IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION and DR. ADAM CORLEY, *Plaintiffs*, v. 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*.	)	Case No.: 6:21-cv-00425-JDK

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT
AND MEMORANDUM IN SUPPORT THEREOF

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For the reasons described below, plaintiffs Texas Medical Association ("TMA") and Dr. Adam Corley respectfully move for summary judgment on Counts I and II of their complaint.[1]

INTRODUCTION

This action under the Administrative Procedure Act ("APA") challenges provisions of an interim final rule issued by defendants ("the Departments") 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) ("NSA").

The NSA creates an arbitration process to resolve reimbursement disputes between certain out-of-network healthcare providers—*i.e.*, physicians, facilities, and other healthcare providers (collectively, "healthcare providers") who are not within a health insurance plan's contracted network—and group health plans and health insurance issuers (collectively, "payors"). When a healthcare provider and payor cannot agree on the appropriate reimbursement amount for covered out-of-network services, either party may initiate arbitration before an independent dispute resolution ("IDR") entity. The arbitration proceeds "baseball-style": after each party submits an offer, the IDR entity must select one of their offers as the reimbursement amount. To guide the IDR entity's decision, Congress specified a detailed list of factors that the IDR entity "shall" and "shall not" consider in determining which party's offer to select. Congress did not assign primacy to any one factor, but rather left it to the IDR entity's discretion to determine how best to weigh the statutory factors in light of all the facts and circumstances of a particular case.

[1] Attached hereto and incorporated herein by reference as Exhibits A and B, respectively, are the declarations of TMA's President, E. Linda Villarreal, MD, and Dr. Corley in support of this motion.

In the September IFR, however, the Departments rewrote the statute under the guise of "interpretation." Without identifying *any* word or phrase that can even arguably be read to impose such a requirement, the Departments claimed that the statute is "best interpret[ed]" to require IDR entities always to select the offer closest to the "qualifying payment amount" ("QPA")—*a number unilaterally calculated by the payor*—unless "credible information" concerning the additional statutory factors "clearly demonstrates" that the QPA is "materially different from the appropriate out-of-network rate." The Departments thus read into the statute a "rebuttable presumption" that requires IDR entities to give outsized weight to a single statutory factor, skewing IDR results in payors' favor and granting them a windfall they were unable to obtain in the legislative process.

For two reasons, the Departments' presumption is unlawful and must be set aside. *First*, the statute cannot reasonably be read to impose such a presumption. Congress painstakingly described the factors IDR entities must consider, and it nowhere provided that the QPA should be afforded more weight than the other factors or otherwise indicated 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 said so. In fact, Congress rejected proposed bills that have would pegged reimbursement to the QPA. Neither agencies nor courts are free to alter statutes by supplying terms that Congress omitted; nor can significant new statutory requirements be found lurking in between the statutory lines or in "penumbras and emanations" from statutory provisions that do not speak to the issue at hand. The statute clearly does not impose the presumption the Departments invented, and that should be the end of the matter.

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. Having waited nine months, the Departments cannot rely on their own delay to create an exigency justifying bypassing notice and comment. In any event, there was no exigency. Arbitrations will not begin occurring until March 2022, five months after the Departments issued the rule. And by setting a deadline of December 27, 2021, Congress itself determined there would be sufficient lead time if final IDR rules were in place by that date. In rushing to issue the rule three months before the statutory deadline, when that time could have been used to provide notice and receive comments, the Departments deprived plaintiffs and other interested parties of an opportunity to be heard, in clear violation of the APA.

STATEMENT OF THE ISSUES

1. Did the Departments act contrary to law and/or exceed their statutory authority when, without any basis in the statutory text, they required IDR entities always to select the offer closest to the QPA unless the IDR entity determines that the additional statutory factors clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate?

2. Did the Departments have good cause for issuing the presumption without providing notice and comment as required by the APA, when they had an entire year to issue final IDR rules and there were still three months before the December 27, 2021 statutory deadline for IDR rules and five months before the first IDR proceedings would begin?

STATEMENT OF UNDISPUTED MATERIAL FACTS

A. The No Surprises Act

The NSA creates a comprehensive framework designed to address surprise medical billing, as well as supplemental requirements imposed on healthcare providers and plans and issuers to

enhance beneficiary transparency regarding the costs they can expect to incur for healthcare items and services. The NSA was enacted on December 27, 2020, as part of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182 (2020), and its requirements generally go into effect on January 1, 2022.

The NSA 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 (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the September IFR and are referred to collectively as "the Departments."[2]

The NSA provides that for emergency services furnished by an out-of-network healthcare provider and non-emergency services furnished by an out-of-network healthcare provider at an in-network facility, plans and issuers may not impose a patient cost-sharing requirement that is greater than the cost-sharing that would apply had the items or services been furnished by an in-network healthcare provider. 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A). The cost-sharing requirement is calculated using a "recognized amount." *Id.* § 300gg-111(a)(1)(C)(iii), (b)(1)(B). The "recognized amount" is (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, the amount determined by a "specified State law," which is a state law that provides a method for

[2] The relevant statutory and regulatory provisions at issue in this case generally appear in triplicate. The NSA's IDR provisions are codified at 42 U.S.C. § 300gg-111(c) (PHS Act), 29 U.S.C. § 1185e(c) (ERISA), and 26 U.S.C. § 9816(c) (IRC). For ease of reference, this brief cites the PHS Act provisions and implementing regulations.

determining the total amount payable by the patient; or (3) if there is no applicable All-Payer Model Agreement and no specified state law, the QPA for that item or service. *Id.* § 300gg-111(a)(3)(H). For each item or service, the QPA is statutorily defined as generally being the median of the contracted rates recognized by the plan or issuer for the same or similar item or service furnished by a healthcare provider in the same or similar specialty and in the same geographic region. *Id.* § 300gg-111(a)(3)(E).

In addition to limiting patient cost-sharing, the NSA also limits the amount that out-of-network healthcare providers can bill to patients. For covered services, the NSA prohibits out-of-network healthcare providers from billing a patient for any amount that exceeds the statutorily calculated patient cost-sharing amount, unless an exception applies. Instead, the statute obligates payors to reimburse out-of-network healthcare 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 determined through a process similar to that for determining patient cost-sharing, but with one significant difference. As with patient cost-sharing, healthcare provider reimbursement 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 healthcare provider. *Id.* § 300gg-111(a)(3)(K). But unlike with patient-cost sharing, if there is no applicable All-Payer Model Agreement or specified state law, Congress declined to set healthcare provider reimbursement at the QPA or otherwise provide a benchmark or mathematical formula.[3] Instead, the NSA authorizes payors to make an initial payment in an amount of their

[3] Congress considered proposed legislation that would have determined healthcare provider reimbursement by relying upon the median in-network rate as a benchmark for calculating payments. *See, e.g.*, H.R. 3630, 116th Cong. (2019); S. 1895, 116th Cong. (2019). But Congress ultimately

choosing, and then channels reimbursement disputes through a carefully balanced process of open negotiation, followed, if necessary, by "baseball-style" arbitration before a certified IDR entity.

B. The IDR Process

The NSA creates a detailed IDR process for resolving disputes between healthcare providers and payors over out-of-network reimbursement. *See* 42 U.S.C. § 300gg-111(c). Among other things, the statute sets forth rules governing how IDR entities can become certified and selected to preside over disputes, *id.* § 300gg-111(c)(4); rules for when multiple disputed items and services can be considered jointly, *id.* § 300gg-111(c)(3); and rules allocating responsibility for paying the IDR entity's fees, *id.* § 300gg-111(c)(5)(F). As relevant here, the statute also sets out a timeline for the IDR process, *id.* § 300gg-111(c)(1)(B), (c)(4)(F), (c)(5)(A)–(B), and the factors that IDR entities "shall" and "shall not" consider in deciding cases, *id.* § 300gg-111(c)(5)(C)–(D).

1. The Timeline for the IDR Process

Congress specified a precise timeline applicable to all parties entering the IDR process. Within 30 days of the healthcare provider's receipt of an initial payment or notice of denial of payment from the payor—which can take a month or more from the date of service to receive—the parties may engage in a 30-day open negotiation process to determine an appropriate payment amount. *Id.* § 300gg-111(c)(1)(A). If the negotiations do not result in an agreed payment amount during those 30 days, either party may, within four days following the conclusion of the open negotiation period, initiate the IDR process. *Id.* § 300gg-111(c)(1)(B).

Once the IDR process is initiated, the parties have three business days jointly to select a certified IDR entity to oversee the proceedings. *Id.* § 300gg-111(c)(4)(F)(i). If they fail to do so,

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rejected that approach in favor of an IDR process that, as discussed below, requires an independent IDR entity to take all relevant circumstances into account, without designating any single factor as more important or entitled to greater weight than the other factors.

the relevant agency, not later than six business days after the initiation of the IDR process, must select a certified IDR entity. *Id.* § 300gg-111(c)(4)(F)(ii). Within 10 days thereafter, each party must submit (1) an offer for a payment amount, (2) any information requested by the IDR entity relating to the offers, and (3) any additional information the party wishes the IDR entity to consider, including information relating to the statutory factors. *Id.* § 300gg-111(c)(5)(B).

Within 30 days of the selection of the certified IDR entity, the IDR entity must determine which party's offer to accept, and then notify the parties. *Id.* § 300gg-111(c)(5)(A). If the parties agree to a payment amount before the IDR entity makes its determination, that payment amount controls. *Id.* § 300gg-111(c)(2)(B). If not, then the IDR entity's decision is "binding" absent a fraudulent claim or evidence of factual misrepresentation. *Id.* § 300gg-111(c)(5)(E)(i).

2. Factors Governing the Payment Determination

Congress directed the Departments, "[n]ot later than 1 year after" the NSA's enactment, *i.e.*, by December 27, 2021, to issue regulations establishing a process under which IDR entities would determine the appropriate payment amount "in accordance with the succeeding provisions of this subsection." *Id.* § 300gg-111(c)(2)(A).

Those "succeeding provisions" describe how the IDR entity should determine the appropriate payment amount. Within 30 days after selection of the IDR entity, the IDR entity must choose one of the parties' offers after "taking into account the considerations specified in subparagraph (C)." *Id.* § 300gg-111(c)(5)(A)(i). Subparagraph (C), entitled "Considerations in determination," spells out in detail the precise factors the IDR entity "shall consider" in "determining which offer is the payment to be applied." *Id.* § 300gg-111(c)(5)(C)(i).

In particular, Congress provided that IDR entities "shall consider" (1) the QPA for comparable items or services furnished in the same geographic area, *id.* § 300gg-111(c)(5)(C)(i)(I); (2) information on five additional circumstances described in subparagraph (C)(ii), *id.* § 300gg-

111(c)(5)(C)(i)(II); (3) any information the IDR entity requests from the parties to the IDR proceeding, *id.*; and (4) any additional information submitted by either party relating to its offer, *id.*

The five additional circumstances Congress required IDR entities to consider in every case are (1) the level of training, experience, and quality and outcomes measurements of the healthcare provider that furnished the item or service, *id.* § 300gg-111(c)(5)(C)(ii)(I); (2) the market share of the healthcare provider or payor in the geographic region where the item or service was provided, *id.* § 300gg-111(c)(5)(C)(ii)(II); (3) the acuity of the individual receiving the item or service or the complexity of furnishing such item or service to such individual, *id.* § 300gg-111(c)(5)(C)(ii)(III); (4) the teaching status, case mix, and scope of services of the facility that furnished the item or service, *id.* § 300gg-111(c)(5)(C)(ii)(IV); and (5) demonstrations of good faith efforts (or lack of good faith efforts) made by the healthcare provider or payor to enter into network agreements, and, if applicable, contracted rates between the healthcare provider and payor during the previous four plan years, *id.* § 300gg-111(c)(5)(C)(ii)(V).

In subparagraph (D), Congress further specified three factors that IDR entities "shall not consider": (1) the usual and customary charges, (2) the amount the healthcare provider would have billed had the NSA's provisions regarding balance billing not applied, and (3) the amount that would have been paid by a public payor, including under Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, or 38 U.S.C. § 1701 *et seq*. *Id.* § 300gg-111(c)(5)(D).

C. Implementing Regulations

The NSA required the Departments to issue implementing regulations on certain issues by specified deadlines, showing that Congress carefully considered how much lead time regulated entities would need to come into compliance with implementing regulations. *See* Compl. ¶ 43. For example, the Departments directed the Secretaries of HHS, Labor, and the Treasury, not later than

July 1, 2021, to establish the methodology that payors must use to determine the QPA, the information payors must share with healthcare providers about how QPAs were calculated, and a process to receive complaints about violations by payors of the rules for calculating QPAs. 42 U.S.C. § 300gg-111(a)(2)(B). And Congress directed the same agencies, not later than December 27, 2021, to promulgate rules implementing the IDR process to resolve disputes between healthcare providers and payors regarding out-of-network reimbursement. *Id.* § 300gg-111(c)(2)(A).

On July 1, 2021, the Departments made publicly available an interim final rule implementing certain of the NSA's surprise medical billing requirements. *See* 86 Fed. Reg. 36,872 (July 13, 2021) ("July IFR"). Among other provisions, the July IFR set forth a methodology for how payors must calculate QPAs, 45 C.F.R. § 149.140(c), and the information payors must share with out-of-network healthcare providers relating to how they calculated QPAs, *id.* § 149.140(d).[4]

On September 30, 2021, the Departments publicly released a second IFR—at issue here—implementing the IDR process and other provisions of the NSA. The September IFR was published in the Federal Register on October 7, 2021, and became effective on that date. 86 Fed. Reg. at 55,980. As relevant here, it requires IDR entities to employ a "rebuttable presumption that the QPA is the appropriate payment amount." *Id.* at 56,060. Specifically, the IDR entity "must," in every case, "select the offer closest to the [QPA] unless" either (1) "the certified IDR entity determines that credible information submitted by either party … clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate," or (2) "the offers are equally

[4] Although not material to the legal claims presented here, for a variety of reasons, the QPA will often be lower than the fair market value of healthcare providers' services as reflected by reimbursement amounts paid in the marketplace. *See* Compl. ¶¶ 68–70. Moreover, the information payors use to calculate QPAs lies solely within their control, and the mandatory disclosures are wholly insufficient to allow the Departments, the IDR entities, and, critically, healthcare providers to ascertain whether a payor has correctly calculated the QPA. *See id.* ¶¶ 47–48, 71.

distant from the [QPA] but in opposing directions." *Id.* at 56,128. "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." *Id.*

Thus, under the September IFR, the IDR entity "must begin with the presumption that the QPA is the appropriate out-of-network rate," and must select the offer closest to the QPA, unless "credible information" regarding the additional factors "rebuts that presumption" and "clearly demonstrates" that the QPA is "materially different" from the appropriate out-of-network rate. *Id.* at 55,996. A "material difference" exists only if "there is substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out of network rate and view the information as showing that the QPA is not the appropriate out-of-network rate." *Id.* at 55,995.

As a result, even if an IDR entity concludes, after considering all the factors Congress directed it to consider, that the offer farther from the QPA better reflects the value of the item or service, the IDR entity may not select that offer unless its proponent satisfies the heightened burden set forth in the September IFR. If the IDR entity does select the offer farther from the QPA, it must provide "a detailed explanation" justifying its decision to reject the offer closer to the QPA. *Id.* at 56,000. That detailed explanation must describe "the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate." *Id.*

The Departments identified no statutory text specifically creating these requirements. Instead, they asserted the statute is "best interpret[ed]" to require IDR entities to employ a rebuttable

presumption in favor of the QPA because, *e.g.*, "[t]he statutory text lists the QPA as the first factor," the other factors "are described in a separate paragraph" and are "subject to a prohibition on considering certain factors," and the statute "sets out detailed rules for calculating the QPA" and requires the QPA to be used in determining patient cost-sharing. *Id.* at 55,996. The Departments also cited various "policy considerations" for "[a]nchoring" the payment amount to the QPA, which they believed would "increase the predictability of IDR outcomes" and "encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs." *Id.*

With regard to the decision to issue the IDR regulations as an interim final rule, the Departments acknowledged that the APA requires notice and comment for legislative rules such as this one. *See* 5 U.S.C. § 553(b); 86 Fed. Reg. at 56,043. They concluded, however, that good cause existed for bypassing that requirement. 86 Fed. Reg. at 56,043. The Departments conceded that the full year between the NSA's enactment on December 27, 2020, and its effective date of January 1, 2022, "may have allowed for the regulations" to be finalized through notice-and-comment rulemaking before the NSA took effect. *Id.* at 56,043–44. Nonetheless, the Departments asserted that providing notice and comment would be "impracticable and contrary to the public interest." *Id.* at 56,043. Specifically, the Departments asserted that IDR rules needed to be in place to allow parties to utilize the IDR process to determine out-of-network rates; that rules issued by the NSA's effective date would not provide parties and IDR entities sufficient time to implement the rules' requirements; and that issuing the rules without notice and comment would allow plans and issuers to account for the rules in finalizing their rates and plan offerings. *See id.* at 56,043–44.

LEGAL STANDARDS

Summary judgment is proper "if the movant shows that 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). "In the context of a challenge under the APA, '[s]ummary judgment is the proper mechanism for

deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review.'" *Texas v. EPA*, 389 F. Supp. 3d 497, 503 (S.D. Tex. 2019) (quoting *Blue Ocean Inst. v. Gutierrez*, 585 F. Supp. 2d 36, 41 (D.D.C. 2008)); *see, e.g.*, *Gulf Fishermens Ass'n v. Nat'l Marine Fisheries Serv.*, 968 F.3d 454, 459–60 (5th Cir. 2020). Under the APA, courts will "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C), or issued "without observance of procedure required by law," *id.* § 706(2)(D).

In assessing an agency's statutory interpretation, courts must first determine whether Congress authorized the agency "to speak with the force of law" with regard 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. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). Under *Chevron*, courts "must give effect to the unambiguously expressed intent of Congress," *id.* at 842–43, deferring to the agency's interpretation only if "the statute is 'truly ambiguous' on the question" at hand and the agency's interpretation is a "permissible construction," *Gulf Fishermens Ass'n*, 968 F.3d at 460. Here, as discussed below, the Departments' presumption in favor of the QPA is not entitled to *Chevron* deference, both because the statute "unambiguously precludes" the Departments' interpretation, *see infra*, Part I.A; *Gulf Fishermens Ass'n*, 968 F.3d at 460, and because Congress did not authorize the Departments to speak with the force of law regarding the standard to be applied by IDR entities in deciding cases, *see infra*, Part I.B.

With regard to the Departments' assertion of good cause for bypassing notice and comment, this Court's review is de novo. *See, e.g.*, *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (evaluating agency's claim of good cause without deference to the agency); *NRDC v.*

Nat'l Highway Traffic Safety Admin., 894 F.3d 95, 113 (2d Cir. 2018) ("When reviewing an agency's claim of good cause, which we do de novo, we must 'examine closely' the agency's explanation as outlined in the rule." (citations omitted)); *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) ("On th[e] question [of good cause], it would appear we owe [the agency's] findings no particular deference."). Regardless, under any standard, the Departments failed to establish good cause for omitting notice and comment. *See infra*, Part II; *Mack Trucks*, 682 F.3d at 93 ("[E]ven if we were to review EPA's assertion of 'good cause' simply to determine if it is arbitrary or capricious, we would still find it lacking." (citation omitted)); *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at *3 (E.D. Tex. Jan. 25, 2017) (agreeing that "nothing in *Johnson* suggests the Fifth Circuit should apply a deferential standard of review for the legal question of whether good cause was satisfied," but noting that the agency's rationale for bypassing notice and comment was "also arbitrary and capricious").

ARGUMENT

I. In Requiring IDR Entities To Presume That The Offer Closest To The QPA Is The Appropriate Reimbursement Amount, The Departments Acted Contrary To Law And In Excess Of Their Statutory Authority.

In requiring IDR entities always to select the offer closest to the QPA unless information concerning the additional statutory factors rebuts a presumption that the QPA is the appropriate out-of-network rate, *see* 86 Fed. Reg. at 55,995, the Departments, under the guise of "interpretation," *id.* at 56,996, improperly added a material term to the statute and, in so doing, fundamentally transformed the IDR process Congress created. This foray into administrative legislation must be set aside so that IDR entities can exercise the discretion Congress granted them to consider the full range of statutory factors in determining which party's offer best reflects the value of the items or services at issue in light of all the facts and circumstances presented in a given case, without an administratively manufactured thumb on the scales in favor of the QPA (and, implicitly, the payor).

A. The statute cannot reasonably be "interpreted" to require IDR entities to employ a rebuttable presumption in favor of the offer closest to the QPA.

1. The Departments improperly added a material term to the statute.

In statutory interpretation, courts "usually start with the text, but more telling here is the [NSA's] lack of text." *Gulf Fishermens*, 968 F.3d at 460. Although the Departments claimed their presumption was the "best interpretation" of the statute, 86 Fed. Reg. at 55,996, they did not identify a single statutory term or phrase that could be "interpreted" to require IDR entities always to "select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party … clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate," *id.* at 56,128. That is because no statutory text imposes such a requirement. The statutory text requires only that the IDR entity "shall consider," 42 U.S.C. § 300gg-111(c)(5)(C)(i), and "tak[e] into account," *id.* § 300gg-111(c)(5)(A)(i), the QPA and the other factors enumerated in the statute, without prioritizing the QPA or subordinating the other factors to it in any way. This case is thus controlled by the "fundamental principle of statutory interpretation that absent provisions cannot be supplied by the courts"—or by administrative agencies. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2381 (2020) (cleaned up).

That principle has particular force here, for at least four reasons. *First*, Congress addressed the IDR process in painstaking and exhaustive detail. In addition to specifying such minutiae as, for example, the timeline for each step of the process, the rules for jointly considering multiple items and services, and the allocation of fees, *see supra*, at 6–7, Congress spelled out with care the precise factors that IDR entities "shall" and "shall not" consider "[i]n determining which offer is the payment to be applied," 42 U.S.C. § 300gg-111(c)(5)(C)–(D). Congress required IDR entities to consider *each* factor in *every* case, and it nowhere specified that the QPA (or any other factor,

for that matter) was "more equal" than the others or should be given presumptive weight in the decisional process. Instead, Congress directed IDR entities to select one of the parties' offers after "taking into account the considerations specified in subparagraph (C)," *id.* § 300gg-111(c)(5)(A)(i), leaving it to the IDR entities' discretion how best to weigh those considerations in light of all the facts and circumstances of a particular case. Especially in a statute as prescriptive as this one, it is "highly improbable" that Congress intended for the QPA to be given presumptive weight but "absentmindedly forgot to mention" it. *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 20 (1979) (internal quotation marks omitted).

Second, "[a]textual judicial"—or administrative—"supplementation is particularly inappropriate when, as here, Congress has shown that it knows how to adopt the omitted language or provision." *Rotkiske v. Klemm*, 140 S. Ct. 355, 361 (2019). Congress knows how to impose a "rebuttable presumption" when it wants to; it has done so in many statutes.[5] Indeed, elsewhere in the Consolidated Appropriations Act, 2021, itself—the same enactment that included the NSA—Congress imposed a "rebuttable presumption."[6] *See Salinas v. U.S. R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021) ("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

[5] *See, e.g.*, 8 U.S.C. § 1158(b)(1)(B)(iii) (creating a "rebuttable presumption" of credibility); 15 U.S.C. § 3608(b) (creating a "rebuttable presumption" of unconscionability); 16 U.S.C. § 5509(e) (creating a "rebuttable presumption" of a statutory violation); 18 U.S.C. § 1388(e) (creating a "rebuttable presumption" of willfulness); *id.* § 1469(a) (creating a "rebuttable presumption" of movement in interstate commerce); 21 U.S.C. § 853(d) (creating a "rebuttable presumption" of forfeiture); 30 U.S.C. § 1466(e) (creating a "rebuttable presumption" of a statutory violation); 39 U.S.C. § 3008(f) (creating a "rebuttable presumption" of mailing after a specified date); *id.* § 3653(e) (creating a "rebuttable presumption" of statutory compliance); 42 U.S.C. § 667(b)(2) (creating a "rebuttable presumption" of correctness of child support calculated according to guidelines); *id.* § 15942(a) (creating a "rebuttable presumption" of exemption from environmental review).

[6] 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…").

purposely in the disparate inclusion or exclusion." (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983))). Had Congress intended to create a rebuttable presumption, "it easily could have written" the statute to say so, as it has frequently done elsewhere. *Texaco Inc. v. Duhe*, 274 F.3d 911, 920 (5th Cir. 2001). "The statute, however, does not do so and no principle of statutory interpretation grants [a court or agency] license simply to rewrite statutory language by ascribing additional, material terms." *Id.*; *see also Alabama v. North Carolina*, 560 U.S. 330, 352 (2010) ("We do not—we cannot—add provisions to a federal statute.").

Third, Congress enacted the NSA against a backdrop of case law holding that where, as here, a statute sets forth a list of factors for a decision maker to consider without assigning priority to any of them, the weighing of the factors is left to the decision maker's discretion. *See, e.g.*, *New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992) ("Because Congress did not assign the specific weight the Administrator should accord each of these factors, the Administrator is free to exercise his discretion in this area."); *Cent. Vt. Ry., Inc. v. ICC*, 711 F.2d 331, 336 (D.C. Cir. 1983) ("As a general rule, when a statute requires an agency to 'consider' a factor, the agency must reach an express and considered conclusion about the bearing of the factor, but need not give any specific weight to the factor." (cleaned up)); *Ramirez v. ICE*, 471 F. Supp. 3d 88, 176 (D.D.C. 2020) ("[I]f Congress did not mandate any particular structure or weight for an agency's consideration of a variety of factors, then the agency is left with discretion to decide how to account for the consideration factors, and how much weight to give each factor." (cleaned up)). In light of this case law, had Congress wanted to constrain IDR entities' discretion in considering the statutory factors by requiring them to give presumptive weight to the QPA, it was incumbent on Congress to say so.

Fourth, a presumption in favor of the QPA is no minor detail, but rather a fundamental alteration of the IDR process. Under the statute as written, IDR entities would consider *all* the

required factors, without any presumptions, and select the offer that, in the IDR entity's judgment, best represents the value of the items or services. The Departments' presumption completely reorients the process, placing the QPA at its center and thereby transforming the process from one that Congress designed to be "independent" to one that tilts decidedly in favor of payors (who calculate the QPA). Indeed, during the legislative process, payors lobbied Congress to use the QPA as a benchmark for healthcare provider reimbursement just as it is used for patient cost-sharing; *but Congress rejected bills to that effect*. *See, e.g.*, H.R. 3630, 116th Cong. (2019); S. 1895, 116th Cong. (2019). The statute cannot be read to impose such a significant requirement *sub silentio*. As Justice Scalia famously put it, "Congress … does not … hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). That principle, which typically is invoked when a party puts more weight on a minor provision than it can bear, applies *a fortiori* here, where the Departments' presumption is supported by *no provision at all*. According to the Departments, Congress imposed a game-changing presumption that "the statute does not even mention." *Gulf Fishermens*, 968 F.3d at 462. Their argument is thus "all elephant and no mousehole." *Id.*

At bottom, "Congress could have limited [IDR entities'] discretion in any number of ways," including by imposing a presumption in favor of the QPA, "but it chose not to do so." *Little Sisters*, 140 S. Ct. at 2380. The Departments are not at liberty to countermand that decision, under the guise of "interpretation" or otherwise. By "adding terms not found in the statute," and "imposing limits on [IDR entities'] discretion that are not supported by the text," the Departments "alter[ed], rather than … interpret[ed]" the statute. *Id.* at 2381.

2. The Departments' points are unavailing.

Unable to identify any statutory text that could even arguably be read to impose a presumption in favor of the QPA, the Departments purported to infer the presumption from isolated bits of

statutory structure and avowed "policy considerations." 86 Fed. Reg. at 55,996 (asserting that various "statutory elements" show that "the statute contemplates that typically the QPA will be a reasonable out-of-network rate"). What already has been said is sufficient to refute this approach. The short answer to all of the Departments' points is that significant new statutory requirements cannot be found hiding between the statutory lines or in "implications from 'penumbras,' 'emanations,' and other legal fictions." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 97 (2012). If Congress had intended to create a presumption in favor of the QPA, it would have said so clearly. It did not, and that should end the matter. *See id.* at 93.

But the Departments' points are also unpersuasive on their own terms. Neither separately nor together do they provide any basis for the Departments' presumption. The Departments observed, for example, that "[t]he statutory text lists the QPA as the first factor." 86 Fed. Reg. at 55,996. That says nothing about whether Congress intended the offer closest to the QPA to be presumptively correct. No canon of interpretation holds that when Congress enumerates factors for a decision maker to consider, the first factor should be given greater weight or presumptively control the outcome. In any list of factors to be considered, some factor necessarily must be listed first. Thus, treating the first-listed factor as entitled to presumptive weight would effectively require Congress to state before every list of statutory factors that it is *not* creating a presumption.

The Departments further observed that "[t]he 'additional circumstances'" the IDR entity must consider "are described in a separate paragraph" and are "subject to a prohibition on considering certain factors." *Id.* So what? This in no way mitigates the force of the statute's command that the IDR entity "shall consider" them. Indeed, those "additional circumstances" are first referenced in the very same paragraph as the QPA (subparagraph (C)(i)). That Congress proceeded to describe them in detail in a separate paragraph does not in any way downgrade them to second-

class status or diminish the requirement that IDR entities "shall consider" them just as much as they "shall consider" the QPA. Likewise, that Congress prohibited consideration of certain factors in no way elevates the QPA. To the contrary, the meticulous care Congress exhibited in enumerating the factors that IDR entities "shall" and "shall not" consider precludes any inference that Congress intended the QPA to be given presumptive weight but somehow neglected to say so.

Nor does it matter that "whereas the statute provides relatively limited guidance on how to consider or define these additional circumstances, the statute sets out detailed rules for calculating the QPA." *Id.* The QPA is a numerical figure, and it is a benchmark for patient cost-sharing under the statute, *see* 42 U.S.C. § 300gg-111(a)(3)(H), so it is hardly surprising that Congress set out "detailed rules" for calculating it. The additional circumstances Congress required IDR entities to consider are largely qualitative factors, like the training and experience of the healthcare provider and the complexity of the item or service. And the statute provides precisely the same "guidance on how to consider" the additional circumstances as it does for the QPA—it lists them all as factors to be considered, together with other information requested by the IDR entity or supplied by the parties, without ascribing preeminence to any single factor. How to weigh the various factors in a given case is left to the IDR entity's sound discretion.

The Departments further observed that the QPA generally will be used to determine patient cost-sharing, "indicating that the QPA is a reasonable out-of-network rate." 86 Fed. Reg. at 55,996. But Congress chose a different methodology for determining healthcare provider reimbursement, one that involves an independent arbitrator considering all the relevant facts and circumstances, showing that Congress clearly did *not* believe the QPA should be determinative for purposes of reimbursement. The Departments may disagree with that choice, but they have no license to nullify it by rewriting the statute to make the QPA presumptively controlling in the IDR process.

The Departments also noted that the statute requires the Departments "to report how payment determinations compare to the corresponding QPA." *Id.* But this shows only that Congress thought it important to collect information about how IDR results compared to the QPA. It says nothing at all about the weight to be afforded the QPA in the IDR process. Congress may have believed, for example, that IDR decisions would provide valuable, independent information that Congress and the Departments could use in assessing the role of the QPA and determining the extent to which IDR entities tended to view the QPA as close to an appropriate reimbursement rate after considering all relevant circumstances. In that case, making the QPA presumptively controlling would *frustrate* Congress's informational purpose. In all events, that Congress wanted this information reported provides no support for elevating the QPA over the other statutory factors.

Finally, the Departments may not read new terms into the statute to advance their "policy considerations." *Id.* It is "a core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014). Whether the Departments' presumption would make the IDR process more "efficien[t]" and "predictab[le]" and "encourage parties to reach an agreement," 86 Fed. Reg. at 55,996, is thus beside the point. A presumption that the payor's offer should always be selected might well produce the same results, but it would plainly be incompatible with the statutory scheme. So too is the Departments' presumption in favor of the QPA.

B. The Departments cannot defend the presumption in favor of the QPA as an exercise of purported authority to supplement the statute's requirements.

In requiring IDR entities to presume that the offer closest to the QPA is the appropriate payment amount, the Departments, in reality, were not "interpreting" the statute at all, but supplementing it by adding a requirement that Congress did not impose. While Congress sometimes

authorizes agencies to impose new requirements that go beyond those set forth in the statute, the Departments' presumption in favor of the QPA cannot be sustained on that basis, for three reasons.

First, that was not the rationale the Departments advanced in the rule. The Departments' rationale in the rule was that the rebuttable presumption was "the best interpretation" of the statute. 86 Fed. Reg. at 55,996. Having claimed in the rule merely to be "interpreting" the statute, the Departments' cannot now defend the rule by asserting that they were exercising authority to supplement the statute. "[A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). That means courts "look to what the agency said, not what it might have said"; they "may not accept [agency] counsel's *post hoc* rationalizations for agency action"; and thus the agency's action can be upheld, if at all, only "on the same basis articulated in the [rule] by the agency itself." *Dish Network Corp. v. Nat'l Lab. Rels. Bd.*, 953 F.3d 370, 379–80 (5th Cir. 2020) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168–69 (1962)).

Second, the Departments lack authority to issue rules dictating to IDR entities how they must decide cases. In authorizing the Departments to promulgate rules implementing the IDR process, Congress expressly provided that, under those rules, IDR entities would "determin[e]" the payment amount "in accordance with the succeeding provisions of this subsection." 42 U.S.C. § 300gg-111(c)(2)(A). In those "succeeding provisions," Congress itself provided all the guidance it deemed necessary with respect to IDR entities' decisional process. And, in marked contrast to numerous other provisions of the statute addressing the IDR process where Congress expressly

left gaps for the Departments to fill,[7] Congress did not assign the Departments any role in dictating how IDR entities should weigh the various statutory considerations or determine which party's offer is the appropriate reimbursement amount. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 37–39 (D.D.C. 2014) (holding that agency lacked authority to issue legislative rules addressing issues as to which Congress had not delegated rulemaking authority).

Third, even if the Departments had some authority to issue rules regarding IDR entities' decisional process, any such rules would have to be consistent with the statute. The Departments clearly could not, for example, issue a rule requiring IDR entities to decide disputes by drawing straws, or requiring them always to select the payor's offer unless the healthcare provider overcomes a presumption that the payor's offer is appropriate. Likewise, for all the reasons above, the Departments' presumption in favor of the QPA is inconsistent with the statute. If Congress had intended the QPA to be given presumptive effect, it would have said so. Congress's decision to list the QPA as one factor to be considered alongside others, without any indication that it should

[7] *See* 42 U.S.C. § 300gg-111(c)(1)(B) (the notification initiating the IDR process must contain "such information as specified by the Secretary" and the process begins upon submission of the notification or "such other date specified by the Secretary"); *id.* § 300gg-111(c)(3)(A) ("[T]he Secretary shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination…."); *id.* § 300gg-111(c)(3)(A)(iv) (batched items and services must be furnished during a 30-day period "or an alternative period as determined by the Secretary"); *id.* § 300gg-111(c)(3)(B) ("the Secretary shall provide" for the treatment of bundled payments); *id.* § 300gg-111(c)(4)(A) ("[t]he Secretary … shall establish a process to certify" IDR entities); *id.* § 300gg-111(c)(4)(A)(vii) (the IDR entity must meet specified requirements and "such other requirements as determined appropriate by the Secretary"); *id.* § 300gg-111(c)(4)(F) ("[t]he Secretary shall … provide for a method" for selecting a certified IDR entity); *id.* § 300gg-111(c)(7)(C) (to be certified, IDR entities must "submit to the Secretary such information as the Secretary determines necessary to carry out the provisions of this subsection"); *id.* § 300gg-111(c)(7)(D) ("[t]he Secretary shall ensure the public reporting" does not disclose privileged or confidential information); *id.* § 300gg-111(c)(8)(A) (fees for participating in the IDR process shall be paid "at such time and in such manner as specified by the Secretary"); *id.* § 300gg-111(c)(8)(B) (the amount of the fee is to be "an amount established by the Secretary"); *id.* § 300gg-111(c)(9) ("[t]he Secretary may modify" deadlines or timing requirements "in cases of extenuating circumstances, as specified by the Secretary").

be given primacy, precludes any rule giving the QPA presumptive effect. *See Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 753 (5th Cir. 2011) (holding agency lacked authority "to create from whole cloth" new provisions supplementing comprehensive statutory scheme).

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

Because the presumption in favor of the QPA is substantively unlawful, it should be vacated on that ground alone, and the Court need not reach the question whether the presumption also is procedurally infirm because it was issued without notice and comment. No amount of notice and comment could authorize the Departments to read into the statute a requirement that does not appear there or to impose a requirement that is inconsistent with Congress's design. To the extent the Court deems it necessary to reach the issue, however, the Departments plainly lacked good cause to bypass notice and comment, and that is an independent basis for vacatur.

Under the APA, before issuing substantive rules, an agency must publish a "notice of proposed rule making," 5 U.S.C. § 553(b), and "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). The purpose of these requirements is to "assure fairness and mature consideration of rules having a substantial impact on those regulated" and to "allow the agency to educate itself before adopting a final order." *Johnson*, 632 F.3d at 931 (cleaned up). In this way, notice and comment are designed to "ensure that affected parties have an opportunity to participate in and influence agency decision making at an early stage, when the agency is more likely to give real consideration to alternative ideas." *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979). "Notice and comment are not mere formalities. They are basic to our system of administrative law." *NRDC*, 894 F.3d at 115.

Because of the fundamental importance of notice and comment to both the quality of and public confidence in the administrative process, the APA's notice-and-comment requirement "must be adhered to scrupulously," and exceptions to it are "narrowly construed." *Texas v. United*

States, 809 F.3d 134, 171 (5th Cir. 2015), *aff'd per curiam by an equally divided court*, 136 S. Ct. 2271 (2016) (mem.). Thus, while an agency may omit notice and comment "when the agency for good cause finds … that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," 5 U.S.C. § 553(b)(B), courts have consistently stressed that this exception must be "read narrowly in order to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed," *Johnson*, 632 F.3d at 928 (quoting *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985)); *see also United States v. Rainbow Fam.*, 695 F. Supp. 294, 304 (E.D. Tex. 1988) (the exception must be "narrowly construed and reluctantly countenanced" (quoting *Mid-Tex Elec. Coop., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987)).

Accordingly, the good cause exception is reserved for "true emergencies only," *Rainbow Fam.*, 695 F. Supp. at 305, "where delay would do real harm," *U.S. Steel*, 595 F.2d at 214; *accord NRDC*, 894 F.3d at 114 (the good cause exception "is generally limited to 'emergency situations, or where delay could result in serious harm.'" (quoting *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004)); *California v. Azar*, 911 F.3d 558, 575 (9th Cir. 2018) ("[T]he good cause exception is usually invoked in emergencies, and an agency must 'overcome a high bar' to do so." (quoting *United States v. Valverde*, 628 F.3d 1159, 1164–65 (9th Cir. 2010)). "The burden is on the agency to establish that notice and comment need not be provided." *NRDC*, 894 F.3d at 113–14.[8]

Here, the Departments cannot satisfy the "high bar" needed to justify proceeding without notice and comment. There was ample time to provide notice and comment and issue final IDR

[8] Good cause has been found, for example, when an agency needed to act urgently to prevent the exposure of children to poisonous pesticides during a harvest season that was "already at hand," *Wash. State Farm Bureau v. Marshall*, 625 F.2d 296, 307 (9th Cir. 1980), or to prevent fatal helicopter accidents, *Haw. Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995).

rules by the statutory deadline of December 27, 2021. And none of the justifications offered by the Departments show that doing so would have been impracticable or contrary to the public interest.

A. There was ample time for notice and comment.

When Congress enacted the NSA on December 27, 2020, it directed the Departments to issue rules implementing the IDR process "[n]ot later than 1 year after" the NSA's enactment, *i.e.*, by December 27, 2021. 42 U.S.C. § 300gg-111(c)(2)(A). Congress thus gave the Departments an entire year to promulgate IDR rules—more than enough time to issue a notice of proposed rule-making, consider comments, and issue final rules. *See, e.g.*, *Johnson*, 632 F.3d at 929 (rejecting assertion of good cause where agency waited seven months after statute's enactment to issue interim rules and observing that "[f]ull notice-and-comment procedures could have been run" in that time); *Rainbow Fam.*, 695 F. Supp. at 305 ("Even a six-month deadline has been held sufficient time in which to offer proposed regulations for comment.")

The Departments, however, waited until late September—nine months—to act. Even if there was an exigency at that time—which, as discussed below, there was not—it could not justify bypassing notice and comment. Any exigency was the product of the Departments' own delay, and "[g]ood cause cannot arise as a result of the agency's own delay." *NRDC*, 894 F.3d at 114; *accord Env't Def. Fund, Inc. v. EPA*, 716 F.2d 915, 921 (D.C. Cir. 1983) ("[T]he good cause exception does not apply when an alleged 'emergency' arises as the result of an agency's own delay …."). If an agency's own delay could create good cause, "an agency unwilling to provide notice or an opportunity to comment could simply wait until the eve of a statutory, judicial, or administrative deadline, then raise up the 'good cause' banner and promulgate rules without following APA procedures." *NRDC*, 894 F.3d at 114–15 (quoting *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981)). Accordingly, "where the failure to offer a proposed

rule for notice and comment may be attributed to the agency's own dilatory tactics, whether intentional or not, this is a 'decisive factor' in rejecting the agency's claim of 'good cause.'" *Rainbow Fam.*, 695 F. Supp. at 305 (quoting *Phila. Citizens in Action v. Schweiker*, 669 F.2d 877, 885 (3rd Cir. 1982)). The Court need proceed no further. The Departments' assertion of good cause can and should be rejected on this basis alone. *See id.* at 305–06; *NRDC*, 894 F.3d at 114–15.

In any event, even when the Departments issued the September IFR on September 30, 2021, there was no "true emergenc[y]," *Rainbow Fam.*, 695 F. Supp. at 305, where taking the time for notice and comment would have done "real harm," *U.S. Steel*, 595 F.2d at 214. Even then, there were still three months until the December 27, 2021 statutory deadline for IDR rules, and more than five months before IDR entities would begin hearing cases in March 2022.[9] The Departments could have used the remaining three months before the statutory deadline for notice and comment and issued final IDR rules on schedule. *See, e.g.*, *U.S. Steel*, 595 F.2d at 211, 213 (concluding that agency could have provided notice and comment in the sixty days between receipt of required information from the state and statutory deadline).

Had the time for notice and comment been taken, no dire harm would have resulted, nor would any statutory purpose have been frustrated. Congress no doubt understood there would be lag time between the NSA's effective date of January 1, 2022, and the first IDR proceedings, and it determined that if final IDR rules were issued by December 27, 2021, there would be sufficient time to stand up the IDR process. If more lead time had been necessary, Congress would have set an earlier deadline, as it did for other rules under the NSA. *See* 42 U.S.C. § 300gg-111(a)(2)(A)(i)

[9] Given the billing cycle for out-of-network services and the statutorily prescribed timeline for open negotiation and initiation of the IDR process, *see supra*, at 6–7, for a claim for an item or service furnished on or after January 1, 2022, the soonest a healthcare provider or payor could reasonably expect to submit an offer as part of the IDR process is approximately March 1, 2022.

(October 1, 2021 deadline for audit process for QPA calculations); *id.* § 300gg-111(a)(2)(B) (July 1, 2021 deadline for methodology for payors to determine the QPA).[10]

This is especially true of the rules establishing the rebuttable presumption. Unlike other IDR rules not challenged here, such as those establishing the requirements for IDR entities to become certified, no lead time at all is necessary with regard to any rules concerning the standard IDR entities should apply in deciding cases. Even setting aside that no such rules are necessary in the first place because the statute is self-executing in this regard, they would not need to be in place any sooner than the initiation of the first IDR proceedings. And when the Departments issued the rules establishing the presumption in late September 2021, there were still *five months* until the first IDR proceedings would begin in March 2022. Thus, even if there were good cause with regard to other portions of the September IFR (which the Court need not decide), there was no conceivable justification for issuing the presumption in favor of the QPA without providing interested parties notice and an opportunity to comment. *See Garner*, 767 F.2d at 120 ("[W]e will not allow a regulation otherwise subject to section 553 procedures to piggyback on regulations properly issued in response to a sudden exigency …."); *Am. Fed'n of Gov't Emps. v. Block*, 655 F.2d 1153, 1157 (D.C. Cir. 1981) (holding that regulations responding "to much more than the exigencies of the moment" must comply with notice-and-comment requirements).

B. The Departments' asserted grounds for good cause are meritless.

Although the Departments conceded they "may have" been able to provide notice and comment and still promulgate final IDR regulations in time for them to be applicable when the NSA took effect, they nonetheless claimed that "it would be impracticable and contrary to the public

[10] The two other December 27, 2021 deadlines in the NSA also relate to matters that do not require significant lead time. *See* NSA § 106(d), 134 Stat. at 2856; 42 U.S.C. § 300gg-118 (rules regarding reports plans must prepare relating to air ambulance services); 29 U.S.C. § 1191d(a) (rules establishing reporting format for voluntary reporting by group health plans to states).

interest" to take the time needed to provide notice and comment. 86 Fed. Reg. at 56,043–44. None of the Departments' purported justifications, however, comes close to establishing a "strong enough reason to invoke the [good cause] exception." *U.S. Steel*, 595 F.2d at 214.

The Departments stated, for example, that payors "require these rules to be in place to determine the out-of-network rates" for covered services, and that "[w]ithout these final rules, providers … will not be able to resort to the Federal IDR process" to obtain adequate compensation for their services. 86 Fed. Reg. at 56,044. But this is merely an explanation for why rules implementing the IDR process are necessary generally. It says nothing whatsoever about why it was necessary to issue the rules without notice and comment three months before the statutory deadline Congress set for IDR rules and five months before the first IDR proceedings would begin. As noted, the Departments conceded it may have been possible to provide notice and comment and issue final IDR rules before the NSA took effect on January 1, 2022, *see id.* at 56,043–44—well before anyone would need to invoke the IDR process to determine out-of-network rates.

The Departments further asserted that rules issued after a notice-and-comment period "would not provide sufficient time for the regulated entities to implement the requirements." *Id.* As discussed above, even if that were true, it would only be because of the Department's own ninth-month delay, which cannot create good cause. And it contradicts Congress's evident judgment that IDR rules issued by December 27, 2021, would provide sufficient lead time. In any event, with regard to the "rebuttable presumption" rules challenged here, the Departments offered no persuasive explanation as to why *any* lead time was necessary. They stated only that "[t]hese interim final rules also set up … requirements to which [IDR entities] must adhere in selecting payment offers," and that "IDR entities will need time to … be prepared to conduct payment determinations for plan years beginning on or after January 1, 2022." *Id.* at 56,044. These conclusory

statements do not remotely show that the Departments' presumption in favor of the QPA needed to be in place five months before the first IDR proceedings would begin. IDR entities did not need months to "prepare" to apply the presumption. As long as the presumption was in place before the first IDR proceedings began, IDR entities could easily apply it. And even if the presumption had not been in place by the time of the first IDR proceedings, the worst that would have happened is that IDR entities would have decided cases by considering all the factors Congress required them to consider without applying a presumption in favor of the QPA—just as Congress provided. Avoiding that outcome is not good cause for bypassing notice and comment.

Nor is there any merit to the Departments' claim that good cause existed because issuing the IDR rules without notice and comment would "allow plans and issuers to account for the regulations as they finalize rates and plan offerings." *Id.* The claim here appears to be that if plans and issuers knew that IDR entities would be required to employ the Departments' presumption in favor of the QPA, they could expect to pay less for covered out-of-network services than they otherwise would and could adjust their rates and plan offerings accordingly—a tacit admission that the Departments built into the IDR rules a new substantive bias in favor of payors that is not present in the statute and that payors thus had not yet incorporated into their rates. *See* 86 Fed. Reg. at 55,996, 56,061 (stating that the presumption will "encourage" parties "to make offers that are closer to the QPA," "aid in reducing prices," and prevent "higher out-of-network rates").

Regardless, this claim boils down to an assertion that it would be desirable to provide regulatory guidance to payors. But a "desire to provide immediate guidance, without more, does not suffice for good cause." *Johnson*, 632 F.3d at 929 (quoting *United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009)); *see also California*, 911 F.3d at 576 ("[A]n agency's desire to eliminate more quickly legal and regulatory uncertainty is not by itself good cause."); *Valverde*, 628 F.3d at 1166

("If 'good cause' could be satisfied by an Agency's assertion … of the need to provide immediate guidance and information, then an exception to the notice requirement would be created that would swallow the rule." (cleaned up)). "Moreover, the goal of reducing uncertainty is undercut by the [Departments'] request for post-promulgation comments, which could … resul[t] in a rule change." *Johnson*, 632 F.3d at 929; *see* 86 Fed. Reg. at 55,985 ("The Departments seek comment on all aspects of these interim final rules."); *California*, 911 F.3d at 576–77 ("[T]he agencies' request for post-promulgation comments in issuing the IFRs casts further doubt upon the authenticity and efficacy of the asserted need to clear up potential uncertainty, because allowing for post-promulgation comments implicitly suggests that the rules will be reconsidered and that the level of uncertainty is, at best, unchanged." (cleaned up)). In all events, payors' asserted interest in regulatory guidance is "purely economic, which does not supply good cause." *Dialysis Patient*, 2017 WL 365271, at *4 (citing *Mack Trucks*, 682 F.3d at 95).

In short, the Departments "were unable to identify any emergency that justified publishing [the presumption] without notice and comment." *Id.* at *5. Nor did they identify any "real harm" that would have resulted if they had taken the time to provide notice and comment before promulgating the presumption. *U.S. Steel*, 595 F.2d at 214. Accordingly, if the rules creating the presumption are not set aside as substantively invalid, they should be set aside as having been unlawfully issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

CONCLUSION

For the foregoing reasons, the Court should vacate, as contrary to law and in excess of statutory authority, the provisions of the September IFR requiring IDR entities to employ a rebuttable presumption in favor of the offer closest to the QPA. *See* Proposed Order (listing the challenged provisions). Alternatively, the Court should vacate those provisions as having been unlawfully issued without the notice and comment required by the APA.

Dated: December 10, 2021

Respectfully submitted,

/s/ *Penny P. Reid*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served on all counsel of record in accordance with the Federal Rules of Civil Procedure through filing with this Court's CM/ECF filing system and by email to defendants' counsel on December 10, 2021.

/s/ *Penny P. Reid*
Penny P. Reid

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION and DR. ADAM CORLEY, *Plaintiffs*, v. 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*.	Case No.: 6:21-cv-00425-JDK

DECLARATION OF E. LINDA VILLARREAL, MD
PRESIDENT OF THE TEXAS MEDICAL ASSOCIATION

I, E. Linda Villarreal, MD, solemnly declare under penalty of perjury and to the best of my knowledge, information, and belief as follows:

1. I am over 18 years of age and with capacity, and I provide this declaration based on my personal knowledge.

2. I am a citizen of the United States and a resident of Edinburg, Texas.

3. I am the President of the Texas Medical Association ("TMA").

4. TMA is a professional, member-driven nonprofit association representing over 55,000 physicians, residents, and medical students. Located in Austin, Texas, TMA has 110 component county medical societies throughout the state. It is the largest state medical society in the United States.

5. TMA stands up for Texas physicians by providing distinctive solutions to the challenges they encounter in the care of patients. Among other objectives, TMA seeks to ensure that Texas physicians receive timely and equitable payment for medical services rendered. This lawsuit is germane to TMA's organizational mission.

6. TMA and its physician members recognize that "surprise medical billing" is a significant problem in Texas and throughout the country. Its physician members have frequently drawn attention to the fact that a confusing health insurance system can leave patients with unexpected out-of-pocket costs and inadequate coverage, and physicians frustrated by limited access to patients and their health plan networks. TMA has supported state legislation that would strengthen insurance plan networks and arm patients with more information to lessen the likelihood of receiving a surprise bill, while preserving physicians' rights to bill for care they provide. TMA also supported Texas' surprise billing law, as passed in 2019. *See* Senate Bill 1264, 86th Leg. Reg. Session (Tex. 2019). In response to incidents of alleged price gouging and surprise medical bills during the COVID-19 pandemic, TMA submitted written comments to the Texas House Committee on Insurance, urging lawmakers to avoid cost-shifting from health plans to patients or physicians, both of whom are facing strained resources as they battle the virus.

7. TMA's members include Texas physicians who provide out-of-network services. Reimbursement for some of those out-of-network services will be resolved through the Texas surprise medical billing law, SB 1264, which is a specified state law for the services, providers, and plans falling within its scope. For services, providers, or plans falling within the NSA but not covered by Texas' surprise medical billing law, out-of-network reimbursement is controlled by the NSA. Absent a mutual agreement of the parties, the amount of reimbursement for those services will likely be determined through the NSA's IDR process. TMA's members include Texas physicians who provide out-of-network services covered by the NSA. Absent a mutual agreement of the parties,

the amount of reimbursement for these services will likely be determined through the NSA's IDR process.

8. The "rebuttable presumption" in favor of the QPA adopted in the September IFR will systematically favor payors and reduce out-of-network reimbursement rates compared to a process in which IDR entities are free to consider all the statutory factors without a presumption that the QPA is an appropriate reimbursement amount. The Departments themselves have acknowledged this, stating that the presumption will "encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA," 86 Fed. Reg. at 56,061, "aid in reducing prices," *id*. at 55996, and prevent "higher out-of-network rates," *id*.

9. The "rebuttable presumption" therefore directly harms the financial interests of TMA's members.

Pursuant to the requirements of 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: 12/10/2021

DocuSigned by:
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E. Linda Villarreal, MD

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION and DR. ADAM CORLEY, *Plaintiffs*, v. 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*.	Case No.: 6:21-cv-00425-JDK

DECLARATION OF DR. ADAM CORLEY

I, Dr. Adam Corley, solemnly declare under penalty of perjury and to the best of my knowledge, information, and belief as follows:

1. I am over eighteen years of age and with capacity, and I provide this declaration based on my personal knowledge.

2. I am an emergency room physician who resides and practices in Tyler, Texas.

3. I work through Precision Emergency Physicians, PLLC.

4. I am reimbursed at an hourly rate for my emergency medical services.

5. The majority of my patients are insured by commercial plans. At least some of my patients will receive services covered by the NSA's rules for out-of-network reimbursement, and at least some of the claims for reimbursement resulting from those services will very likely be resolved through the NSA's IDR process.

6. I also own a percentage of Hospitality Health ER, a freestanding emergency department in Tyler, Texas.

7. Some patients who receive medical treatment at Hospitality Health ER are covered by commercial plans. At least some of these commercially-insured patients will receive services covered by the NSA's rules for out-of-network reimbursement, and at least some of the claims for reimbursement resulting from those services will very likely be resolved through the NSA's IDR process.

8. The September IFR imposes a "rebuttable presumption" that the offer closest to the QPA is the appropriate reimbursement amount. The QPA, however, will often be below fair market value for the services provided.

9. Requiring IDR entities to presume that the offer closest to the QPA is the appropriate reimbursement amount will result in lower reimbursement rates and, correspondingly, will cause my hourly compensation for out-of-network services to decrease.

10. The presumption in favor of the QPA will also reduce out-of-network reimbursements paid to Hospitality Health ER.

11. Accordingly, the September IFR directly harms my financial interests.

Pursuant to the requirements of 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: 12/8/2021

DocuSigned by:
Adam Corley
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Dr. Adam Corley

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION and DR. ADAM CORLEY, *Plaintiffs*, v. 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*.	Case No.: 6:21-cv-00425-JDK

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Before the Court is plaintiffs' motion for summary judgment. Being fully advised in the premises, the Court finds that the motion should be **GRANTED** as to Count I [and/or Count II].

It is, therefore, **ORDERED** that the motion is hereby **GRANTED** as to Count I [and/or Count II], and the following provisions are hereby **VACATED**:

a. 45 C.F.R. § 149.510(a)(2)(viii); the second sentence 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).

b. 26 C.F.R. § 54.9816-8T(a)(2)(viii); the second sentence 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).

c. 29 C.F.R. § 2590.716-8(a)(2)(viii); the second sentence 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).