in the legislative process. Every tool of statutory construction—including text, structure, purpose, and legislative history—demonstrates just how far the Departments have overreached.

The Departments' presumption is unlawful and must be set aside for two main reasons. *First,* the statute cannot reasonably be read to impose such a presumption. Congress painstakingly described the factors IDR entities must consider, and

nowhere in the statute does Congress provide that the QPA should be afforded more weight than the other factors or otherwise indicate that the additional statutory factors are second-class considerations relevant only to the extent they overcome a presumption in favor of the QPA. If Congress had intended the QPA to be given presumptive weight in determining healthcare provider reimbursement, it undoubtedly would have done so. In fact, Congress rejected proposed bills that would have pegged reimbursement to the QPA.

Second, the Departments unlawfully issued the challenged provisions without providing notice and comment as required by the APA. The good cause exception the Departments invoked is a narrow safety valve designed to deal with emergency situations where delay would cause serious harm. Those exceptional circumstances plainly do not exist here. Congress gave the Departments an entire year to promulgate regulations implementing the statute's IDR provisions—more than enough time to provide notice and comment. Instead, the Departments waited ***nine months*** and are relying upon their own delay to create an exigency justifying bypassing notice and comment.

As a result of the September Rule's illegal presumption, Plaintiffs GCEP and Brett Cannon, M.D., along with the patients that Dr. Cannon and GCEP's members care for, will suffer severe and irreparable harm if the September Rule is not set

aside. The attached declarations demonstrate that these injuries are "'neither remote nor speculative, but actual and imminent.'" *Ne. Florida Chapter Ass'n of Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 896 F.2d 1283, 1285 (11th Cir. 1990) (citation omitted). Plaintiff Brett Cannon, M.D. and GCEP member Dee William Pettigrew explain that the QPA presumption will reduce the out-of-network reimbursement they will receive and will have "severe consequences for patients and providers alike." Pettigrew Decl. ¶ 11; *see also* Cannon Decl. ¶ 10, 11. This reduction in reimbursement will strain providers' resources and thereby make it more difficult for patients to be treated. *See* Cannon Decl. ¶ 13.

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 underpayments cannot be resolved 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. 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 "under compensation 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 GCEP and Dr. Cannon, GCEP's members, and the patients they serve, this Court should preliminarily enjoin enforcement of 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.

STATEMENT OF UNDISPUTED MATERIAL FACTS

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

1.

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.[3] 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

[3] 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.

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).

2.

To protect patients from such "surprise bills," the 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). Instead, the Act obligates payors to reimburse out-of-network providers at the "out-of-network rate" as defined in the statute, less any cost-sharing from the patient. *Id*. § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D). The "out-of-network rate" is governed by any applicable All-Payer Model Agreement under section 1115A of the Social Security Act or, if there is no such agreement, then by any applicable specified state law providing a method for determining the total amount of reimbursement for the out-of-network provider. *Id*. § 300gg-111(a)(3)(K). If there is not applicable All-Payer Model Agreement or an applicable state law,[4] Congress declined to set

[4] Georgia is one of several states that has implemented a state surprise medical billing law. For some claims, this will serve as the "specified state law" that will

healthcare reimbursement at the QPA, as it did for the cost-sharing requirement under 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(II), or otherwise provide a benchmark or mathematical formula. Rather, the Act 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 thirty-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 thirty-day period, either party may initiate binding arbitration before an independent dispute resolution arbitrator, who determines the fair payment amount. *Id.* § 300gg-111(a)(3)(K), (c)(1)(B).

A. Congress Selected The IDR Arbitration Process

3.

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-

govern the healthcare provider out-of-network reimbursement. However, this law is not as comprehensive as the Act, and for many of out-of-network services, the Act's IDR process will be used to determine provider reimbursement. For example, the Georgia law does not cover self-insured health plans, under which the majority of private sector plan enrollees receive their benefits. *See* Ga. Code Ann. § 33-20E-1 *et seq.* (2021), known as the "Surprise Billing Consumer Protection Act."

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).

4.

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) (emphasis supplied); *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[.]") (emphasis supplied). 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). 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).

5.

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).

B. Congress Rejected Setting The QPA As The Presumptive Benchmark In The Arbitrator's Selection

6.

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* 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 ("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.").

7.

However, Congress repeatedly rejected these proposals—instead mandating six factors that arbitrators "shall" consider and prescribing no particular weight or presumption for any one factor. Congress did so for important policy reasons:

> Practically speaking, the dispute resolution scheme now contemplated by the agencies poses at least two problems that Congress expressly sought to avoid when creating a payment negotiation process of open negotiations between insurers and providers. First, creating a presumption that the appropriate payment amount is the median in-network rate risks distorting already complex market dynamics in our healthcare system in a way that will likely lead to ***systematic underpayment*** of in-network and out-of-network providers. Second, and relatedly, those distortions will create ***unforetold harms to patients culminating in reduced access to affordable care***—the very type of harm the No Surprises Act was supposed to help cure.

Brief for Members of Congress As Amici Curiae Supporting Plaintiffs, Texas Medical Association et al., Civil Action No. 6:21-CV-00425 (E.D. Tex. Dec. 9, 2021) (emphasis supplied) (attached hereto as "Exhibit C"). Stated differently, mandating a presumption in favor of the median in-network rates significantly

undermines the only tool a provider has to negotiate a fair price, which risks distorting private market dynamics by artificially setting prices. The nation's already stressed healthcare system could become over-strained, leading to fewer providers and services—especially in rural and lower-income areas. Congress thus favored a "first, do no harm" approach that incentivizes insurers and providers to settle their own disputes through reasonable negotiations and does not incentivize insurers to lower in-network rates and narrow networks.

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

8.

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 supplied). Contradictory to the Act's mandatory language that IDR arbitrators "shall" consider

all of the Subparagraph C Factors, the September Rule allows the arbitrator to consider the non-QPA factors only if 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"); *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").

9.

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, the arbitrator 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 Departments' September Rule requires no such explanation if the arbitrator selects the offer closest to the QPA.

A. Significance Of Presumption

10.

This presumption in favor of the QPA is significant because the QPA typically undervalues the services that physicians and hospitals provide, in large part due to the methods Defendants chose for calculating the QPA.[5] This is why Secretary

[5] 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

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"). These detrimental effects are discussed more thoroughly in Section I(B), *supra*.

B. Departments' Delay In Issuing The September Rule

11.

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

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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.

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.

12.

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 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. Plaintiffs GCEP And Provider Brett Cannon, M.D.

13.

The Georgia College of Emergency Physicians is a non-profit association that represents the interests of emergency physicians and their patients throughout Georgia. GCEP was founded in 1968 to provide resources and information to assist emergency physicians in managing their practices and engaging in advocacy efforts with respect to legislation and regulations that impact emergency medicine. Current GCEP membership is approximately 900 emergency physicians. GCEP is active in legislative issues and was a principal member of the physician coalition which helped bring about laws defining the "prudent layperson" standard in Georgia in 1996, tort reform in 2005, and surprise billing legislation in 2020. GCEP's mission is to improve the quality of emergency care for patients in Georgia and to help the multitude of emergency physicians in the state provide high-quality care while maintaining stable practices. GCEP strongly supports Congress's goal of protecting patients from "surprise billing" and advocates 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. GCEP brings this suit on behalf of its provider members (generally emergency room physicians) whose reimbursement for out-of-network services will be determined through the IDR process and who will be harmed by the unlawful presumption the Departments imposed in the September Rule.

14.

Plaintiff Brett Cannon, M.D. is a licensed physician who practices emergency medicine in Georgia. Dr. Cannon works through and has an ownership interest in The Bortolazzo Group, LLC, a physician group that partners with hospitals and health systems to provide, among other services, emergency medicine and has done so for over ten years. Dr. Cannon is a member in good standing of GCEP. His practice treats all patients without regard to their insured status or ability to pay.

ARGUMENT AND CITATION TO AUTHORITY

Because the aforementioned aspects of the September Rule are manifestly contrary to law and will irreparably harm Plaintiffs GCEP and Dr. Cannon, GCEP's members, and the patients they serve, this Court should preliminarily enjoin enforcement of 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.

"To support a preliminary injunction, a district court need not find that the evidence positively guarantees a final verdict in plaintiff's favor." *Levi Strauss & Co. v. Sunrise Int'l Trading Inc.*, 51 F.3d 982, 985 (11th Cir. 1995). Instead, the Court has discretion to grant a preliminary injunction where a movant demonstrates four elements: (1) a likelihood of success on the merits; (2) that irreparable injury is

likely to be suffered absent preliminary relief; (3) the balance of the equities tips on the favor of the movant; and (4) the injunction is in the public interest. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Jysk Bed'N Linen v. Dutta-Roy*, 810 F.3d 767, 774 (11th Cir. 2015). Where the government is the party opposing a preliminary injunction, "its interest and harm merge with the public interest." *Swain v. Junior*, 958 F.3d 1081, 1091 (11th Cir. 2020). For the reasons set forth below, Plaintiffs are able to satisfy all elements—thereby requiring the issuance of a preliminary injunction in this matter.

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," *Atlanta Indep. Sch. Sys.*, 740 F. Supp. 2d at 1341, 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* Fed. R. Civ. P. 65(a)(2) ("Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing"); *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 Because The Departments' Action Is Contrary To The Unambiguous Terms Of The No Surprises Act

Under the APA, courts "may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. Further, a reviewing court is required to "hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). *See Catalyst Pharm., Inc. v. Becerra*, 14 F.4th 1299, 1306 (11th Cir. 2021). Reviewing courts may set aside an agency actions for a variety of reasons, including:

> [W]here the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Alabama-Tombigbee Rivers Coal. v. Kempthorne, 477 F.3d 1250, 1254 (11th Cir. 2007).

In assessing an agency' statutory interpretation, courts must first determine whether Congress authorized the agency "to speak with the force of law" in regards to the issue at hand. *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). If so, then courts evaluate the agency's interpretation under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Where the intent of Congress is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Autauga Cty. Emergency Mgmt. Commc'ns Dist. v. Fed. Commc'ns Comm'n*, 17 F.4th 88, 98 (11th Cir. 2021) (*quoting Chevron, U.S.A., Inc.*, 467 U.S. at 842–43). After consideration of the statutory construction, including the text, context, legislative history, and purpose of the No Surprises Act, the September Rule is contrary to the unambiguous terms of the No Surprises Act. The Departments' presumption is unlawful and must be set aside because the statute cannot reasonably be read to impose such a presumption in favor of the QPA, and the Departments unlawfully issued the challenged provisions without providing notice and comment as required by the APA.

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 supplied). 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 supplied). 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) (emphasis supplied). 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. 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 supplied)). 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. Thus, 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. 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 (emphasis supplied). 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. Defendants have distorted Congress's design by bifurcating the arbitrator's determination of the appropriate payment rate, when it is clear the Subparagraph C factors were meant to be considered together.

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.

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. *See generally Harris v. Garner*, 216 F.3d 970, 977, fn. 4 (11th Cir. 2000) ("So long as legislative history is not used to contradict the plain meaning of the statutory language, we see no inconsistency in pointing out that both the statutory language and legislative history lead to the same

interpretative result."). 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.[6]

[6] *See* "Exhibit C," Brief for Members of Congress As Amici Curiae Supporting Plaintiffs, Texas Medical Association et al. ("Before Congress passed the No Surprises Act, lawmakers proposed various bills that mandated payment of the median in-network rate in price disputes between insurers and out-of-network

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

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providers. Each of these proposals failed to become law . . . . This history confirms what the No Surprises Act's text makes plain: 'Congress has directly spoken to the precise question at issue.' *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). Congress had before it a binary decision. It could pick the benchmark-rate approach, or the independent dispute resolution approach. *See* H.R. Rep. No. 116-615 Pt. 1, at 56 ('Two payment rate options have emerged as the predominant contenders . . .'). Congress plainly chose the latter. *See* 42 U.S.C. § 300gg-111(a)(1), (a)(3)(K), (c)(1), (c)(5).").

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***" (emphases 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.

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 these are "policy choice[s] on which courts should defer to Congress in the first instance, and to the administrative agency in the absence of a clear congressional mandate. Here, Congress has made the policy choice." *Chem. Mfrs. Ass'n v. Nat. Res. Def. Council, Inc.*, 470 U.S. 116, 138 (1985). 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.'" *Chevron, U.S.A., Inc.*, 467 U.S. at 842–43; *see also Util. 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 Because It Is Contrary To The Act's Plain Meaning And Is Procedurally Defective

The Departments may argue that their interpretation of the Act's "Payment determination" provision is owed deference under *Chevron*, 467 U.S. at 837 (1984). It is not.

1. The Departments' Interpretation Is Contrary To The Act's Plain Meaning

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." *Chevron*, 467 U.S. at 843 n.9 (1984). 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.

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.[7] *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. Further, any suggestion that *Chevron* step two is implicated any time a statute does not expressly negate the existence of a claimed administrative power is perverse to the fundamentals of administrative law and contradicted by precedent. *See Bayou Lawn & Landscape Servs. v. Sec'y of Labor*, 713 F.3d 1080, 1085 (11th Cir. 2013) ("[I]f congressional silence is a sufficient basis upon which an agency may build a rulemaking authority, the relationship between the executive and legislative branches would undergo a fundamental change and 'agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with Chevron . . . and quite likely the Constitution as well'" (*quoting Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C.

[7] In fact, the interim final rule does not conduct the type of interpretative exercise in which *Chevron* generally applies. 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.

Cir. 1995))); s*ee also Ry. Labor Execs.' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*); *Coffelt v. Fawkes*, 765 F.3d 197, 202 (3d Cir. 2014) ("[e]ven where a statute is silent on the question at issue, such silence does not confer gap-filling power on an agency unless the question is in fact a gap—an ambiguity tied up with the provisions of the statute" (internal quotation marks and citations omitted)).

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 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)).[8]

2. The September Rule Is Procedurally Defective

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 Mead Corp.*, 533 U.S. at 227). Under the APA, federal agencies are required to provide notice and comment, unless they "for good cause"

[8] 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)").

find that such procedures "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). The Departments cannot satisfy the high bar necessary to establish "good cause" here. *See State of Fla. v. Dept. of Health and Human Servs.*, 19 F.4th 1271, 1304 (11th Cir. 2021) ("The good cause exception should be read narrowly and applied reluctantly") (Lagoa, Barbara, *dissenting*); *United States v. Dean*, 604 F.3d 1275, 1279 (11th Cir. 2010). 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. This argument is discussed in more detail in Section I(C), *infra*.

3. The Departments' Interpretation Is Unreasonable

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.'" *Util. 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.

C. The Departments Lacked Good Cause For Bypassing Notice And Comment

As briefly mentioned in Section I(B)(2), *supra*, *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*, 579 U.S. at 220 (*quoting Mead Corp.*, 533 U.S. at 227); *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"). As noted in Count II of Plaintiffs' Complaint, 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 "undermine[d] the purpose of notice and comment—to allow an agency to reconsider, and sometimes change, its proposal based on the comments of affected persons." *Miami-Dade Cty. v. EPA*, 529 F.3d 1049, 1059 (11th Cir. 2008) (internal quotation marks and citations omitted).

Here, the Departments cannot satisfy the high bar necessary to establish "good cause". 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 "an agency cannot create urgency by its own delay; indeed, such delay demonstrates a lack of urgency." *State of Fla. v. Dep't of Health & Hum. Servs.*, 19 F.4th 1271, 1304–05 (11th Cir. 2021) (Lagoa, Barbara, dissenting) (*citing Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114–15 (2d Cir. 2018)). 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.

II. Plaintiffs And Patients They Serve Will Suffer Irreparable Harm Absent A Preliminary Injunction

The September Rule's presumption in favor of the QPA will irreparably harm Plaintiffs Brett Cannon, M.D. and GCEP, along with its other members. *First*, the September Rule will irreparably harm Dr. Cannon and GCEP's other members when

they are forced to accept unfairly low reimbursement rates as a result of the Departments' unlawful presumption. The Departments' creation of a presumption that the appropriate payment amount is the median in-network rates risk market distortions because such rates do not necessarily account for the costs of providing care in the unique circumstances of each billing dispute. *See* Letter of Am. Med. Ass'n to Departments at 5 (Dec. 6, 2021), https://www.regulations.gov/comment/CMS-2021-0156-5178. Under a benchmark systems where insurers only pay in network rates to out-of-network providers, providers, such as Plaintiffs, lose leverage to negotiate in-network rates, leaving insurers incentivized to lower those rates or drop higher costs providers from their network. In turn, this would lead to inadequate payment to in-network and out-of-network providers. In crafting the Act and opting to eschew a benchmark system, Congress recognized this risk of systematic underpayment. *See* Cong. Budget Office Cost Est., S. 1895 Lower Health Care Costs Act at 7 (July 16, 2019) (estimating average payment rates dropping by 15 to 20 percent below current average), https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.

Further, 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 Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) ("In the context of preliminary injunctions, numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable."); *see also Cunningham v. Adams*, 808 F.2d 815, 821 (11th Cir. 1987) ("An injury is 'irreparable' only if it cannot be undone through monetary remedies.").

Second, the September Rule is *already* irreparably harming, and threatens to further harm, Dr. Cannon and GCEP's other 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 reduce 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 "'neither remote nor speculative, but actual and imminent.'" *Ne. Florida Chapter Ass'n of Gen. Contractors of Am.*, 896 F.2d at 1285. The declaration submitted by Dee William Pettigrew, III, M.D. makes clear that, based on his experience, the September Rule's presumption in favor of the QPA will strain providers' resources

and "make it more difficult for them to treat patients." Pettigrew Decl. ¶ 12. Because of the presumption, the declarations submitted by Dr. Pettigrew and Dr. Cannon explain that "some insurance providers are already leveraging the September IFR as a means of lower rates as they believe they can pay reduced amounts as out-of-network providers under the [September Rule's] presumption in favor of the QPA." Pettigrew Decl. ¶ 13; Cannon Decl. ¶ 14. As a result, the presumption will have "significant and devastating" effects on providers and their abilities to serve the public's healthcare needs—including those in the most vulnerable populations. Pettigrew Decl. ¶ 16; Cannon Decl. ¶ 17. To prevent this litany of irreparable harms, the Rule should be stayed.

III. The Balance Of Equities And The Public Interest Strongly Favor A Preliminary Injunction 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. *Nken v. Holder*, 556 U.S. 418, 435 (2009)("The third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party."). 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. Because the purpose of a preliminary injunction is merely to

preserve the status quo, the government will not suffer any harm. *See Univ. of Texas v. Camenisch*, 451 U.S. 390, 395, 101 S. Ct. 1830, 1834 (1981). An injunction will not remove or delay any of the patient protection provisions of the NSA, because insurers will still have to calculate their cost-sharing as if the providers were in-network, and providers will still be forbidden from balance-billing the patient. The only party that will suffer harm from the issuance of an injunction is insurers, as they will not be able to take advantage of the windfall the September Rule gives them. Moreover, 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. 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 Dr. Cannon and other members of GCEP. 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. 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.[9] Consistent underpayments to providers will prompt them to take measures to reduce their expected losses, such as by limiting medical services.

Finally, there is clearly a robust public interest in safeguarding prompt access to health care. 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

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[9] *See Influence of Out-of-Network Payment Standards on Insurer-Provider Bargaining: California's Experience*, Am. J. of Managed Care (Aug. 5 2019), https://www.ajmc.com/view/influence-of-outofnetwork-payment-standards-on-insurer-provider-bargaining-californias-experience?p=1.

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 preliminary injunction 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 this 28th day of January, 2022.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

GEORGIA COLLEGE OF EMERGENCY PHYSICIANS and BRETT CANNON, M.D., Plaintiffs, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	CIVIL ACTION NO. 1:21-cv-05267-MHC

CERTIFICATE OF COMPLIANCE

The foregoing **PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT THEREOF** is double-spaced in 14 point Times New Roman font and Plaintiffs have obtained Leave from the Court to exceed the page limitations of Local Rule 7.1(D).

Respectfully submitted this 28th day of January, 2022.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
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GEORGIA COLLEGE OF EMERGENCY PHYSICIANS and BRETT CANNON, M.D., Plaintiffs, vs. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	CIVIL ACTION NO. 1:21-cv-05267-MHC

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a copy of the within and foregoing **PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT THEREOF** with the Clerk of Court using the CM/ECF system, which will

automatically send email notification of such filing to the following parties of record addressed as follows:

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