IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civ. No. 1:21-cv-3031 (RJL)

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Rules 7(h)(2) and 7(n), plaintiff Association of Air Medical Services (AAMS) moves for an order granting summary judgment on all claims in the Complaint and vacating the challenged portions of the interim final rules (IFRs) promulgated by defendants. *See Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) and *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). AAMS relies upon the declarations attached to the Complaint and, for further support, submits its memorandum of points and authorities, the declaration of Christopher Eastlee, and the declaration of Robert Sannerud.[1] A proposed order accompanies this motion.

As more fully set forth in the accompanying memorandum of points and authorities, AAMS is entitled to summary judgment on its claims because the IFRs were issued in excess of statutory jurisdiction, authority, or limitations and are arbitrary, capricious, an abuse of discretion, and contrary to law in violation of the Administrative Procedure Act.

[1] Relief on AAMS's claims does not turn on the administrative record. The statutory text, regulatory text, and preambles to IFR Parts I and II establish that the challenged provisions must be set aside under the Administrative Procedure Act.

Congress enacted the No Surprises Act to end surprise billing and remove patients from the middle of payment disputes between group health plans or issuers and air ambulance providers. The Act forces plans and issuers to come to the negotiating table with air ambulance providers and agree on a fair and reasonable rate for their critical services. Otherwise, the air ambulance provider and the plan or issuer must resolve their dispute through an independent dispute resolution (IDR) process Congress carefully designed. Either way, patients are not left with surprise bills.

Congress's design, however, was undone by the Departments' issuance of the IFRs. IFR Part II makes the "qualifying payment amount" (QPA)—which plans and issuers determine unilaterally—presumptively dispositive of any payment dispute and *requires* the IDR entity to select the offer that is closest to that amount. It does so notwithstanding the statutory directive that the IDR entity "shall consider" an enumerated list of circumstances, only one of which is the QPA. IFR Part I compounds this error by purposefully depressing the QPA for air ambulance services in a manner contrary to the statutory text and wholly divorced from market realities. In sum, the IFRs flip the statutory text on its head.

The Court should grant summary judgment to AAMS and enter final judgment:

(a.) Setting aside the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021):

- 45 C.F.R. § 149.510(c)(4)(ii)(A), 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A), and 29 C.F.R. § 2590.716-8(c)(4)(ii)(A)'s direction that "[t]he certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network

rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer."

- 45 C.F.R. § 149.520(b)(2), 26 C.F.R. § 54.9817-2T(b)(2), and 29 C.F.R. § 2590.717-2(b)(2)'s related direction limiting consideration of "Additional information submitted by a party" only to information that is "credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section," and "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate."

(b.) Setting aside the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021):

- 45 C.F.R. § 149.140(a)(1), 26 C.F.R. § 54.9816-6T(a)(1), and 29 C.F.R. § 2590.716-6(a)(1)'s direction that "[s]olely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract."
- 45 C.F.R § 149.140(a)(7)(ii)(B), 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B),[2] and 29 C.F.R. § 2590.716-6(a)(7)(ii)(B)'s provision that "[i]f a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in

[2] 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B) does not include "or issuer."

each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605)."

- 45 C.F.R. § 149.140(a)(12), 26 C.F.R. § 54.9816-6T(a)(12), and 29 C.F.R. § 2590.716-6(a)(12)'s provision that "except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty."

Dated: December 10, 2021

Respectfully submitted,

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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ORAL ARGUMENT REQUESTED

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GLOSSARY

AAMS	Association of Air Medical Services
ERISA	Employee Retirement Income Security Act
IDR	Independent Dispute Resolution
IFR	Interim Final Rule
MSA	Metropolitan Statistical Area
NSA	No Surprises Act
PHSA	Public Health Service Act
QPA	Qualifying Payment Amount

INTRODUCTION

This case concerns two interim final rules (IFRs) issued by the Departments[1] to implement the No Surprises Act (NSA). The IFRs impose through administrative fiat policies that Congress considered and rejected. They defy the statute's text and purpose and threaten patients' access to critical emergency care.

Congress intended for the NSA to end surprise billing and remove patients from the middle of payment disputes between group health plans or issuers and air ambulance providers. Prior to the NSA, when a plan or issuer declined to contract with or pay an appropriate out-of-network rate to an air ambulance provider, the plan or issuer would leave the patient responsible for the unpaid portion of the air ambulance provider's invoice—a so-called surprise bill. The NSA forces plans and issuers to come to the negotiating table with air ambulance providers and agree to pay a fair and reasonable rate for their critical services. Otherwise, the air ambulance provider and the plan or issuer must resolve their dispute through an independent dispute resolution (IDR) process in which an IDR entity considers all of the many circumstances enumerated in the NSA—with none given special weight—and then selects one of the parties' offers as the appropriate out-of-network rate. Either way, patients are not left with surprise bills. Congress modeled the IDR process on baseball-style arbitration, which is an efficient mechanism that produces fair payments by incentivizing both parties to submit good faith, reasonable offers.

Congress's design, however, was swiftly undone when the Departments issued the IFRs before notice and comment in July and October 2021.[2] Critical elements of the IFRs diverge wildly from the structure Congress created with the NSA.

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[1] Collectively, the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management.

[2] *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021); *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021).

IFR Part II makes the "qualifying payment amount" (QPA)—which plans and issuers determine unilaterally—*presumptively dispositive* of any payment dispute and *requires* the IDR entity to select the offer that is closest to that amount. 45 C.F.R. § 149.510(c)(4)(ii)(A).[3] In this way, the Departments have imposed an IDR process that is not "independent" and effectively forces the IDR entity to ignore the mandatory considerations that Congress actually enacted. The Departments are transparent on that point, admitting that they wanted to "allow for predictability" and "certainty" by "encourag[ing] plans, issuers, providers, and facilities to make offers that are closer to the QPA" and to "avoid the Federal IDR process altogether." 86 Fed. Reg. at 56,061. But that is not what Congress enacted. A preordained IDR process is neither an independent process nor faithful to Congress's directive to consider multiple enumerated circumstances in making a decision. Indeed, it is a bureaucratic rubber stamp, not a meaningful dispute resolution process.

Second, IFR Part I compounds this error by purposefully depressing the QPA for air ambulance services in a manner contrary to the statutory text and wholly divorced from market realities. Under the statute, the QPA is supposed to be the median of the "contracted rates recognized by the plan" offering the "same or similar" service provided by a provider in the "same or similar specialty" and "geographic region." Public Health Service Act (PHSA) § 2799A-1(a)(3)(E)(i)(I).[4] IFR Part I twists this language by excluding myriad contracted rates between air ambulance providers and plans or issuers, including rates from the most common type of contract between air ambulance providers and plans or issuers: the single case agreement. Inexplicably, it excludes rates from single case agreements from QPA calculations for air ambulance services while including

[3] For ease, we cite to the regulations as codified in title 45 of the Code of Federal Regulations. The regulations as codified in title 26 and title 29 of the Code of Federal Regulations are the same in all material respects.

[4] For ease, we cite to the provisions amending the Public Health Service Act only, by citing to the PHSA itself. The provisions enacted into ERISA and the Internal Revenue Code are the same in all material respects.

those same rates in QPA calculations for other services. IFR Part I also irrationally lumps independent air ambulance providers and hospitals that provide air ambulance services into a single specialty, while taking the exact opposite approach with freestanding and hospital-based emergency facilities. Finally, IFR Part I requires plans and issuers to use overbroad geographic boundaries that allow rates from one location to drive payments in other locations that are states or even oceans away.

The Departments' approach flouts the statutory text and cannot be squared with Congress's carefully designed regime. The Departments concede as much, explaining that they purposefully adopted standards designed to deflate the QPA for air ambulance services because of concerns about patient cost-sharing (86 Fed. Reg. at 36,891), a concern that Congress deemed irrelevant to calculating the QPA for air ambulance services.

In sum, the Departments that Congress entrusted to implement the NSA have flipped the statutory text on its head. They have made the independent dispute resolution process into a rubber stamp for an administratively deflated QPA, all in service of policies that Congress already considered and rejected in the NSA itself. The IFRs warp Congress's balanced and equitable design into an indefensibly one-sided scheme that unfairly disfavors air ambulance providers. Worse yet, the IFRs put the viability of their critical services—the very thing Congress sought to preserve—at risk. The IFRs are in excess of statutory limits, arbitrary, capricious, and contrary to law. Summary judgment should be entered and the challenged portions of the IFRs set aside.

BACKGROUND

A. AAMS and the air ambulance industry

The Association of Air Medical Services (AAMS) is the international trade association that represents over 93% of air ambulance providers in the United States, which collectively operate over 1,000 helicopter and 200 fixed-wing air ambulances. Eastlee Decl. ¶ 2.

Air medical services are often the only lifeline that critically ill and injured patients have to definitive care, especially in rural areas. Traumas, stroke, heart attacks, burns, and high-risk neonatal or pediatric cases account for 90% of all helicopter transports. Eastlee Decl. Ex. 1 at 2. Without helicopter air ambulances, more than 85 million Americans would not be able to reach a Level 1 or 2 trauma center within an hour when these emergent circumstances arise. *See id.* And the faster a person who suffers a trauma or other medical emergency reaches a hospital, the better the overall outcome. *See* Hannah Pham et al., *Faster On-Scene Times Associated with Decreased Mortality in Helicopter Emergency Medical Services (HEMS) Transported Trauma Patients*, 2 Trauma Surgery & Acute Care Open 1, 4 (2017). Air ambulance providers thus fill a critical gap in America's emergency medical system.

Air ambulance providers have one goal: efficiently deliver the highest quality of transport safety and patient care. Eastlee Decl. Ex. 1 at 2. They are on call 24 hours a day, seven days a week, and aim to respond within minutes. *Id.* Air ambulance providers do not determine whether or when a patient should be transported, nor are they aware of a patient's ability to pay or health insurance status at the time of transport. *Id.*; *see also* Foster Decl. (Dkt. 1-5) ¶ 9; Preissler Decl. (Dkt. 1-6) ¶ 9; Portugal Decl. (Dkt. 1-7) ¶ 9; Sannerud Decl. ¶ 9. Instead, first responders or treating physicians decide whether and when a patient needs to be transported, and air ambulance providers do not question that decision. Eastlee Decl. Ex. 1 at 2. Indeed, in many states, providers have a duty to respond as a condition of licensure. *Id.* Air ambulance providers determine only whether aviation conditions are safe to fly the patient. *Id*.

Numerous federal and state regulations govern air ambulance operations. Providers typically must maintain an air carrier certificate from the Federal Aviation Administration to conduct on-demand operations, maintain a state-issued ambulance license, and satisfy the rules for participation in Medicare, Medicaid, and other federal healthcare programs. Eastlee Decl. Ex. 1 at 2. Not surprisingly, the delivery of on-demand, life-saving air ambulance services in this heavily

regulated space is inherently and unavoidably costly. To successfully operate, air ambulance providers must make substantial investments in specialized aircraft, air bases, technology, personnel (often with certifications), and regulatory compliance systems. *Id.* at 2; *see also* Foster Decl. ¶ 6; Preissler Decl. ¶ 6; Portugal Decl. ¶ 6; Sannerud Decl. ¶ 6. And to maintain a 24-hour on-demand service from an air base, an air ambulance provider commonly staffs 4 pilots, 4 nurses, 4 paramedics, and 1 mechanic at the base. These fixed costs make up the bulk of a provider's costs. Variable costs—like fuel and consumed medical supplies—constitute a relatively small portion of the provider's costs. Xcenda, *Air Medical Services Cost Study Report* 9-10 (Mar. 24, 2017), perma.cc/H4M3-W93D.

Although an air ambulance provider's costs are mostly fixed, the volume of transports varies greatly. Eastlee Decl. Ex. 1 at 3; *see also* Foster Decl. ¶ 9; Preissler Decl. ¶ 9; Portugal Decl. ¶ 9; Sannerud Decl. ¶ 9. Emergent transports are unpredictable and vary across both geography and time for reasons outside the provider's control. Eastlee Decl. Ex. 1 at 3. For instance, rural areas may only need an air ambulance on an infrequent basis, but, when the need arises, it is most often critical. *Id.*

To maintain their ongoing operations, air ambulance providers must be able to cover their costs. But air ambulance providers cannot earn sufficient revenue to cover their costs of operation from uninsured patients or patients insured by government healthcare programs like Medicare and Medicaid. Foster Decl. ¶ 7; Preissler Decl. ¶ 7; Portugal Decl. ¶ 7; Sannerud Decl. ¶ 7; Xcenda, *supra*, at 15. As such, air ambulance providers depend on reasonable payments from group health plans and issuers, whether through in-network agreements or other negotiated payment arrangements. *Id.*

Group health plans and issuers often decline to contract with independent air ambulance providers due to structural features of air ambulance operations. For example, because of the emergent nature of transports, plans and issuers cannot steer patients toward particular air ambulance

providers in exchange for discounted rates like they can for scheduled medical services. *Accord* Eastlee Decl. Ex. 1 at 3; *see also* Foster Decl. ¶ 5; Preissler Decl. ¶ 5; Portugal Decl. ¶ 5; Sannerud Decl. ¶ 5. Additionally, because the volume of transports in some areas can be low, plans and issuers have little incentive to prioritize contracting with air ambulance providers. *See* Eastlee Decl. Ex. 1 at 3.

The different types of air ambulance provider models also affect network contracting with plans and issuers. Most air ambulances are operated by independent providers, authorized by federal and state governments. Eastlee Decl. Ex. 1 at 2. Some air ambulances are, however, operated by a hospital or community organization, or split between two entities. *Id.* Entities that bill through a hospital can be contracted as part of the hospital's network agreement with a plan or issuer for a larger portfolio of services. Eastlee Decl. Ex. 1 at 4; Ex. 4 at 3. Air ambulance transport rates in hospital contracts are likely to be far lower than the true cost of providing air ambulance services because the rate is just one line item in a much larger agreement, not heavily negotiated, and represents only a small volume of services. *Id.* By contrast, independent air ambulance providers do not offer other services, and any agreement they reach must alone cover the costs of providing air ambulance services. *Id.*

The disincentives for plans and issuers to contract with air ambulance providers has historically placed patients and air ambulance providers in an impossible situation. Patients need emergency air ambulance transportation, and air ambulance providers have a duty to provide it as safely and efficiently as possible without regard to the patient's ability to pay.

With air ambulance providers out-of-network, patients could be responsible for paying out-of-pocket substantial portions of the bills for critical air ambulance services. If the plan or issuer refused to pay a reasonable out-of-network rate and the patient could not afford the balance, the burden of covering the cost would fall on the air ambulance provider, jeopardizing its ability to recoup sufficient revenue to cover its costs and deliver services.

B. The No Surprises Act

To address this problem, Congress enacted the NSA, which the President signed into law on December 27, 2020. *See* Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 tit. I, div. BB. As its title suggests, the NSA aims to stop surprise billing and remove patients from the middle of payment disputes between plans or issuers and nonparticipating providers (meaning providers that do not have a network agreement or other contract with the plan or issuer for the services), while ensuring that critical services remain available to the public. Prior to the Act, group health plans or issuers could make a below-cost payment for the air ambulance services to the patient and then instruct the provider to bill the patient. That practice put the patient in the position of conducting a three-way arbitration of the payment amount, which was untenable.

The Act generally requires plans and issuers to apply the same cost-sharing levels to participating and certain nonparticipating services, prevents the nonparticipating providers from balance-billing patients, and provides an IDR resolution process for plans and issuers and nonparticipating providers to reach a fair payment amount. The NSA strikes a thoughtful and equitable balance among all interested parties—it relieves individual patients from bearing disproportionate costs for nonparticipating services, while ensuring that plans and issuers pay and nonparticipating providers receive reasonable amounts.

Given the unique nature of air ambulance services, Congress addressed them separately in Section 105 of the Act. It includes the same provisions three times over—by amending the Public Health Service Act, the Employee Retirement Income Security Act (ERISA) of 1974, and the Internal Revenue Code—so that it protects individuals enrolled in group health plans and individual insurance plans, among others.

The Act includes two key protections for patients with respect to "nonparticipating" air ambulance services, *i.e.*, those providers that do not have a network agreement or other contract with the insurer to provide the services. *First*, it treats patient cost-sharing as if the patient had

received the care from a participating provider. It provides that when a patient "receives air ambulance services from a nonparticipating provider" and the "services would be covered if provided by a participating provider," the individual's cost-sharing amount "shall be based on rates applicable to a participating provider" and "shall be counted towards the in-network deductible and in-network out-of-pocket maximum." PHSA § 2799A-2(a). *Second*, the nonparticipating provider cannot bill the individual for more than the cost-sharing amount. *See* PHSA § 2799B-5. This prohibition on "balance billing" reflects a policy judgment by Congress to distribute the costs of air ambulance services among plans and issuers, rather than individual patients.

To make these important patient protections sustainable for providers, Congress also designed a comprehensive scheme to obligate plans and issuers to fairly compensate nonparticipating air ambulance providers for these services to their patients. A plan or issuer must pay a nonparticipating provider an amount "equal to the . . . [determined] out-of-network rate" less the patient cost-sharing amount. *See* PHSA § 2799A-2(a)(3). The NSA sets up a two-stage process for resolving disputes about the appropriate out-of-network rate. The parties first engage in open negotiations and, if negotiations fail, they enter the IDR process to have a neutral party independently determine the amount payable. *See id.* § 2799A-2(b)(1)(A)-(B).

To incentivize plans and issuers and providers to reach an agreement, Congress based the IDR process on final-offer or baseball-style arbitration. This type of dispute resolution "is designed to not only persuade parties to settle their disputes to avoid unpredictable and uncompromising hearings, but also to submit reasonable proposals before the hearing." Matt Mullarkey, Note, *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). Each party must submit to the certified IDR entity a final payment offer, along with any information requested by the IDR entity and any other information the party wants to submit. PHSA § 2799A-2(b)(5)(B). The IDR entity must then

"select one of the offers submitted" by the parties (*Id.* § 2799A-2(b)(5)(A)) with the losing party bearing the costs of the process (*id.* § 2799A-2(b)(5)(E) (incorporating § 2799A-1(c)(5)(F)).

The NSA details the circumstances the IDR entity shall consider in determining the payment amount. *See* PHSA § 2799A-2(b)(5)(C). Notably, it provides that the IDR entity "*shall consider*" "the qualifying payment amounts" (QPA) for the applicable year for "comparable" services "in the same geographic region," any information requested by the IDR entity, *and* "*any* information submitted by either party," including "information on any [additional] circumstance" listed in the statute. *See id.* § 2799A-2(b)(5)(C)(i)(I), (II) (emphasis added). The Act then lists additional circumstances that the IDR entity "shall consider":

> (I) The quality and outcomes measurements of the provider that furnished such services.
>
> (II) The acuity of the individual receiving such services or the complexity of furnishing such services to such individual.
>
> (III) The training, experience, and quality of the medical personnel that furnished such services.
>
> (IV) Ambulance vehicle type, including the clinical capability level of such vehicle.
>
> (V) Population density of the pick up location (such as urban, suburban, rural, or frontier).
>
> (VI) 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 and the plan or issuer, as applicable, during the previous 4 plan years.

Id. § 2799A-2(b)(5)(C)(ii).

The QPA is defined by the statute. PHSA § 2799A-2(c)(2) (incorporating PHSA § 2799A-1(a)(3)). It is the "median of the contracted rates recognized by the plan or issuer" "for the same or a similar item or service . . . by a provider in the same or similar specialty" as of January 31, 2019, that are offered in the same insurance market (i.e., the individual market, large group market,

small group market, or self-insured group health plan market) and in the same geographic region, increased by the consumer price index. *Id.* § 2799A-1(a)(3)(E)(i).

The Act does not weight or deem any circumstance presumptively dispositive or reasonable. Instead, the IDR entity must consider them all. This was purposeful. Congress considered and rejected a proposal that would have mandated that payment be "the recognized amount," *i.e.*, an amount set by state law or the median contracted rate. *See* Ban Surprise Billing Act, H.R. 5800, 116th Cong. § 2(a) (2020) (proposing new PHSA § 2719A(f)). Instead, under the NSA, after considering the QPA, any information submitted by the parties, the additional circumstances, and any requested information, the IDR entity then selects one of the party's offers.

To ensure the timely implementation of the Act, Congress directed the Secretaries of Health and Human Services, of the Treasury, and of Labor to engage in rulemaking by specified statutory deadlines. By July 1, 2021, the Secretaries were to "establish through rulemaking" the "methodology" to "use to determine the qualifying payment amount"; the "information" the plan or issuer must "share with the nonparticipating provider . . . when making such a determination"; the "geographic regions . . . taking into account access to items and services in rural and underserved areas, including health professional shortage areas"; and "a process to receive complaints of violations." PHSA § 2799A-1(a)(2)(B). And within one year of enactment, *i.e.*, by December 27, 2021, the Secretaries were to "establish by regulation one independent dispute resolution process" under which "a certified IDR entity . . . determines . . . the amount of the payment" for qualified air ambulance services. *Id.* § 2799A-2(b)(2)(A).

C. The Interim Final Rules

The Departments issued two IFRs before notice and comment. But the voluminous IFRs are "interim" in name only. They create rights and impose obligations on plans and issuers and air ambulance providers. They are designed to operate indefinitely by enacting calculations that adjust with the consumer price index (86 Fed. Reg. at 36,894) and fee structures that the Departments

will "review and update . . . annually" (*id.* at 56,005). And though the Departments invited comments on some aspects of the IFRs, they have no legal obligation to review and consider comments, much less issue final, superseding rules. The IFRs have already taken effect and are applicable to insurance plan and policy years beginning on or after January 1, 2022. *Id.* at 36,872, 55,980.

1. IFR Part II: IDR process

The Departments issued the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) to govern the IDR process. Though it purports to implement the IDR process that Congress envisioned, IFR Part II instead defeats the purpose of the statutory IDR process by giving the flawed QPA nearly conclusive weight.

Specifically, IFR Part II commands that "[t]he certified IDR entity *must* select the offer closest to the [QPA]" unless either: "[1] the certified IDR entity determines that credible information submitted by either party [as required or permitted by IFR Part II] *clearly demonstrates* that the [QPA] is materially different from the appropriate out-of-network rate, or [2] the offers are equally distant from the [QPA] but in opposing directions." 45 C.F.R. § 149.510(c)(4)(ii)(A) (emphasis added). "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.*

IFR Part II requires the submission of some information, including "[i]nformation requested by the certified IDR entity relating to the offer," "information on the size of the provider's practice," "information on the practice specialty," "information on the coverage area of the plan, the relevant geographic region for purposes of the [QPA], whether the coverage is fully-insured or partially or fully self-insured," and "[t]he [QPA]." 45 C.F.R. § 149.510(c)(4)(i)(A)(*3*), *id.* § 149.520(b)(1) (applying most of the provisions of 45 C.F.R. § 149.510 to the air ambulance services IDR process).

IFR Part II then relegates to afterthoughts the remaining factors Congress required the IDR entity to consider. It strictly limits a party to submitting additional information provided it "relates to" the additional "circumstances" that the statute enumerates and requires the IDR entity to consider. *See* 45 C.F.R. § 149.520(b)(2); *compare* PHSA § 2799A-2(b)(5)(C)(ii). It necessarily does not permit the submission of any *other* information a party may want to submit (45 C.F.R. § 149.520(b)(2)), despite the statute's provision that a party "may submit *any* information relating to [its] offer . . . , including information" relating to the additional circumstances (PHSA § 2799A-2(b)(5)(B)(ii)). And IFR Part II limits consideration even of these additional circumstances only for purposes of rebutting the IFR-created presumption of choosing the offer closest to the QPA and only provided the information satisfies a heightened credibility standard. 45 C.F.R. § 149.520(b)(2). That is, to be "credible," the information must be "information that upon *critical analysis* is worthy of belief and is trustworthy." 45 C.F.R. § 149.510(a)(2)(v) (emphasis added). This heightened credibility standard, suggesting a strong dose of skepticism, contrasts with IFR Part II's directive that "it is not the role of the certified IDR entity to determine whether the QPA has been calculated by the plan or issuer correctly." 86 Fed. Reg. at 55,996.

2. IFR Part I: Qualifying payment amount methodology

The Departments issued the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021), to, among other things, address the QPA calculation. *See* PHSA § 2799A-1(a)(2)(B).

Though the Departments suggest in the preamble that the "statutory intent" of the Act was to "ensur[e] that the QPA reflects market rates under typical contract negotiations" (86 Fed. Reg. at 36,889), IFR Part I instead establishes a methodology that purposefully deflates those rates for air ambulance providers. As noted above, the Act defines the QPA as the "median of the [1] contracted rates recognized by the plan or issuer" "[2] for the same or a similar item or service . . . [3] by a provider in the same or similar specialty" that are [4] offered in the same geographic region

and insurance market, increased by the consumer price index. PHSA § 2799A-1(a)(3)(E)(i). IFR Part I distorts those elements in three ways, depressing the QPA at nearly every turn.

First, IFR Part I limits the pool of "contracted rates recognized by the plan or issuer" that are used to calculate the median rate for QPA purposes. *See* PHSA § 2799A-1(a)(3)(E)(i). IFR Part I defines a "contracted rate" as the "total amount . . . that a group health plan has contractually agreed to pay a . . . provider of air ambulance services for covered items and services." 45 C.F.R. § 149.140(a)(1). But it then excludes large swaths of agreements reached between air ambulance providers and plans and issuers, providing that "[s]olely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a[n] . . . air ambulance provider and a plan . . . does not constitute a contract." *Id.*

Second, IFR Part I considers all air ambulance providers to be a single provider specialty. Though it defines a "provider in the same or similar specialty" generally as "the practice specialty of a provider, as identified by the plan consistent with the plan's usual business practice," it completely excepts air ambulance services from this definition. 45 C.F.R. § 149.140(a)(12). Instead, "with respect to air ambulance services, *all* providers of air ambulance services are considered to be a single provider specialty." *Id.* (emphasis added). The Departments made this exception, even while specifically requiring that contracted rates for hospital emergency departments and free-standing emergency departments be calculated separately. 86 Fed. Reg. at 36,892. The Departments offered no justification for treating air ambulances differently from other types of providers in this way.

Third, IFR Part I defines a "geographic region" "[f]or air ambulance services" as "one region consisting of all metropolitan statistical areas . . . in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up." 45 C.F.R. § 149.140(a)(7)(ii)(A). When a plan or issuer does not have "sufficient information" to calculate

the median contracted rate, the geographic region becomes "one region consisting of all metropolitan statistical areas . . . in each Census division and one region consisting of all other portions of the Census division." *Id.* § 149.140(a)(7)(ii)(B). There are only nine Census divisions in the country, determined by geographical contiguity. *See Census Regions and Divisions of the United States*, Census.gov (last visited Nov. 22, 2021), https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf. For example, the South Atlantic division spans from Florida to West Virginia, and Hawaii and Alaska join the West Coast states in the Pacific Division. This broad definition of "geographic region" creates only two categories of pick-up location density, sometimes lumping together vastly different parts of the country, even though the Act explicitly contemplates at least four gradations of pick-up location density—"such as urban, suburban, rural, or frontier"—as an additional circumstance the IDR entity must consider. PHSA § 2799A-2(b)(5)(C)(ii)(IV).

The plan or issuer then must calculate the "median contracted rate" by "arranging in order from least to greatest the contracted rates . . . in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty . . . in the geographic region in which the item or service is furnished and selecting the middle number." 45 C.F.R. § 149.140(b)(1). The QPA equals the median contracted rate increased consistent with the consumer price index and multiplied by the number of "loaded miles," i.e., the number of miles the individual is transported. *Id.* § 149.140(c)(1)(v).

ARGUMENT

The Administrative Procedure Act (APA) authorizes courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (2)(C). "[W]hen review is based upon the administrative record . . . [s]ummary judgment is an appropriate procedure for resolving a challenge to a federal agency's

administrative decision." *PayPal, Inc. v. Consumer Fin. Prot. Bureau*, 512 F. Supp. 3d 1, 6 (D.D.C. 2020) (first and third alterations in original) (quoting *Bloch v. Powell*, 227 F. Supp. 2d 25, 31 (D.D.C. 2002)). "In such cases, the district court 'sits as an appellate tribunal' and 'the entire case . . . is a question of law.'" *Id.* (omission in original) (quoting *Am. Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)); *see also Policy & Research, LLC v. United States Dep't of Health & Hum. Servs.*, 313 F. Supp. 3d 62, 74 (D.D.C. 2018) (similar).[5]

The IFRs are in excess of statutory authorization, contrary to law, and arbitrary and capricious, and the challenged portions should be set aside.

I. IFR PART II'S WEIGHTING OF THE QPA IS INCONSISTENT WITH THE STATUTORY TEXT (COUNT I)

Congress specifically addressed whether the QPA should bear special weight in the IDR process. Congress decided it should *not*. IFR Part II's attempt to override this legislative choice contradicts the statutory text and thus exceeds the Departments' statutory authority.

Courts review an agency interpretation of a statute under the familiar *Chevron* two-step framework. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984); *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016). The Departments present their QPA presumption as the "best interpretation" of the statute. *See* 86 Fed. Reg. at 55,996.[6] But that is belied by the statute's text.

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[5] Relief on AAMS's claims does not turn on the administrative record. The statutory text, regulatory text, and preambles to the IFRs establish that the challenged provisions must be set aside. Insofar as the Departments rely on the administrative record, AAMS reserves the right to address their arguments based on the administrative record.

[6] There is a "threshold inquiry—sometimes called Chevron 'step zero,'" which asks "whether Congress has delegated interpretive authority to the agency in question." *Prime Time Int'l Co. v. Vilsack*, 930 F. Supp. 2d 240, 248 (D.D.C. 2013), *aff'd sub nom. Prime Time Int'l Co. v. U.S. Dep't of Agric.*, 753 F.3d 1339 (D.C. Cir. 2014). Through the NSA, Congress delegated expressly authority to "establish by regulation one independent dispute resolution *process*" under which "a certified IDR entity . . . determines, subject to subparagraph (B) and the succeeding provisions of this subsection, the amount of the payment under the plan or coverage" for qualified air ambulance

A. At *Chevron* step one, the Court must first determine "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842-843. "If 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." *Id.* To assess whether Congress has spoken directly, "the court begins with the text, and employs 'traditional tools of statutory construction'" (*Prime Time Int'l Co. v. Vilsack*, 599 F.3d 647, 683 (D.C. Cir. 2016)—including the "statute's text, legislative history, and structure[,] as well as its purpose" (*Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) (citation omitted)). All of these tools point only one way: the statute unambiguously precludes the special weighting of the QPA in IFR Part II.

The NSA provides that the IDR entity shall, "taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such services determined under this subsection for purposes of subsection (a)(3)." PHSA § 2799A-2(b)(5)(A). The "considerations specified in subparagraph (C)" that the IDR entity "*shall consider*" are numerous—the QPA, any information requested by the IDR entity, and any information provided by a party, including information on the provider's quality and outcomes measurements, the medical personnel's level of training, experience, and quality, the acuity of the individual and complexity of service, ambulance vehicle type, population density of the pick-up location, and each party's demonstration of good faith efforts to reach a contracted rate (*id.* § 2799A-2(b)(5)(C) (emphasis added))—with only three narrow exceptions (*id.* § 2799A-

services. PHSA § 2799A-2(b)(2)(A) (emphasis added). Congress's express delegation of authority to set up a single *process* implies a lack of authority to regulate concerning the substance of the decision-making. The Departments admit as much in characterizing their QPA presumption as an "interpretation" of the statute, not as a gap Congress left them to fill. 86 Fed. Reg. at 55,996.

2(b)(5)(C)(iii)).[7] The statute treats each of these factors equally, with no weight placed on any particular one. The IDR entity considers them all and selects an offer.

IFR Part II, by contrast, announces that the certified IDR entity "*must* select the offer closest to the qualifying payment amount." It leaves only two narrow exceptions to this rule: If "[1] the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate, or if [2] the offers are equally distant from the [QPA] but in opposing directions." 45 C.F.R. § 149.510(c)(4)(ii)(A) (emphasis added). In those narrow circumstances, the 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." *Id.*

IFR Part II also sharply limits the information the IDR entity may consider. While the statute says that a party may submit "any information" it wants for consideration (PHSA § 2799A-2(b)(5)(B)(ii)), with two narrow exceptions (*id.* § 2799A-2(b)(5)(B)(iii)), IFR Part II goes in the opposite direction and limits the information the IDR entity may consider to the list of "circumstances described in paragraphs (b)(2)(i) through (vi)" of the regulation and, again, only if that information is "credible" and "clearly demonstrate[s] that the [QPA] is materially different from the appropriate out-of-network rate." *See* 45 C.F.R. § 149.520(b)(2) (listing the additional circumstances applicable to air ambulance providers). Rather than broad permissive submission of information for totality-of-the-circumstances consideration, IFR Part II puts blinders onto the IDR entity after tying its hands through a mandate to select the offer closest to the QPA.

All of this twists Congress's design inside-out. The NSA prescribes *independent* dispute resolution and mandates that the IDR entity "*shall consider*" all the information submitted, and

[7] The NSA provides that the IDR entity should not consider the provider's usual and customary charges, the amount that the provider would have billed the patient absent the ban on balance billing, or the reimbursement rate that would be paid under governmental health programs.

the factors enumerated in the statute (save three narrow data points), and then select one of the offers. IFR Part II writes the independence out of the process laid out in the statute. No longer does the IDR entity determine *independently* a reasonable payment amount based on circumstances prescribed by Congress nor can it even consider all the information that Congress intended. Instead, the IDR entity is forced to choose the QPA in all but the most exceptional of cases.[8]

The EPA made similar missteps in *American Corn Growers Ass'n v. EPA*, 291 F.3d 1 (D.C. Cir. 2002). The statute there directed states to take five factors into consideration when deciding what "best available retrofit technology" controls to place on a pollutant causing a Class I visibility impairment. *Id.* at 5. By regulation, EPA required one of the statutory factors to be considered on a "group or 'area-wide' basis" while all the others were considered only on a "source-specific basis." *Id.* at 6. The D.C. Circuit vacated the rule as inconsistent with the statutory text and structure in two relevant ways. *Id.* First, "[a]lthough no weights were assigned, the factors were meant to be considered together by the states. . . . To treat one of the five statutory factors in such a dramatically different fashion distorts the judgment Congress directed the states to make." *Id.* Second, EPA's dictation of how to consider certain factors "unlawfully constrains the states' statutory

[8] Congress's choice not to give special weight to the QPA was a deliberate legislative compromise. As the Chairman and Ranking Member of the House Ways and Means Committee have explained, Congress considered multiple proposals, including proposals in which the median in-network rate would be the benchmark for payment, with IDR serving as a mechanism for adjusting the benchmark. October 4 Ltr. (Dkt. 1-1). *See, e.g.*, Ban Surprise Billing Act, H.R. 5800, 116th Cong. § 2(a) (2020). Congress rejected that approach and instead chose one that "directs the arbiter to consider all of the factors without giving preference or priority to any one factor." *Id.* This choice was "the express result of substantial negotiation and deliberation among those Committees of jurisdiction, and reflects Congress's intent to design an IDR process that does not become a de facto benchmark." *Id.* More than 150 members of Congress expressed the same sentiment: that "[t]he process laid out in the law expressly directs the certified IDR entity to consider each of these listed factors should they be submitted, capturing the unique circumstance of each billing dispute without causing any single piece of information to be the default one considered." Nov. 5 Letter (Dkt. 1-2).

authority because under the Act it is the states—not EPA" that must make the relevant determinations. *Id.* at 7.

Each is instructive here. The NSA gives no weight to the circumstances the IDR entity should consider, and it gives complete discretion to the IDR entity who must have "sufficient medical, legal, and other expertise" (PHSA § 2799A-1(c)(4)) to make the payment determination. By "treat[ing] one of the [] statutory factors in such a dramatically different fashion" and "constrain[ing] the [IDR entity's] statutory authority," the QPA presumption contravenes the NSA's text. *Am. Corn Growers Ass'n*, 291 F.3d at 6-7.

The conflict between the statute and IFR Part II is further made clear when "consider[ing] the provisions at issue in context." *Am. Fed'n of Lab. & Cong. of Indus. Orgs. v. Fed. Election Comm'n,* 333 F.3d 168, 172 (D.C. Cir. 2003). The QPA is just one factor among many that Congress weaved into an "independent dispute resolution" process. A predetermined outcome is irreconcilable with a system modeled on final-offer or baseball-style dispute resolution that Congress directed would be "independent."

Final-offer dispute resolution uses a streamlined all-or-nothing approach designed to encourage parties to settle their disputes and to submit reasonable offers. Mullarkey, *supra*, at 246. It necessarily assumes (as Congress did) that there is an unknown amount that reasonably reflects a fair value—because, were the reasonable amount known, there would be no dispute. With the reasonable amount unknown, each party must then make an offer and submit information to persuade the arbiter that its offer is the closest to the reasonable amount. Each dollar that a claimant adds to its offer or that a respondent deducts from its offer decreases its chances of winning by placing it further from the unknown reasonable amount. *Id.*

Congress's design thus encourages plans and issuers and air ambulance providers to resolve their payment disputes through negotiations to avoid having to risk it all in an IDR determination with little guidance as to what a particular IDR entity would view as the reasonable payment

amount. And, to the extent the parties cannot reach an agreement through negotiation, final-offer dispute resolution creates strong incentives for both sides to put forth their most reasonable offer to encourage the certified IDR entity to select theirs as the most reasonable. The need to make a reasonable offer is reinforced by the statute's mandate that the losing party must bear the costs of the IDR process. Final-offer dispute resolution is thus meant to efficiently adjudicate a dispute where the right answer is *un*certain and the clear outcome *un*predictable. There is no point to engaging in such a process where an outcome is foreordained.

The Departments, however, concluded that "emphasizing the QPA will allow for predictability." 86 Fed. Reg. at 56,061. In their view, "[t]his certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor" and "may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period." *Id.* Thus, the express purpose of IFR Part II is to short-circuit the final-offer dispute resolution process that Congress did enact and to render it effectively meaningless. An insurer has zero incentive to negotiate a fair and reasonable payment amount with an air ambulance provider when it knows that its administratively deflated QPA amount will inevitably be the outcome. An agency rule with an express goal that is the opposite of "the unambiguously expressed intent of Congress" (*Chevron*, 467 U.S. at 843) is in excess of statutory limits. Congress created an independent dispute resolution process because it wanted an *independent* dispute resolution process, not one in which outcomes are predetermined. IFR Part II's mandates otherwise conflict with the statutory text and must be set aside.

B. The statutory text is unambiguous, and the Court need not proceed past *Chevron* step one to dispose of IFR Part II. Even if the Court disagrees and proceeds to *Chevron* step two, the Departments' choice—to give the QPA presumptively dispositive weight—is not a reasonable one and falls outside the range of permissible rules the Department could have adopted.

Under step two of *Chevron*, the Court "evaluates the same data" as "under *Chevron* step one, but using different criteria." *Bell Atl. Tel. Cos.*, 131 F.3d at 1049. "[U]nder step two [the court] consider[s] text, history, and purpose to determine whether these *permit* the interpretation chosen by the agency." *Id.* Courts must reject an agency's choice among conflicting policies where "it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned." *Chevron*, 467 U.S. at 845 (quoting *United States v. Shimer*, 367 U.S. 374 (1961)). For the reasons we have already described, the Departments' decision to place presumptively dispositive weight on the QPA is inconsistent with the statutory text and with the Act's legislative history, structure, and purpose. It could not be clearer that the Departments' chosen policy is "not one that Congress would have sanctioned" (*id.*) because Congress considered and rejected it.

By strictly curtailing the IDR entity's ability to independently select the amount of payment, IFR Part II contravenes the statutory text and design. Congress rejected the approach that the Departments have taken. Their construction of the statute in IFR Part II is, accordingly, an unreasonable one and should be set aside.

II. IFR PART I'S INTENTIONAL DEFLATION OF THE QPA IS ARBITRARY, CAPRICIOUS, AND CONTRARY TO LAW (COUNT II)

While IFR Part II makes the QPA presumptively dispositive in dispute resolution, IFR Part I aggravates the error by intentionally depressing the QPA for air ambulance services in a manner contrary to the statutory text to further policies wholly divorced from market realities which Congress did not adopt. Under the statute, the QPA is supposed to be the median of the "contracted rates recognized by the plan" offering the "same or similar" service provided by a provider in the "same or similar specialty" and "geographic region." PHSA § 2799A-1(a)(3)(E)(i)(I). IFR Part I distorts this language in three ways: (1) it excludes most types of contracted rates between air ambulance providers and plans or issuers; (2) it treats hospital and independent air ambulance

services as providers in the "same or similar specialty"; and (3) it uses overbroad geographic regions that generate QPAs wholly divorced from real-world pricing in reasonable geographic markets. The result is a QPA that is, by the Departments' own admission, administratively deflated for independent air ambulance service providers in pursuit of a policy—reducing patient cost-sharing beyond participating levels, at the expense of access to air ambulance services—that Congress rejected in the Act. *See* 86 Fed. Reg. at 36,891.

A. The Departments' QPA methodology for payment for nonparticipating air ambulance services is contrary to law, arbitrary, and capricious

Congress defined the QPA as the "median of the contracted rates recognized by the plan or issuer . . . as the total maximum payment . . . under such plans or coverage." PHSA § 2799A-1(a)(3)(E)(i)(I). The Departments are now implementing that definition through a QPA methodology that runs contrary to the statute in three critical ways. First, the QPA methodology categorically excludes certain "contracted rates recognized by the plan or issuer" from the calculation of the median when the statute itself contains no such exclusions. Second, the QPA methodology treats air ambulance services furnished by hospitals and independent air ambulance providers as comparable notwithstanding the statutory requirement that the providers have the same or similar specialty. Third, the QPA methodology pulls contracted rates from geographic areas that are so overbroad that they defeat the congressional design of the statute and lead to absurd results. Each of the flaws in IFR Part I is inconsistent with the statutory text and is the product of arbitrary and capricious decision-making.

1. The QPA methodology impermissibly excludes myriad contracted rates from the calculation of the median

a. The statutory starting point for calculating the QPA requires taking "the median of the contracted rates recognized by the plan or issuer" as of January 31, 2019 "for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided

in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary." PHSA § 2799A-1(a)(3)(E)(i)(I).

Though the statute does not define "contracted rates," "the absence of a statutory definition does not render a word ambiguous." *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012) (quoting *Natural Res. Def. Council v. EPA*, 489 F.3d 1364, 1373 (D.C. Cir.2007)). Instead, "[i]n the absence of an express definition, [courts] must give a term its ordinary meaning." *Id.* (citing *FCC v. AT & T, Inc.*, 562 U.S. 397, 403 (2011)). A "contracted rate" is an amount paid or charged under a contract. Black's Law Dictionary (11th ed. 2019) (defining "contract" as "[a]n agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law," and "rate" as "[a]n amount paid or charged for a good or service").

The meaning of the statute is plain: if the plan or issuer recognizes a rate from an in-network contract as the total maximum payment under a plan or coverage, then the plan or issuer must include that rate in its calculation of the median. The same holds true for any amount paid or charged under any other type of contract, including any single case agreement, letter agreement, or similar contractual arrangement. If the plan or issuer recognizes the amount as the total maximum payment under a plan or coverage, then it counts, and the plan or issuer must include it in the calculation of the median. The phrase means what it says. It is not ambiguous.

The Departments acknowledged the capaciousness of the statutory phrase "contracted rate" by first defining it broadly as "mean[ing] the total amount (including cost sharing) that a group health plan or health insurance issuer has *contractually agreed to pay* a participating provider, facility participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager." 45 C.F.R. § 149.140(a)(1) (emphasis added). But they then excised whole categories of contracts that otherwise would have readily fit within their definition, providing that:

> Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, *does not constitute a contract.*

Id. (emphasis added).

The regulation is contrary to law because it carves out an additional, sweeping exclusion from the statutory term "contracted rate." That term is unambiguous, expansive, and limited only by the statutory requirement that the plan or issuer recognize the amount paid or charged as the total maximum payment under a plan or coverage. "Broad general language is not necessarily ambiguous when congressional objectives require broad terms." *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980). Congress could have further limited the contracted rates that a plan or issuer must include in calculating the QPA, but it did not. The Departments tacitly acknowledge that the term "contracted rate" encompasses single case agreements, letter agreements, or other contractual arrangements by the very fact they had to include an exception excising them. But the Departments cannot change the statutory text through rulemaking, especially when they bypass the notice-and-comment process through an interim final rule.

b. The Departments' choice in excluding vast swaths of contracted rates is also arbitrary and capricious.[9] Where an agency rule 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," it is arbitrary and capricious and must be set aside. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

[9] The magnitude of the exclusion is striking—AAMS members report that in 2019, somewhere around half of out-of-network claims were resolved through single case agreements that are excluded from the QPA calculation in IFR Part I. Eastlee Decl. Ex. 5 at 3.

In excising particular contracts, the Departments reasoned that discarding contracted rates from numerous species of contractual arrangements "most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." 86 Fed. Reg. at 36,889. Nowhere in the statute does Congress say that the QPA must reflect "market rates" as contained only in "typical" in-network contracts between air ambulance providers and plans and issuers. Congress's silence in that regard is unsurprising because the history of network contracting in the air ambulance industry has been anything but typical. As AAMS explained in its comment letters to the Departments, AAMS members have routinely sought in-network contracts with plans and issuers. Eastlee Decl. Ex. 4 at 2-3. But they have typically failed to secure such contracts because plans and issuers insist on volume discounts that are incompatible with the cost structure and operations of air ambulance providers. *Id.* The Departments acknowledged this historical phenomenon in the preamble to IFR Part I when they observed that only 25% of air ambulance transports in 2012 and 31% in 2017 were made under a traditional in-network contract. 86 Fed. Reg. at 36,923. Taking the Departments at their word—that Congress meant for the QPA to reflect market rates under "typical contract negotiations" in the air ambulance industry—then the only "rational connection between the facts found and the choice made" is to include in the QPA methodology the contracted rates from letter agreements, single case agreements, and other similar species of contracts that have always been ubiquitous in the air ambulance industry. *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156 (1962)). Indeed, one-off agreements are logically *more* indicative of the market rate for air ambulance services because they are in fact a rate negotiated for the specific service at arm's length, *unlike* rates contained in in-network agreements with hospitals.[10] The Departments' choice to exclude the types of contracts they

[10] The Departments compounded this error by completely and totally failing to consider and mitigate against distortions of the QPA caused by contracted rates with little or no claim volume. The

acknowledge are ubiquitous in the industry (86 Fed. Reg. at 36,923) "runs counter to the evidence before the agency" and is arbitrary and capricious. *Id.*

The arbitrariness of the regulation is further evidenced by the Departments' different treatment of single case agreements in other contexts. For example, the Departments defined the terms "participating emergency facility" and "participating health care facility" to include any facility with a contractual relationship with a plan or issuer through a single case agreement. *See* 45 C.F.R. § 149.30. If a single case agreement creates a contractual relationship that renders the contracting facility a participating emergency or health care facility, then the rates fixed through a single case agreement should similarly be treated as contracted ones that the plan or issuer must include in its calculation of the median contracted rate for the QPA. The Departments' inconsistent treatment of single case agreements is irrational.

The Departments' explanation for this differential treatment is that excluding single case agreements from the QPA "most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contact negotiations" but that "[i]n contrast" "it is reasonable that an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual's care to be delivered on an in-network basis, and therefore, that the balance billing protections should apply." 86 Fed. Reg. at 36,882 & n.48. Deeming the same arrangement a contractual relationship for one purpose but not another on the basis that an individual "expect[s]" it is a contract but the "market" does not is an irrational explanation for this differential treatment. These contracts are contracts when viewed from either

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Departments, for example, could have excluded rates that have zero or little claim volume or prioritized rates with higher claim volumes. The Departments apparently know *how* to do so (*see e.g.*, 45 C.F.R. § 149.140(a)(15)(ii)(B) (requiring contracted rates to account for 25 percent of the claims volume to be a first sufficient information year after 2022); they just chose *not* to do so for air ambulance providers despite knowing that in-network agreements can and do include rates that are paid infrequently or never paid at all.

perspective. They should be treated consistently. *Cf. Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996) (agency action arbitrary and capricious by treating take-or-pay payments and take-or-pay settlement payments differently). IFR Part I's exclusion of common contractual arrangements from the QPA calculation must be set aside.

2. The QPA methodology arbitrarily treats air ambulance services furnished by different specialties the same

Congress defined the QPA as the median of the plan's or issuer's contracted rates "for the same or similar item or service that is provided *by a provider in the same or similar specialty*." PHSA § 2799A-1(a)(3)(E)(i)(I) (emphasis added). In addition, Congress instructed IDR entities to consider only those QPAs for air ambulance services that are *comparable* to the air ambulance services disputed in IDR. PHSA § 2799A-2(b)(5)(C)(i)(I). And Congress acknowledged the variety of provider specialties in the air ambulance industry when enacting data-reporting requirements, specifically requiring claims data to identify "whether the provider of such services is part of a hospital-owned or sponsored program, municipality-sponsored program, hospital independent partnership (hybrid) program, independent program, or tribally operated program in Alaska." PHSA § 2799A-8(b)(1)(B).

The Departments have nevertheless ignored this reality and treated independent air ambulance providers and hospitals providing air ambulance services as a "single provider specialty" for purposes of the QPA calculation. 45 C.F.R. § 149.140(a)(12). Of course, the Departments actually knew when they issued IFR Part I that independent air ambulance providers and hospitals are different specialties and offer services that are *not* comparable. As AAMS explained in its comment letters to the Departments, some hospitals contract with plans and issuers to furnish a wide range of emergency and scheduled services in addition to air ambulance transports. Eastlee Decl. Ex. 4 at 3. They can negotiate a wide range of rates with plans and issuers, accepting rates that may be far lower than the costs of providing those services in exchange for higher rates for other

services. They can and do accept rates for air ambulance transports that are below market—and even below cost—in order to secure contracts that are economically rational across all service lines. In contrast, independent air ambulance providers offer one service: air ambulance transports.

The Departments recognized the distinction in the preamble to IFR Part I, when they observed that hospitals "sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers." 86 Fed. Reg. at 36,891. Yet the Departments still lumped the two specialties together, reasoning that "participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider," and "they should not be required to pay higher cost-sharing amounts (such as coinsurance or a deductible) solely because the air ambulance provider assigned to them has negotiated higher contracted rates in order to cover its higher costs, or because it has a different revenue model, than other types of air ambulance providers." *Id.* The Departments' policy of erasing cost-sharing differentials between air ambulance transports furnished by hospitals and independent providers was a policy Congress rejected in the statute. Congress understood that plans and issuers would calculate QPAs for different specialties and instructed IDR entities to account for it by considering only QPAs for comparable services.

The Departments' different treatment of hospital emergency departments and standalone emergency departments underscores the arbitrariness of their approach towards the air ambulance industry. "[W]here a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute." 86 Fed. Reg. at 36,892. The decision to treat hospital emergency departments and freestanding emergency departments as different specialties—while treating hospitals and independent air ambulance providers as a single specialty—"applies different standards to similarly

situated entities." *Anna Jaques Hosp. v. Sebelius*, 583 F.3d 1, 7 (D.C. Cir. 2009). The Departments offer no "reasoned explanation" for this differential treatment. The Departments' sole stated purpose is to intentionally deflate the QPA for air ambulance services to reduce patient cost-sharing below participating levels. But that premise is a "factor[] which Congress has not intended [the Departments] to consider" for the QPA methodology for air ambulance services (*State Farm*, 463 U.S. at 43) because Congress specifically did not tie patient cost-sharing to the QPA for air ambulance services, as we explain below.

The Departments' QPA methodology assumes that Congress got it wrong and the air ambulance industry is homogeneous. That is unsupportable. The Court should reject the treatment of hospitals and independent air ambulance providers as a single specialty because it is contrary to law and arbitrary under the Departments' own reasoning elsewhere in IFR Part I.

3. The QPA methodology uses overbroad geographic regions that defeat the structure of the statute and will produce absurd results

Congress directed the Departments to establish through rulemaking "the geographic regions applied for purposes of [the QPA], taking into account access to items and services in rural and underserved areas, including health professional shortage areas." PHSA § 2799A-1(a)(2)(B)(iii). The Departments have now issued a regulation that requires plans and issuers to determine the QPA using either the combined metropolitan statistical areas (MSAs) of a state, or the remainder of the same state, depending on where the air ambulance provider picks up the patient. 45 C.F.R § 149.140(a)(7)(ii)(A). If the plan or issuer has insufficient information to determine the QPA in that initial geographic region, then the plan or issuer must determine the QPA using all MSAs in the Census division or all other areas in the Census division. *Id.* § 149.140(a)(7)(ii)(B). The Departments embraced the broad geographic delineation of Census divisions ostensibly to minimize the possibility that the plan or issuer will have insufficient information and therefore resort to using a third-party database to determine the QPA. 86 Fed. Reg. at

36,892-36,893. That is, of course, a problem of the Departments' own making because they have excluded numerous contracted rates from the QPA calculation. *See supra* at 22-26.

Even on its own terms, it is an arbitrary geographic delineation with respect to air ambulance services. Census divisions are vast—there are only nine of them for the entire country. *See Census Regions and Divisions of the United States*, Census.gov (last visited Oct. 29, 2021), perma.cc/4QWX-7738; *see also* 86 Fed. Reg. at 36,893. The use of Census divisions reaches well beyond any reasonable construction of "geographic *region*" with respect to air ambulance services. For example, a contracted rate from Alaska or Hawaii could dictate the QPA in California; or a contracted rate in Florida could dictate the QPA in Washington, D.C. Congress never intended for geographically and economically unique markets to dictate payments in completely different markets that are thousands of miles and even oceans apart. That is clear because Congress authorized plans and issuers to determine the QPA using third-party claims databases where the plan or issuer lacks a sufficient number of contracted rates. Congress thus recognized that there must be limits to the size of the geographic region and provided a solution: using a third-party database.

The geographic regions chosen by the Departments are absurdly overbroad. They are far broader than an area any helicopter air ambulance base could cover, which is generally somewhere less than a 200-mile radius depending on the geography and population density of the area. *See also* Xcenda, *supra*, at 12 (average patient-loaded transports were 56 miles for Medicare air ambulance transports). They also defeat the structure of the statute, which says to use third-party databases rather than ballooning the relevant geographic region when there is an insufficient number of contracted rates. The oversized geographic regions would also produce irrational outcomes for air ambulance providers who will have to contend with contracted rates from distant states dictating payment in different markets. The Departments' unexplained failure "to consider [this] important aspect of the problem" (*State Farm*, 463 U.S. at 43) when setting exceedingly broad geographic regions warrants setting aside this provision of IFR Part I.

B. The Departments' policy of deflating the QPA to drive patient cost-sharing below participating levels is inconsistent with the statutory text and purpose

The Departments' primary justification for intentionally deflating the QPA for air ambulance providers is to ensure that individuals are not "required to pay higher cost-sharing amounts." 86 Fed. Reg. at 36,891. The NSA already limits cost-sharing for nonparticipating air ambulance services to participating levels, and the Department apparently seeks to reduce individual cost-sharing even further. While AAMS fully supports reducing individual cost-sharing to participating levels, the Departments' deflation of the QPA has the perverse effect of benefitting plans and issuers by reducing what they pay air ambulance providers and, by extension, reducing individual access to air ambulance and other critical services. These were not policies that Congress adopted in the NSA for air ambulance services, for good reason. The Departments' determination that they should deflate the QPA to reduce patient cost-sharing is contrary to the statute and threatens access to air ambulance services when the Departments also makes the deflated QPA the presumptive out-of-network rate payable to air ambulance providers.

In the NSA, Congress limited individual cost-sharing for nonparticipating air ambulance services by requiring the application of "the same requirement that would apply if such services were provided by . . . a participating provider," with any coinsurance or deductible "based on rates that would apply for such services if they were furnished by such a participating provider." PHSA § 2799A-2(a)(1). Congress then defined the plan's or issuer's "total plan or coverage payment" to the nonparticipating air ambulance provider as the "amount by which the out-of-network rate . . . for such services . . . exceeds the cost sharing amount." *Id.* § 2799A-2(a)(3)(B). The out-of-network rate for air ambulance services is not the QPA but, instead, the payment amount determined through open negotiation or through the IDR process. *Id.* § 2799A-1(a)(3)(K)(ii).

With respect to cost-sharing, Congress treated nonparticipating air ambulance services differently than other nonparticipating emergency services. The NSA ties individual cost-sharing for

other nonparticipating emergency services to the "recognized amount," which, absent a specified state law, *is* the QPA. PHSA § 2799A-1(a)(3)(H)(ii). For air ambulance services, however, the cost-sharing is "the same requirement that would apply if such services were provided by . . . a participating provider." PHSA § 2799A-2(a)(1). Congress knew how to mandate use of the QPA for cost-sharing, and it plainly chose a different methodology for air ambulance services.

In IFR Part I, the Departments have nevertheless mandated that the cost-sharing requirement "be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount . . . or the billed amount for the services."45 C.F.R. § 149.130(b)(2). The Departments suggest that the QPA is one potential methodology for ensuring that the individual's coinsurance or deductible is "based on rates that would apply for such services if they were furnished by such a participating provider." 86 Fed. Reg. at 36,884. And the Departments explain that they codified the QPA methodology because it furthers their view of "the statute's general intent to protect participants, beneficiaries, and enrollees from excessive bills, and to remove the individuals as much as possible from disputes between plans and issuers and providers of air ambulance services." *Id.*

The text of the NSA, however, is unambiguous: any co-insurance or deductible for air ambulance services is "based on rates that would apply for such services if they were furnished by such a participating provider." PHSA § 2799A-2(a)(1). A participating provider is merely one "who has a contractual relationship with the plan or issuer." *PHSA* § 2799A-1(a)(3)(G)(ii). The rates that "would apply" for participating air ambulance services are any which the provider charges under "a contractual relationship with the plan or issuer," with no exclusion of single case agreements, letter agreements, or similar contractual arrangements, all common methods for resolving payment. The Departments cannot ignore the statutory text and mandate through rulemaking what Congress considered for nonparticipating air ambulance services and ultimately passed

on. Their rationale for deflating the QPA is rooted in their directive to use the QPA for cost-sharing, which exceeds their statutory authority.

The Departments' efforts to further reduce individual cost-sharing by counter-textually tethering cost-sharing to the QPA cannot be squared with the NSA. The Departments' use of this flawed premise as a justification to intentionally deflate the QPA to further reduce patient cost-sharing underscores the arbitrary and capricious nature of their QPA methodology.

III. THE COURT SHOULD SET ASIDE THE UNLAWFUL PORTIONS OF THE IFRS

Because the portions of the IFRs that we have just described do not pass muster under the APA, the Court must set aside the challenged portions.

When reviewing agency actions under the APA, this Court "may set aside only the part of a rule found to be invalid." *Catholic Soc. Serv. v. Shalala*, 12 F.3d 1123, 1128 (D.C. Cir. 1994) (quotation marks omitted). That power comes from 5 U.S.C. § 706(2)(A), which provides that a "reviewing court shall hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Because the APA defines an "agency action" as "the whole *or a part of* an agency rule" (5 U.S.C. § 551(13) (emphasis added)), this definition "obliges reviewing courts to carefully limit their review" because "agency action" that is "not in accordance with law" (*id.* § 706(2)(A)) "can encompass only 'a part of an agency rule.'" *Catholic Soc. Serv.*, 12 F.3d at 1128 (quoting 5 U.S.C. § 551(13)). "It would, therefore, exceed the statutory scope of review [provided in the APA] for a court to set aside an entire rule where only a part is invalid, and where the remaining portion may sensibly be given independent life." *Id.*; *see also Nio v. U.S. Dep't of Homeland Sec.*, 385 F. Supp. 3d 44, 68 (D.D.C. 2019) (holding that the APA provided the court authority to vacate only the unlawful requirement of a guidance document rather than the entire guidance).

As a matter of practice, this Court routinely sets aside only the unlawful portions of agency actions. *See Sorenson Commc'ns. Inc. v. FCC*, 755 F.3d 702, 710 (D.C. Cir. 2014); *Conservation L. Found. v. Pritzker*, 37 F. Supp. 3d 254, 271-272 (D.D.C. 2014) (concluding it would be "less disruptive and equally effective" to vacate only a portion of an interim final rule provision); *Wilmina Shipping AS v. U.S. Dep't of Homeland Sec.*, 75 F. Supp. 3d 163, 171 (D.D.C. 2014) (citing the APA's definition for "agency action" for its authority to vacate only part of an agency's order); *Am. Hosp. Assoc. v. Azar*, 2019 WL 5328814, at *2 (D.D.C. Oct. 21, 2019); *see also Philip Morris USA Inc. v. FDA*, 202 F. Supp. 3d 31, 58 (D.D.C. 2016). Courts regularly do so without discussion. *See AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 397 (1999) (invalidating only one portion of an FCC regulatory scheme while upholding the remainder); *Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 464 (D.C. Cir. 2017) (vacating only the unlawful applications of a general rule). And scholars agree this routine practice adheres to the APA. *See, e.g.*, Jonathan F. Mitchell, *The Writ-Of-Erasure Fallacy*, 104 Va. L. Rev. 933, 1013 (2018) (explaining how courts "preserve . . . the agency's action[s] that do not present legal difficulties, simply by characterizing the legal and illegal components as distinct agency 'actions'" as defined in the APA).

Because "only a few discrete provisions violate the law," the Court should vacate the specific elements of the IFRs that AAMS has challenged. *Pritzker*, 37 F. Supp. 3d at 271.

CONCLUSION

The Court should grant summary judgment to AAMS and enter final judgment:

(a.) Setting aside the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021):

- 45 C.F.R. § 149.510(c)(4)(ii)(A), 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A), and 29 C.F.R. § 2590.716-8(c)(4)(ii)(A)'s direction that "[t]he certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR

entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer."

- 45 C.F.R. § 149.520(b)(2), 26 C.F.R. § 54.9817-2T(b)(2), and 29 C.F.R. § 2590.717-2(b)(2)'s related direction limiting consideration of "Additional information submitted by a party" only to information that is "credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section," and "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate."

(b.) Setting aside the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021):

- 45 C.F.R. § 149.140(a)(1), 26 C.F.R. § 54.9816-6T(a)(1), and 29 C.F.R. § 2590.716-6(a)(1)'s direction that "[s]olely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract."
- 45 C.F.R § 149.140(a)(7)(ii)(B), 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B),[11] and 29 C.F.R. § 2590.716-6(a)(7)(ii)(B)'s provision that "[i]f a plan or issuer does not

[11] 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B) does not include "or issuer."

have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605)."

- 45 C.F.R. § 149.140(a)(12), 26 C.F.R. § 54.9816-6T(a)(12), and 29 C.F.R. § 2590.716-6(a)(12)'s provision that "except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty."

Dated: December 10, 2021

Respectfully submitted,

/s/ *Brain R. Stimson*
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, *Plaintiff,* v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants.*	Civ. No. 1:21-cv-3031

DECLARATION OF ROBERT A. SANNERUD IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I, Robert A. Sannerud, state and allege as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein. I make this declaration in support of the motion for summary judgment of Plaintiff Association of Air Medical Services.

Background

2. I am the Chief Financial Officer of Critical Care Services, Inc., d/b/a Life Link III ("Life Link III"). Life Link III is a non-profit provider of air ambulance services. Founded in 1985 as one of the first independent, non-profit medical consortiums in the country to transport critically ill patients by air, today Life Link III delivers rotor-wing air ambulance services from ten (10) air bases located across Minnesota and Wisconsin and fixed-wing air ambulance services co-located at the rotor wing air base located in Blaine, Minnesota. Today, Life Link III is the largest air medical consortium in the country. On behalf of over 70 individual hospitals and ten regional healthcare systems, Life Link III serves predominantly the upper Midwest and has been recognized internationally for its superior level of patient care and commitment to advancing the air medical transport industry as a whole. Life Link III's services are accredited by CAMTS (Commission on

Accreditation of Medical Transportation Systems), ensuring the highest standards of quality and safety are met on every patient transport.

3. I have served as the Chief Financial Officer at Life Link III for 13 years. Prior to serving as Chief Financial Officer with Life Link III, I have consulted in and served as the Chief Financial Officer for healthcare companies, many in turnaround situations, for over 30 years.

4. In my role as Chief Financial Officer, I am responsible for the analysis, internal reporting, and projection of the financial performance of Life Link III's air bases. To fulfill my responsibility, I lead a team of financial personnel that monitors and analyzes the costs of operating Life Link III's air bases; the health care insurance coverage of the individual patients transported by Life Link III; the anticipated and collected payments by third-party payors such as group health plans, private insurance plans, and government healthcare programs; and the patient liabilities (*e.g.*, coinsurance) and collections after third-party payments. We use the same data to project future financial performance.

Life Link III's Business Model and Operations

5. I am involved in Life Link III's contracting with commercial third-party payors such as group health plans and health insurance issuers. Life Link III generally favors entering into network contracts with commercial third-party payors because such arrangements foster greater financial certainty and administrative efficiency. Life Link III generally uses good faith, reasonable efforts to try to procure in-network contracts with commercial third-party payors. But we are often unable to procure such contracts because the commercial third-party payors decline to offer or accept rates that align with the cost structure of Life Link III.

6. To deliver services, Life Link III necessarily incurs costs related to air bases, aircraft, maintenance, specialized equipment, training, certifications and licenses, and regulatory compliance. Those costs are fixed, substantial, and generally unavoidable. They are also common to all air ambulance providers (though they may vary somewhat by geography).

7. The revenue that Life Link III receives for transporting patients covered by commercial third-party payors is integral to Life Link III's ability to operate because most of Life Link III's patients are covered through government healthcare programs or are uninsured. Government healthcare programs such as Medicare and Medicaid pay take-it-or-leave-it rates that do not cover the costs of transports. Most transports of uninsured patients are conducted on a charitable basis and generate a nominal amount of revenue at best. Life Link III must either make up the difference on transports of patients covered by commercial third-party payors, or shutter air bases with payor mixes that yield aggregate revenues below costs.

8. My experience is that the operation and financial performance of every air base is unique in certain respects. Notably, the financial performance of an individual air base varies based on the overall number of transports, the percentage of the transports that are for patients with commercial health coverage, and the amounts actually paid by commercial third-party payors, regardless of whether Life Link III has entered into a network contract with the payor. Air bases with lower percentages of transports of patients with commercial health coverage are more financially sensitive to changes in the amounts paid by commercial third-party payors than air bases with higher percentages of such patients. Likewise, air bases that operate in states where the predominant commercial third-party payors decline to offer or accept rates aligned with costs are more financially sensitive to changes in the amounts paid than air bases in states where the predominant commercial third-party payors are willing to align rates with costs.

9. The analysis of the financial performance of an air base involves a measure of business judgment because the overall number of transports and the payor mix varies weekly, monthly, and yearly. Those variations are outside the control of Life Link III because first responders (e.g., police departments and state patrol) and other providers (e.g., physicians and ground ambulance services) are the ones that dispatch Life Link III to conduct transports. Life

Link III responds when called so long as flight conditions allow it. The nature and extent of the patient's health coverage have no bearing on whether Life Link III responds.

10. Consequently, my prospective financial analyses of air bases customarily takes into account historical and current data on flight volume, historical and current data on payor mix, applicable legal and regulatory mandates, current market conditions with commercial third-party payors, rate information supplied by third-party healthcare payment databases, and the business judgment that I have developed through years of experience in the industry.

The Adverse Impact of the No Surprises Act and the Interim Final Rules

11. I am presently evaluating the impact that implementation of the federal No Surprises Act will have on the future financial performance of Life Link III's air bases. I assume that implementation of the Act under the Interim Final Rules (the "Rules") promulgated by the Departments of Health and Human Services, the Treasury, and Labor and the Office of Personnel Management will drive payments by group health plans or issuers to a level at or below the group health plans' or issuers' median in-network rate for an air ambulance transport. I draw that assumption because the group health plan or issuer will have no rational business reason to enter into a network contract with an air ambulance provider at a rate exceeding the maximum amount which the group health plan or issuer must pay under the Act. I further assume that the maximum amount payable under the Act as implemented by the Rules is the group health plan's or issuer's median in-network rate.

12. I am very concerned that with the Rules taking effect that Life Link III will be increasingly unable to procure in-network contracts because the commercial third-party payors will decline to offer or accept rates that align with the cost structure of Life Link III, secure in the knowledge that the QPA set by the Rules and favored in the IDR process will ensure that they will pay rates lower than those previously negotiated through good-faith arms-length commercial negotiations.

13. The following recent factual developments in Life Link III's negotiations for 2022 in-network contracts with payors with whom it currently and historically has had such agreements support my conclusions expressed in paragraph 12, above, and lead me to conclude that the Rules will fundamentally alter the commercial landscape for air ambulance reimbursement in a manner that will cause both monetary and non-monetary harm to Life Link III and its business model. Life Link III has, during the fall, been in negotiations with a major Minnesota payor regarding the renewal of its in-network provider agreement for 2022. In those negotiations, the payor proposed 2022 reimbursement rates for air ambulance services that were substantially lower than those provided in 2021, ranging from 22% to 33% less overall. Life Link III informed the payor that that proposal was unacceptable to Life Link III, as it did not consider the level of care and services rendered to patients, and invited further negotiations. In late October 2021, following publication of the second part of the Rules, the payor unilaterally announced that it would implement its proposed lower fee schedule starting January 1, 2022, essentially daring Life Link III to go out-of-network, knowing that Life Link III would be subject to lower rates under the Rules than it previously had under its negotiated network provider agreement with this payor. The timing of this payor's action is not coincidental—the Rules are changing the commercial landscape in air ambulance-payor negotiations even before they have formally gone into effect on January 1, 2022. Life Link III will be unable to recover the revenue foregone if the Rules are allowed to continue in force, and their existence is distorting the behavior of payors in the marketplace and upending decades of sustained commercial practice wherein Life Link III was able to negotiate fair and equitable arms-length network-provider contracts with the payors in its principal areas of service.

14. One of the data points that I am considering in my evaluation is the recent report by FAIR Health that from 2017 to 2020, "[t]he average estimated allowed amount [for the base rate for an air ambulance transport] rose 60.8 percent, from $11,608 to $18,668." *Air Ambulance*

Services in the United States: A Study of Private and Medicare Claims, A FAIR Health White Paper, September 28, 2021, at p. 2, n.1. These costs "do not include mileage fees." *Id.*

15. FAIR Health states in its report that "[a]n allowed amount is the total fee negotiated between an insurance plan and a provider for an in-network service; the allowed amount includes both the insurer's and the member's share of the total fee. Because payors' contracted network rates are proprietary, FAIR Health employs an imputation methodology to determine benchmarks for allowed amounts. First, FAIR Health calculates the ratios of actual allowed amounts to charges for groups of procedure codes on a regional basis. The resulting ratios are applied to the actual charges for each specific procedure at the local (geozip) level to develop an 'imputed' or 'estimated' allowed amount for each claim line." *Id.* at p. 7, n.12

16. FAIR Health describes itself as "an independent nonprofit that collects data for and manages the nation's largest database of privately billed health insurance claims and is entrusted with Medicare Parts A, B and D claims data for 2013 to the present." FAIR Health – About Us, *available at*: https://www.fairhealth.org/about-us (last visited Dec. 8, 2021). FAIR Health underscores that "[a] testament to the fairness and reliability of our data, New York, Connecticut, and many other states have adopted FAIR Health's cost information as the guidepost in laws protecting consumers, and for many other purposes." *Id.*

17. The Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services has certified FAIR Health as a Qualified Entity (QE). *Qualified Entity Program, available at*: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/QEMedicareData (last visited Dec. 8, 2021). FAIR Health participates in the CMS QE Program, "which enables organizations to receive Medicare claims data under Parts A, B, and D for use in evaluating provider performance." *Id.*

18. My experience in the air ambulance industry is that the "allowed amount" for an air ambulance transport is typically the total amount that a group health plan or issuer (together

with the plan member or insured) actually pays for the transport. My experience is that the plans' or issuers' allowed amount is the same (or substantially similar) regardless of whether the plan or issuer has a network contract with the air ambulance provider. In other words, my experience is that group health plans and issuers typically make out-of-network payments for air ambulance transports at levels at or slightly below their in-network allowed amounts for the service. Presumably this is done to create an incentive for network contracting.

19. If all group health plans and issuers began paying $18,668 or less for the base rate for an out-of-network air ambulance transport, effective January 1, 2022, then all 10 of Life Link III's air bases would experience reductions in revenue for calendar year 2022. My business judgment is that the reductions in revenue would be so great that all 10 of Life Link III's air bases would cease to cover their costs, and it would become necessary for Life Link III to evaluate closure or consolidation of some or all of those air bases as soon as possible in calendar year 2022. The reductions in revenue and related operational impacts would be even greater if all group health plans and issuers began paying a total of $18,668 or less for an out-of-network air ambulance transport, effective January 1, 2022.

20. The impact of all group health plans and issuers paying $18,668 or less for the base rate for out-of-network air ambulance transports would have a ripple effect throughout the industry because group health plans and issuers would have a compelling economic incentive to terminate or renegotiate any existing network contracts at base rates in excess of $18,668 per transport. Such conduct by group health plans and issuers would lead to additional base closings or consolidations. Again, the impact would be even greater if all group health plans and issuers began paying a total of $18,668 or less for out-of-network air ambulance transports.

21. The narrowing of Life Link III's operational footprint through the closing or consolidation of air bases would reduce Life Link III's geographic service area and, by extension, the public's access to air ambulance services provided by Life Link III.

22. The economic and social harms would be irreparable because of the challenges inherent in operating air bases, particularly in rural communities. Once the physical plant of the air base is shuttered, the aircraft and equipment are relocated or sold. The flight crew is reassigned or released. After these changes are made, they cannot readily be undone. The equipment and crew cannot just be recalled and reassembled by Life Link III. Life Link III has to obtain capital, and then deploy the capital together with corporate resources to re-create the air base from scratch, marshal the equipment and facilities, recruit new and highly-trained personnel to work at the air base, and obtain the requisite licenses and regulatory approvals (which, standing alone, can take years). The opening of a new air base requires a substantial investment of capital and resources in the best of times and will undoubtedly become more challenging in an environment where government policy is causing a reduction in the commercial rates paid to air ambulance providers nationwide.

***

I declare under penalty of perjury as set forth in 28 U.S.C. § 1746 that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed on December 10, 2021, at Hennepin County, Minnesota.

Robert A. Sannerud, MBA, CPA, CGMA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civ. No. 1:21-cv-3031 (RJL)

DECLARATION OF CHRISTOPHER EASTLEE

I, Christopher Eastlee, state as follows:

1. I am over the age of eighteen. If called as a witness in this action, I could testify to the facts stated herein.

2. I am the Vice President of Public Affairs at the Association of Air Medical Services (AAMS). AAMS is the international trade association that represents over 93% of air ambulance providers in the United States. Together, AAMS's over 300 members operate an estimated 1,000 helicopter air ambulances and 200 fixed-wing air ambulances. AAMS represents every emergency air ambulance care model, including for profit and non-profit providers, hospital-based organizations, independent organizations, urban and rural providers, and many hybrid variations.

3. AAMS represents and advocates on behalf of its members in a variety of forums. AAMS advocates on behalf of its members to government bodies and officials to enhance its members' ability to deliver quality, safe, and effective medical care and transportation. As part of that mission, AAMS communicates the position of its membership as it relates to new legislation and regulations to the relevant government decision-makers.

4. In response to the No Surprises Act and subsequent rulemakings, AAMS provided comment letters to the Departments of Health and Human Services, the Treasury, and Labor

(collectively, the Departments) to convey additional background information about the air ambulance industry and its members' views on those rulemakings. AAMS also met with the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) to convey similar information.

5. On June 15, 2021, AAMS submitted a comment letter to the Departments, a true and correct copy of which is attached hereto as Exhibit 1.

6. On June 28, 2021, AAMS met with OIRA and submitted a PowerPoint presentation, a true and correct copy of which is attached hereto as Exhibit 2.

7. On September 3, 2021, AAMS met with OIRA and submitted a PowerPoint presentation, a true and correct copy of which is attached hereto as Exhibit 3.

8. On September 7, 2021, AAMS submitted another comment letter, a true and correct copy of which is attached hereto as Exhibit 4.

9. On December 6, 2021, AAMS submitted another comment letter, a true and correct copy of which is attached hereto as Exhibit 5.

10. As another way to further its mission, AAMS brings litigation on behalf of its members to challenge government action that will harm them, including the instant litigation.

11. As the Vice President of Public Affairs at AAMS, I have worked closely with many AAMS member businesses to understand how the Departments' implementation of the No Surprises Act in the IFRs will affect member businesses. Based on information that I have obtained regarding the IFRs and my expertise in the air medical services industry, I believe that the Interim Final Rules will inflict substantial harm on many of AAMS's members.

12. AAMS's membership includes PHI Health, LLC, Global Medical Response, Inc., Air Methods Corporation, and Critical Care Services, Inc., d/b/a Life Link III. Each of these AAMS members will be harmed by the IFRs. *See* Foster Decl. (Dkt. 1-5), Preissler Decl. (Dkt. 1-6), Portugal Decl. (Dkt. 1-7), Sannerud Decl. ¶¶ 11-22.

I declare under penalty of perjury as set forth in 28 U.S.C. § 1746 that the foregoing is true and correct to the best of my knowledge, information, and belief.

Executed on December 10th, 2021, in Alexandria, Virginia.

Christopher Eastlee

Exhibit 1

ASSOCIATION OF AIR MEDICAL SERVICES

June 15, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Ave N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, DC 20220

Dear Secretaries Becerra, Walsh and Yellen:

I write to offer the views of the Association of Air Medical Services (AAMS) on the tri-departmental rulemakings prescribed by the No Surprises Act, Pub. L. No. 116-260 (2020) (the "Act"). AAMS is the international trade association that represents over 93 percent of air ambulance providers in the U.S. Together, our 300 members operate more than 1,000 helicopter air ambulances and 200 fixed wing air ambulance services across the United States. AAMS represents every emergency air ambulance care model, including hospital-based aircraft, independent aircraft at bases in rural areas far from hospitals, and many hybrid variations.

AAMS strongly supports the goal of the Act, which is removing patients from payment negotiations between healthcare providers, and insurers and group health plan sponsors, through an independent dispute resolution process (IDR). We believe the implementation of the Act will succeed if air ambulance providers, insurers, group health plan sponsors, and IDR entities receive the information they need to resolve payment questions efficiently and fairly. It is critical that the tri-departmental rulemakings promote transparent disclosures of air ambulance cost information, in-network rate information, and out-of-network payment information.

Fair payments that cover the costs of delivering air ambulance services will help ensure that air ambulances can continue to sustain operations in rural and underserved areas and preserve the emergency medical system that saves American lives every day. The preservation of the emergency medical system is especially important to Americans in underserved and rural communities who lack access to definitive care, *e.g.*, trauma centers and other tertiary care providers.[i] In this regard, fair payment for air ambulance services enables the equitable delivery of definitive care to all Americans.

AAMS recognizes that the tri-departmental rulemakings will unfold over the course of 2021 and address relevant policy issues. We look forward to partnering with the Departments throughout the year to help the Administration advance the purposes of the Act and the policy of health equity. For now, AAMS offers its views on two threshold issues in the rulemakings: the Qualifying Payment Amount (QPA) and the information considered in the IDR process. We also provide additional background about the air ambulance industry that informs our views on both issues.

I. The Air Ambulance Industry is Unique in Ways Important to the Rulemakings

AAMS believes that Congress included specific language regarding air ambulance providers in the Act because the air ambulance industry is unique. The industry is an integral part of the emergency medical system, first responders (*e.g.*, local police and fire departments) and community physicians determine the utilization of the services, the service has both healthcare and aviation components, many air ambulance providers operate on a standalone basis (that is, they are not affiliated with a hospital), the fixed and variable costs of delivering a heavily-regulated healthcare and aviation service are high, and insurers and group health plan sponsors have historically paid for most of the services on an out-of-network basis. No other industry within the health sector shares all of these characteristics with the air ambulance industry.

Air medical services are often the only lifeline that critically ill and injured patients may have to definitive care, especially in rural areas. Without helicopter air ambulances, eighty-five million Americans cannot reach a Level 1 or 2 Trauma Center within one hour. Traumas, strokes, heart attacks, burns, and high-risk neonatal/pediatric cases account for 90 percent of all helicopter air ambulance transports. All of those conditions are emergent and require a higher level of care than what is typically found at a community hospital.

Air ambulance providers play no role in deciding whether or when to transport a patient. They respond to calls from first responders (in accordance with state and local protocols) and treating physicians, and closely adhere to the treatment plan the physician prescribes. When helicopter air ambulance services are requested, air ambulance providers determine only whether the aviation conditions are safe to fly the patient. They do not question a first responder's or physician's request for services (in many states a "duty to respond" is a condition of EMS licensure) and are never aware of the patient's ability to pay or their health insurance status. The goal is to provide the highest quality of transport safety and patient care efficiently and do so by responding to transport requests within minutes.

Air ambulances operate under a more complex regulatory regime than most providers, including multiple federal and state agencies. In addition to Federal program enrollment, air ambulances frequently must obtain two additional levels of authorization: (i) an air carrier certificate from the Federal Aviation Administration (FAA) to conduct on-demand operations under 14 C.F.R. Part 135 (*i.e.,* Part 135 certificate) and (ii) a state-issued ambulance license. A Part 135 certificate is required for conducting air transportation, while the state ambulance license is necessary for providing medical ambulance operations and billing for the services rendered.

This federal and state regulatory overlay is important, as more than 33 percent of helicopter air ambulance flights will cross a state border and nearly all will cross a county or municipal boundary. Nearly all fixed wing air ambulances cross state borders. The unfettered interstate delivery of services is possible partly because the Airline Deregulation Act preempts many state laws.

The delivery model for air ambulance services may vary depending on whether the federal and state authorizations are held by a hospital, a community organization, or a standalone air ambulance provider, or split between two different entities. While delivery models vary, a majority of air ambulance providers are standalone operators that hold both federal and state authorizations and are not affiliated with a single hospital or community organization.

The delivery of on-demand, heavily-regulated, life-saving air ambulance services in emergencies requires investments in specialized aircraft, air bases, technology, personnel, and regulatory compliance systems. Those investments involve substantial fixed costs. The Act requires air ambulance providers to report their costs to the Departments to inform policymaking and regulation. As stated previously, AAMS supports the reporting of cost data to the Departments because it will help them assess the fairness of payments for air ambulance services.

AAMS also supports the consideration of payment data because insurers and group health plans have historically paid for air ambulance services on an out-of-network basis instead of entering into network contracts with air ambulance providers. In particular, we support a regulation that requires IDR entities to request and consider payment data, and assess the fairness of the air ambulance provider's and the payor's offers against the backdrop of the QPA (which reflects in-network rates), and out-of-network payments to providers.

We note these points to illustrate how the air ambulance industry is different from other industries within the health sector. Congress acknowledged this when it established provisions specific to air ambulance providers and chose to address their services separately from others. We urge the Departments to keep these differences in mind and account for them in the rulemakings.

II. Qualifying Payment Amount (QPA)

A. Median Contracted Rate for Comparable Services

The median rate should be based on fair market rates for services that are comparable in terms of transport type (emergency vs. non-emergency), vehicle type (fixed-wing vs. rotor-wing), transport distance, geographic region, and provider type (providers that bill through a hospital system vs. those that do not). The QPA is defined as the median of the contract rates recognized by the plan or insurer as the total maximum amount in 2019 for the same or similar item or service provided by a provider in the same or similar specialty in the geographic region. In determining the median amount, we believe it is critical to define "same or similar item or service" based on comparable services. Comparable services should be those that are provided by the same transport type (*e.g.,* emergency or non-emergency), vehicle type (*e.g.,* fixed wing or rotary wing), transport distance (*e.g.,* the distance from the air base to the drop-off point), and geographic region (*e.g.,* for rotor wing transports, the interstate or intrastate service area of the aircraft; for fixed wing transports, the international or interstate service area of the aircraft). Because all of these factors may impact the rates paid for the services, the Departments should determine the median based on the rates for "like" claims that take the same factors into consideration. The median rate should derive from a broad range of contracts so that any outliers do not skew the final amount. Additionally, we urge the Departments to consider the following concepts in interpreting the phrase "same or similar item or service."

i. Health Equity for Vulnerable Communities

The implementation of the Act should enable emergency air ambulances to continue serving rural populations that otherwise lack access to definitive care. In many rural communities, air ambulances are an increasingly important service due to the lack of access to the definitive care that is readily available to the rest of the population. Most hospital systems and high-level tertiary centers are located in urban and suburban areas. And, over the past 10 years, many rural hospitals have closed or reduced services, leaving many communities with few options for definitive care.[ii] In these areas, air ambulance services are more critical than ever and may be patients' only option connecting them to timely definitive care.

Unfortunately, the volume of emergent and unplanned transports rendered in rural communities can vary greatly across both geography and time for reasons that are outside the control of the air ambulance provider. The emergent and unplanned nature of the transports also means that insurers and group health plan sponsors cannot steer patient volume to air ambulance providers in exchange for discounted rates. These structural features of air ambulance services are natural disincentives for insurers and group health plan sponsors to contract with air ambulance providers.

We urge the Departments to keep in mind that the volume of services rendered is not an indication of a community's need for the service. A rural community without a hospital may only need a helicopter on an infrequent basis, but when the need arises, it is most often critical. The rulemakings should advance health equity by promoting fair payments to air ambulance providers that preserve rural access to definitive care in life-or-death situations.

ii. Differences in Negotiated Rates

Stand-alone entities and entities that bill through, for example, a hospital system should not be compared to one another when calculating a median. Comparable services should also reflect differences in organizations' structures, which can influence how entities arrive at their negotiated rates. For instance, entities that bill through a hospital system may enter a network agreement with an insurer based on the universe of services that the hospital system offers and may look at this entire universe of hospital services when negotiating payment. In some cases, they may not have the resources to focus on a discrete service-line such as air ambulance. These agreements may include rates for services that the entities themselves do not offer but that are folded into the larger contract with no discussion or negotiation; they may also include rates for a service the hospital used to offer but no longer provides. As a result, air ambulance transport rates in these contracts may be far lower than the true cost of providing care in the area. If air ambulance transports are not a service the hospital system provides, the hospital system has little or no incentive to negotiate a fair rate because it is not an amount for which the hospital system will ever seek payment. In contrast, a stand-alone entity that conducts its own billing will typically ensure that contract rates reflect only the services offered. For the vast majority of standalone entities, the final rates must be sufficient to offset the costs of rendering the services in the community. These entities typically negotiate an adequate rate that will sustain their operations.

Given the differences in how these types of organizations approach rate negotiations for individual services, the two entity structures should not be compared to one another nor these rates blended into one median amount. Furthermore, the number of claims actually paid at the median amounts should be made available to the IDR entities.

iii. Geographic Regions

Geographic regions should align with the actual service areas of air ambulances. The QPA takes into account the "geographic region in which the item or service is furnished," and the National Association of Insurance Commissioners ("NAIC") has proposed the use of Individual and Small Group Market Geographic Rating Areas provided for by the Market Rules and Rate Review Final Rule (45 C.F.R. pt. 147), which includes a mix of county-level, 3-digit ZIP code-level, or MSA+1 level regions within each individual state as the geographic regions for determining QPAs for all emergency services under the Act. These regions are inappropriate for air ambulances for two reasons. First, the number of in-network air ambulance contracts in some areas may be too small to derive a QPA that represents contract rates for the same or similar services. Second, the service areas of air ambulances do not align with the borders of those areas. Air ambulances move patients across state borders over 33 percent of the time.

The guiding principles for determining the geographic region for the QPA should be fair payment to healthcare providers and health equity for rural communities, not administrative convenience. The geographic region should be tailored to the actual service area of the specific air ambulance provider (which affects the costs the air ambulance provider incurs in delivering the services). A tailored approach is fairer because it is more likely to yield a QPA that represents any contract rates that air ambulance providers have accepted for the actual service area.

B. Database Default

The Departments should request and begin to collect paid claims amounts for establishing a reliable database default. When there is insufficient information to calculate a median of the contracted rates, the rate for an item or service will be determined "through use of any database that is determined . . . to not have any conflicts of interest and to have sufficient information reflecting allowed amounts paid" to providers and facilities. We appreciate the Departments' efforts to identify a reliable data source and the acknowledgement that there may not always be sufficient information for calculating a median contract rate. However, currently, no reliable database exists for air ambulance services.

AAMS is interested in establishing such a database and welcomes the opportunity to partner with the Departments on how to achieve this. As an initial step to obtaining this data, we offer two suggestions on how the Departments may request and begin to collect paid claims data. First, as a condition of certification, IDR entities are required to submit to the Secretary of Health and Human Services "such information as the Secretary determines necessary to carry out" the public reporting of information on IDR. One piece of information the Secretary could require IDR entities to report is the average actual non-contracted paid claims amount. These amounts would not be made public, but could be used to develop a national database to serve as a back-up when there is insufficient information to calculate the median. The Secretary could establish a fee for access to the database to support its creation and operation. Second, the Departments could require insurers to report this information to the Secretary, and to the public, through the Transparency in Coverage regulations. Both approaches are within the Departments' statutory authority and could go a long way towards creating a meaningful database on air ambulance service payments.

III. Independent Dispute Resolution

A. Initial Payment & Denial of Payment

If an insurer or health plan fails to respond to a provider's claim submission within the 30-day period, it should be deemed a denial. Within 30 days of a provider or facility submitting a bill for services, a health plan or insurer must issue an initial payment or notice of denial of payment. Following this decision, the negotiation period and subsequent IDR process begin. While the Act makes clear that insurers must take action within 30 days, we are concerned that insurers may fail to meet this requirement, which would prevent providers from advancing to the negotiation phase. Any delays in responses from group health plans or issuers only prolong the time to reach a final resolution, contrary to Congress's vision for the "timely and efficient provision of determinations [.]"

If the health plan or insurer fails to respond within 30 days of the original claim submission, the Departments should deem this a denial that triggers the negotiation process, and starts the clock on the IDR process.

B. IDR Entity Certification

The Departments should require that IDR entities request average non-contracted paid claims amounts from the parties. The Departments are charged with establishing a process for certifying IDR entities that ensures that they carry out their responsibilities. The Act authorizes the Departments to revoke an IDR entity's certification if it demonstrates a pattern or practice of noncompliance. Separately, the Act requires the parties to submit to the IDR entity (i) an offer for a payment amount, and (ii) "such information as requested by the certified IDR entity." Together, these provisions authorize the Departments to require IDR entities to request specific information from parties in IDR as a condition of IDR certification.

We recommend that the Departments require IDR entities to request that, with respect to a dispute regarding calendar year 2022, the provider submit the average non-contracted paid claims amount during calendar year 2020 (to be updated by an inflation factor with respect to a dispute regarding a future calendar year). This information is important because it reflects the amounts that health plans and insurers were willing to pay before the Act was implemented. The information will provide the parties and the IDR entity with a more complete and transparent factual basis for assessing the dispute. The increased transparency should incentivize negotiated resolutions that save both the parties and the public time and money.

The failure to request this information should result in decertification of the IDR entity.

C. Weighing of Factors

IDR entities should give primary weight to the average actual non-contracted paid claims amount submitted by the provider, and have the discretion to discount or reduce the weight of the median contracted rate. In selecting the final payment amount, the IDR entity must consider the (i) QPA, (ii) the additional circumstances enumerated in the Act (*e.g.*, quality and outcomes measurements), and (iii) any additional information that the

parties provided. Congress did not specify how IDR entities must weigh these factors. We believe the Departments should require IDR entities to give primary weight to the average actual non-contracted paid claims amount submitted by the provider. IDR should be an avenue for reaching a fair payment that covers the costs of delivering air ambulance services and thereby advances health equity for vulnerable communities. The amounts that group health plans and insurers previously paid for services should be the starting point for this discussion.

We do not believe that contract rates alone are a reasonable guidepost for the IDR process. As previously discussed, the structural features of air ambulance services are disincentives for network contracting. Those disincentives have been compounded by consolidation in the insurance industry, which has increased the market power of insurers and made it even more challenging for air ambulance providers to negotiate fair payments for their services. AAMS members continue to work with insurers to reach in-network agreements but are having less and less success in doing so. In fact, AAMS members have found that some of the largest health insurers have no in-network agreements with providers. It would be unfair for IDR entities to consider only contract rates when air ambulance providers are actively working to reach agreements with insurers without success. If IDR entities consider only contract rates, they will incentivize insurers and group health plans to terminate their most reasonable provider contracts, reduce their engagement in good faith negotiations with the terminated providers, and insist on widespread acceptance of unfair contract rates imposed on small numbers of providers through the exercise of market power. Unfortunately, we have already seen these consequences emerge, with insurers terminating reasonable provider contracts in an attempt to drive down contract rates in advance of the rulemakings.

A fairer approach would be for the Departments to account for the history of out-of-network payments for air ambulance services by requiring that IDR entities give primary weight to the average actual non-contracted paid claims amount. In service areas with little or no network contracting, the average actual non-contracted paid claims amount represents what insurers and group health plans will pay, and what air ambulance providers will accept short of initiating litigation. The primary weighting of that amount will strengthen the incentive for efficient negotiated resolutions that save the parties and the public time and money.

D. Complete Payment Denials; Coverage Based Denials

The Departments should acknowledge in the final rule that the Act reaches disputes where the group health plan sponsor or insurer offers the air ambulance provider a payment of $0.00 (including for medical necessity denials). The Act reaches any dispute where the group health plan or group or individual health insurance coverage covers air ambulance services provided by a participating provider, the nonparticipating air ambulance provider bills for a transport, and the group health plan sponsor or insurer pays or offers to pay $0.00 to the provider (the Act uses the term "notice of denial of payment," which means that no payment is or will be made to the provider). While the Act is unambiguous, insurers and group health plan sponsors may nonetheless try to circumvent the IDR process by unilaterally declaring that the services were medically unnecessary, non-emergent (and therefore not a covered emergency service), or otherwise beyond the reach of the Act. To mitigate the potential gaming of the IDR process, the Departments should acknowledge in the preamble to any final rule that the Act does exactly what it says, and reaches disputes where the group health plan sponsor or insurer pays or offers to pay the air ambulance provider a payment amount of $0.00 for any reason.

If insurers and group health plan sponsors can game the system by deciding unilaterally that air ambulance transports are medically unnecessary or non-emergent, then patients will receive balance bills and the Act will not achieve its purpose. The tri-departmental rulemakings should maintain the integrity of the IDR process and vindicate the purpose of the Act.

In addition, the Departments should align the rulemakings with other federal laws by requiring that IDR entities apply a prudent layperson standard when adjudicating payment disputes that present medical necessity questions.

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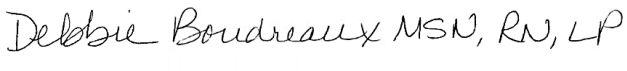
Thank you for the opportunity to provide these initial comments. We believe it is critical to protect patients' use of air ambulance services, both in emergency situations or when requested by a physician, patient, or family member in a non-emergency situation. Air ambulance services are vital to our healthcare system and there must be a reliable mechanism in place to financially support these operations. We look forward to working with the Departments on these important issues. If you have any questions, please contact AAMS Vice President of Public Affairs Christopher Eastlee at ceastlee@aams.org.

Sincerely,



Cameron Curtis, CMM, CAE
President & CEO
Association of Air Medical Services

Deborah Boudreaux, MSN, RN, CCRN, C-NPT, LP, CMTE
Chairman and Region IV Director, AAMS
Teddy Bear Transport, Cooks Children Medical Center

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[i] Branas, C.C., E.J. MacKenzie, J.C. Williams, H.M. Teeter, M.C. Flanigan, A.J. Blatt and C.S. ReVelle. "Access to Trauma Centers in the United States." JAMA: Journal of American Medical Association vol. 293 no. 21 (2005): 2,626-2,633.

[ii] Government Accountability Office, "RURAL HOSPITAL CLOSURES Number and Characteristics of Affected Hospitals and Contributing Factors"; GAO-18-634; August 2018

Exhibit 2

No Surprises Act Implementing Regulations

Association of Air Medical Services (AAMS)

June 28, 2021

Overview of the Air Ambulance Industry

- **Integral Role in the Emergency Medical System**: Air ambulances are often the only lifeline critically ill and injured patients have to care, especially in rural areas.
- **Emergency Air Ambulance Providers Play No Role in Determining Patient Transports**: Emergency air ambulance providers are only requested by physicians and first responders; they only determine whether aviation conditions are safe to fly. Most state licensures include a duty to respond.
- **Air Ambulances Operate Under a Complex Regulatory Scheme**: Air ambulances frequently must obtain two levels of authorization: federal (FAA Part 135 Certificate) and state (state licensure in one or more states).
- **AAMS:** AAMS represents over 93 percent of air ambulance providers in the U.S., with 300 members operating more than 1,000 helicopter air ambulances and 200 fixed wing air ambulance services.

Defining the Qualifying Payment Amount (QPA)

Taking an Expansive View of the QPA

- **Lack of Networks**: Insurers have historically paid for most air ambulance services on an out-of-network basis. Where a lack of networks exist, historical and non-contracted rates should also be considered.
- **Volume Disadvantage**: The volume of emergent and unplanned transports in rural communities can vary greatly, creating a natural disincentive for insurers to contract.
- **Comparable Services**: The median rate should be based on rates for services that are comparable in terms of transport, vehicle type, transport distance, geographic region, and provider type. For example, stand-alone entities and entities that bill through a hospital system may differ in their approaches to rate negotiations.

Aligning Geographic Regions with Service Areas

Ensuring that Geographic Regions Reflect Care Delivery

- **Limited Number of In-Network Contracts**: In some areas, there may be too small a number of in-network contracts to derive a representative QPA that provides fair market rates.
- **Air Ambulance Services Do Not Align with State Borders**: More than **33 percent** of helicopter air ambulance flights will cross a state border and **nearly all** will cross a county/municipal boundary.

Complete Payment Denials

Preventing Surprise Billing Due to Medical Necessity

- **The Act Reaches Offers of $0.00 Payment**: Insurers must send to providers "an initial payment **or** notice of denial of payment"; Congress did not exempt any payment types.
- **Future Surprise Billing Risk**:. Insurers may attempt to game the system by deciding that air ambulance transports are medically unnecessary or non-emergent.
- **Undermining the Act's Purpose**: This process was intended to cover payment denials-otherwise a loophole exists. Providers will have no avenue for dispute resolution.

Recommendations

- **QPA**: The QPA should be based on fair market rates for services that are comparable in terms of transport type (emergency vs. non-emergency), vehicle type (fixed-wing vs. rotor-wing), transport distance, geographic region, and provider type (providers that bill through a hospital system vs. those that do not) and derive from a broad range of contracts so that any outliers do not skew the final amount.

- **Geographic Regions**: Geographic regions should align with the actual service areas of air ambulances, not necessarily states or subdivisions of states.

- **Medical Necessity**: The final rule should acknowledge that the Act reaches disputes where the group health plan sponsor or insurer offers the air ambulance provider a payment of $0.00 (including for medical necessity denials).

Exhibit 3

No Surprises Act Interim Final Rule – Part I

Association of Air Medical Services (AAMS)

September 3, 2021

Introductions

- Christopher Eastlee, Vice President of Government Affairs, AAMS
  - AAMS represents over 93 percent of air ambulance providers in the U.S., with 300 members operating more than 1,000 helicopter air ambulances and 200 fixed wing air ambulance services.
- Jason B. Caron, Partner, McDermott Will & Emery, LLP, Counsel to AAMS
- Brian Stimson, Partner, McDermott Will & Emery, LLP, Counsel to AAMS

Air Ambulance Industry & Historic Market Conditions

- **Integral Role in the Emergency Medical System**: Air ambulances are often the only lifeline critically ill and injured patients have to care, especially in rural areas.
- **AAMS Members Regularly Seek In-Network Agreements with Payers**: Air ambulance providers succeed in reaching agreements in many cases, but struggle to secure agreements with some payers due to their market dominance and business strategies.
- **The Market Has Not Provided Incentives for Payers to Reach Solutions**, but the need for air ambulance services remains critical.

Addressing Flaws with the Qualifying Payment Amount (QPA)

The QPA Will Have Unintended Consequences

- **Lumps Air Ambulance Providers Together**: The QPA fails to distinguish between:
  - Independent and hospital-based providers;
  - Emergency rotor-wing and emergency and non-emergency fixed wing providers; and
  - Active and shuttered providers.
- **Excludes Relevant Data**: Due to air ambulance utilization patterns, a significant number of contracts with payers are single case agreements (SCAs). The IFR excludes these agreements from the definition of "contracted rate," as well as historic payments.

Addressing Flaws with the QPA

The QPA Will Have Unintended Consequences

- **Use of Census Divisions Will Produce Absurd Results**: If a geographic area is determined based on all metropolitan statistical areas (MSAs) in a Census division and all other areas in the Census division, a rate in Hawaii or Alaska could dictate the QPA for a pick-up in California.

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Consequence: The methodology will produce QPAs that are below fair market rates. If providers are forced to exit the market, patients will lose access to critical services.

Addressing Flaws with the QPA

Opportunities to Fix the QPA

The QPA could more closely approximate fair market rates if it:

- Differentiates between air ambulance provider types;
- Includes SCAs and historic payments; and
- Removes Census divisions from the geographic region definition.

Irrespective of whether the Departments elect to address the flaws with the QPA methodology, they should at least mitigate the unintended consequences of the methodology in the Part II rule:

- Require payers to disclose information about the limitations of the QPA; and
- Instruct IDR entities to give the QPA no presumptive weight.

Aligning the Approach to Coverage Denials with the Act

The IFR's Approach to Coverage Denials Will Perpetuate Surprise Billing

- The IFR states that "notice of denial of payment" does not include a notice of benefit denial due to an adverse benefit determination (ABD).
- This interpretation allows payers to exempt claims from IDR and skirt the ban on surprise billing.
- In these instances, the payer will neither send an initial payment or notice of denial of payment, and the provider will never reach the IDR process. The provider instead sends a surprise bill to the patient, who may appeal to the payer's ABD through the internal and external appeals processes.

Aligning the Approach to Coverage Denials with the Act

The IFR's Approach to Coverage Denials Will Perpetuate Surprise Billing

- Payers deny more than approximately 50 percent of claims for nonparticipating air ambulance services on coverage grounds.
- Yet, AAMS members report that approximately 90 percent of those denials are later overturned on appeal.
- This means that patients must appeal more than 45 - 55 percent of all claims for nonparticipating air ambulance services to obtain the payments to which they were always entitled.

This approach is self-defeating and does not reflect Congressional intent. Air ambulance services should qualify as essential health benefits in emergency situations.

Ensuring Equal Weighting of Factors in IDR

Congress Established a List of Factors that IDR Entities Must Consider and it Did Not Assign Any One Factor Greater Weight

- In selecting the final payment amount, Congress requires IDR entities to consider a range of factors, including: the QPA, acuity of the patient, ambulance vehicle type, and demonstrations of good faith to enter network contracts, among other elements.
- There is no evidence that Congress intended to give the QPA greater weight. If Congress had wanted the QPA to be the primary consideration in IDR, it could have specified that preference.
- U.S. Senators and Representatives have clearly expressed their intent for factors to be weighed equally, stating that **no single piece of information should be considered the default**.

Encouraging Transparency in IDR

Parties Should Have Additional Time to Respond to New Information Presented in IDR

- Information disclosed in open negotiations should be admissible in IDR, and the parties should share their submissions with the IDR entity.
- The Act imposes a 10-day deadline for parties to submit claims and supporting information to the IDR entity.
- This timeline may be adjusted for "**extenuating circumstances**." This should include the presentation of new information that was not disclosed in negotiations.
- The receiving party should have at least 5 days to respond to the information.

Encouraging Fairness in IDR

Parties Should Have the Right to Batch Claims to the Fullest Extent Possible, and Access IDR Without Delay

- The Departments should liberally construe terms such as "the same provider or facility" to maximize batching, and allow batching for periods of up to 180 days.
- The Departments should not delay the availability of IDR past the effective date of the statutory ban on balance billing.
- A delay would contravene the text and structure of the Act and would not be a valid exercise of enforcement discretion.

Exhibit 4

ASSOCIATION OF AIR MEDICAL SERVICES

September 7, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Ave N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, DC 20220

Dear Secretaries Becerra, Walsh and Yellen:

I write to offer the views of the Association of Air Medical Services (AAMS) on the tri-departmental Interim Final Rule ("IFR"), *Requirements Related to Surprise Billing; Part I*, as prescribed by the No Surprises Act, Pub. L. No. 116-260 (2020) (the "Act"). AAMS is the international trade association that represents over 93 percent of air ambulance providers in the U.S. Together, our 300 members operate more than 1,000 helicopter air ambulances and 200 fixed wing air ambulance services across the United States. AAMS represents every emergency air ambulance care model, including aircraft based at hospitals, independent aircraft at bases in rural areas far from hospitals, and many hybrid variations.

AAMS strongly supports the goal of the Act, which is removing patients from payment negotiations between healthcare providers and payers, through an independent dispute resolution process ("IDR"), while maintaining patient cost sharing at reasonable levels. We believe the implementation of the Act will succeed if air ambulance providers, payers, and IDR entities receive the information they need to resolve payment questions efficiently and fairly. It is critical that this IFR and the upcoming tri-departmental rulemakings promote transparent disclosures of air ambulance cost information, in-

network rate information, and out-of-network payment information.

Fair payments that cover the costs of delivering air ambulance services will help ensure that air ambulances can continue to sustain operations in rural and underserved areas and preserve the emergency medical system that saves American lives every day. The preservation of the emergency medical system is especially important to Americans in underserved and rural communities who lack access to definitive care, e.g., trauma centers and other tertiary care providers.

We look forward to working with the Departments to help the Administration advance the purposes of the Act and promote health equity. We appreciate the opportunity to provide comments on the IFR and offer views on this first rulemaking, as well as considerations we believe the Departments should take into account as you develop the forthcoming rulemaking focused on the IDR process. In this comment letter, we first address language in IFR Part I that misapprehends current market conditions and the ambulance industry's relationship to the insurance industry. Then we share our perspectives on three core issues: fixing the Qualifying Payment Amount ("QPA") methodology, aligning the Departments' approach to coverage denials in the IFR with the Act, and encouraging transparency in IDR.

I. The Departments Should Align Their Prior Statements with Historical Market Conditions

We understand the Departments are interested in removing patients from payer-provider payment discussions, and we believe that is best accomplished when plans and issuers make fair and efficient payments to air ambulance providers. We were disheartened to see language in the IFR that misapprehends the historical market conditions and relationship that air ambulance providers share with plans and issuers. AAMS rejects the suggestions in the preamble and economic analysis that air ambulance providers stay out-of-network as a business strategy for maximizing revenues or profits and engage in aggressive collection practices. The experience of AAMS members is the exact opposite. Our members regularly seek in-network agreements with plans and issuers, and succeed in securing such agreements in some cases. But they also struggle mightily to reach network agreements with certain plans and issuers due to the market dominance and business strategies of those payers. AAMS members cannot establish network agreements with payers who express no interest in reaching such agreements nor can our members enter agreements that are financially unsustainable.

We attribute the experience of AAMS members to a variety of factors unique to the market for air ambulance services. To deliver the services, air ambulance providers must incur substantial fixed costs for specialized aircraft, airbases, equipment and highly skilled aviation and medical professionals. All helicopter and many fixed-wing air ambulance transports are emergent and almost always unscheduled, and all emergency air ambulance flights must be requested by a physician or trained first-responder. In rural areas, the services are critical to saving lives but the number of flights may be lower and even less predictable than in more populated areas. None of these factors align with the volume discounting model employed by plans and issuers, and so it should come as little surprise that dominant payers have foregone network contracting.

The Departments should align their statements in IFR Part II with historical market conditions, or

at least acknowledge the good-faith, fact-based disagreement that AAMS members have with the insurance industry about those conditions. Our members work tirelessly to reach in-network agreements that adequately cover the cost of services and it is incorrect to state that air ambulance providers are staying out-of-network as a business tactic. AAMS believes that a misunderstanding of historical market conditions and the business practices of providers and payers has skewed policy toward the QPA methodology and other aspects of IFR Part I. That misunderstanding should be corrected.

II. The Departments Should Fix the QPA Methodology, which is Fundamentally Flawed

The QPA methodology in IFR Part I will have unintended consequences for access to emergency air ambulance services, especially in rural America. We view the QPA as a tool for holding patient cost sharing to reasonable levels, particularly in emergency situations, and not as a final rate-setting mechanism. The QPA, however, factors into the selection of the final payment amount in IDR, and other commenters have asked the Departments to put a thumb on the scale by ordering IDR entities to give primary weight to the QPA. The conversion of IDR into a rubber stamp for the QPA would be awful policy because the QPA methodology in IFR Part I will already produce QPAs that are below fair and reasonable payment amounts for air ambulance services, and therefore threaten the economic viability of air ambulance providers. If air ambulance providers have no meaningful recourse in the IDR process, and must accept QPAs as final, then they will be forced to exit the market and patients will lose access to their critical services. We discuss the fundamental flaws in the current QPA methodology below.

***The QPA Methodology Lumps Dissimilar Air Ambulance Providers Together*:** Under IFR Part I, the median contract rate for the QPA turns on the rates for the "same or similar item or service" rendered by a provider in the same or similar specialty in the geographic region. In their definition of "same or similar item or service," the Departments failed to draw critical distinctions between those that bill for services through a hospital system and those that do not, emergency rotor-wing and emergency and non-emergency fixed wing providers, and active and shuttered providers. Each of these distinctions can drive the costs of delivering the service, as well as the rate negotiated between the provider and the plan or issuer. Yet the Departments lumped all of the arrangements together to derive one median amount, which is an inherently unreliable methodology.

For example, a hospital system that contracts with an air ambulance provider may enter into an agreement with a plan or issuer based on the full range of hospital services, including rates for air ambulance services that the hospital system no longer offers or hopes to offer in the future. These rates may be far below market rates and may be included in the final contract without any negotiation because the hospital system will never seek payment for the air ambulance services and, therefore, has no incentive to negotiate an adequate amount.

In contrast, providers of air ambulance services who only bill for those services must ensure that rates with plans and issuers are sufficient to maintain services in a community. Otherwise, they cannot cover their costs. It is not credible for the Departments to treat independent rates negotiated at arm's length the same as below-market, phantom rates that are accepted by hospital systems because they will never be charged to plans or issuers.

The Departments acknowledge legitimate differences between contracting arrangements elsewhere in IFR Part I. Notably, the Departments recognize that standalone emergency departments may have a different relationship to plans and issuers when compared to emergency departments that bill through a hospital system.[1] The Departments should similarly recognize the distinctions between air ambulance contracting arrangements.

***The QPA Methodology Arbitrarily Excludes Relevant Data*:** The QPA methodology excludes a wide range of contracts that make up the market today and, instead, focuses on only a small portion of payment arrangements. The QPA methodology excludes, for example, historic out-of-network payments, letters of agreement, arrangements used to supplement a payer's network, incentive-based and retrospective arrangements, and single case agreements ("SCAs"). Given these broad exclusions, the methodology will not produce QPAs that reflect how payers and providers have historically resolved payment disputes at arm's length, nor will the methodology measure of the cost of services. Rather, the QPA will capture the small number of in-network arrangements that payers and providers negotiated at arm's length, together with arrangements that were accepted without vigorous negotiation (including, for example, the hospital system contracts described above). Instead of using complete and robust data to build a bridge to fair and sustainable payments, the QPA will have the unintended consequence of exacerbating the historical market conditions that prompted Congress to pass the Act in the first place.

The inclusion of all relevant contractual arrangements is important because no reliable database exists to determine a median contracted rate for air ambulance services in the case of "insufficient information." There is no existing database that contains a representative number of the air ambulance transports in a given state. Nor is there an existing database that distinguishes between emergency and non-emergency transports. At this juncture, the only viable pathway for generating a fair and reliable QPA is to include all relevant contractual arrangements in the QPA methodology. Going forward, AAMS is interested in creating a database and welcomes the opportunity to partner with the Departments in establishing one.

***Census Divisions Will Produce Absurd Results*:** If there is an insufficient number of contracted rates at the state level to determine a median contracted rate, then IFR Part I requires the determination of the QPA using all metropolitan statistical areas ("MSAs") in a Census division or all other areas in the Census division. Given the unique nature of air ambulance services, this means that a rate from Hawaii or Alaska may dictate the QPA for a pick-up in California. We do not believe this is what Congress envisioned when it tied payment rates to geography. The features of one geographically and economically unique market should not dictate payments in another completely different market. There are better approaches—such as including SCAs and historic payment rates in the QPA methodology—that do not mix payment rates established in markets that are thousands of miles, and in some instances oceans apart.

[1] 86 *Fed. Reg.* 36,872, 36,892 (July 13, 2021) ("[W]here a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute.")

In sum, the final QPA methodology should: (1) differentiate between air ambulance provider types, (2) include SCAs in the definition of "contracted rate" and consider historical payment information, and (3) remove Census divisions from the geographic region definition. Together, these changes might produce QPAs that more closely approximate fair market rates and might better sustain access to air ambulance services.

The Departments Should Mitigate the Unintended Consequences of the QPA: Regardless of whether the Departments elect to address flaws in the QPA methodology, the Departments should, at a very minimum, include provisions in the Part II rule to mitigate the unintended consequences of the QPA methodology. As a first step, they should require payers to disclose information about the limitations of the QPA to providers. The information should include: the number of contracts used to calculate the QPA; the rates, types of air ambulance providers, and volumes of claims in the QPA; out-of-network volume and payment amounts; volume and payment amounts for all other arrangements (e.g., SCAs); and a description of each contract omitted from the QPA methodology and the reasons for the omission. Disclosure of this information will allow providers to assess whether payers' calculations were performed correctly and will better equip both parties to evaluate the reasonableness of their positions. If providers have confidence that the calculations were correct and that the median is based on a sufficient number of contracts and is reasonable, then the likelihood of settlement will increase, and the resort to IDR will decrease. Such disclosures will align with the Departments' goal of promoting greater cost transparency and could go a long way in reducing the number of disputes that enter IDR, which is good for patients, providers, and payers alike.

In addition, the Departments should instruct IDR entities to give the QPA no presumptive or special weight in the IDR process. IDR entities should evaluate payments to air ambulance providers with an open mind and the benefit of payer disclosures on the limitations of the QPA. If the QPA methodology is finalized in its current form, it will not be reliable for any purpose besides calculating patient cost sharing. The IDR entity should have an understanding of these limitations and should be able to consider the QPA in context.

III. The Departments Should Align Their Approach to Coverage Denials with the Act

The Act establishes that payers must issue an initial payment or notice of denial of payment within 30 days of receiving the information necessary to make a claim determination. However, the Departments state in the IFR that the term "notice of denial of payment" does not include a notice of benefit denial due to an adverse benefit determination ("ABD"). The Departments note that there is supposedly a "significant distinction" between an ABD (which may be disputed through the appeals processes), and a denial of payment or initial payment that is less than the billed amount (which may be disputed through IDR).

We believe the Departments have misinterpreted the Act and that IFR Part I effectively enables payers to exempt claims from the IDR process and the ban on surprise billing by denying the claims on coverage grounds (e.g., medical necessity). In these instances, the payer will neither send an initial payment or notice of denial of payment to the provider, and the provider will never reach the IDR process. The provider instead sends a surprise bill to the patient, who may appeal the payer's ABD through the payer's internal and external appeals processes.

The process under IFR Part I is inconsistent with the text and structure of the Act. Section 105(a)(1) of the Act says that if a participant, beneficiary, or enrollee receives air ambulance services from a nonparticipating provider, and the individual's plan or coverage covers "such services" when rendered by a participating provider, then the group health plan or health insurance issuer must send an initial payment or notice of denial of payment to the provider not later than 30 calendar days after the nonparticipating provider transmits the bill for "such services." The plan's or issuer's obligation attaches if the plan or coverage covers at least some services in the general class of air ambulance services, in at least some circumstances. If the plan or coverage excludes all participating air ambulance services, only then is the plan or issuer relieved from the obligation to send an initial payment or notice of denial of payment. Absent an unusual situation, where the plan or coverage excludes all participating air ambulance services, the Act gives payers a binary choice: issue a payment or issue a notice of denial of payment. The Act does not provide for a third option nor does it draw a distinction between the types of notices of denial that are subject to the Act.

The IFR Part I approach is self-defeating on its face because it necessarily perpetuates the practice of surprise billing. Under IFR Part I, providers render emergency care only for a payer to later determine that the care was unnecessary and deny coverage. Providers left with unreimbursed services may then bill a patient, or otherwise risk financial harm, and the patient receives no protection under the Act. Congress passed a law to end surprise billing, and plainly did not intend for surprise billing to continue in the matter allowed by IFR Part I.

Based on our experience, the unintended consequences of the IFR will be stark. Payers deny more than 50 percent of claims for nonparticipating air ambulance services on coverage grounds. Yet, our members typically tell us that approximately 90 percent of those denials are later overturned on appeal, which means that patients must appeal 45 – 55% percent of all claims for nonparticipating air ambulance services to obtain the payments to which they were always entitled. The practice of denying nonparticipating air ambulance claims initially and then providing coverage following appeal is rampant. This practice has the effect of stalling payments for services, and the finalization of IFR Part I would only perpetuate this practice. IFR Part I would maintain the status quo by keeping patients in the middle of more than 50 percent of air ambulance payment disputes. We do not believe that Congress or the Departments intend for this result.

The Departments should align the final Part I rule with the text and structure of the Act, and include coverage denials (including medical necessity denials) in the regulatory definition of "notice of denial of payment." Alternatively, the Departments should use the Part II rulemaking to require payers to cover all emergency air ambulance services as essential health benefits whenever they qualify as emergency services rendered in connection with an emergency medical condition under the "prudent layperson" standard. The application of the "prudent layperson" standard during the initial claims adjudication would greatly reduce the number of coverage denials.

IV. The Departments Should Encourage Transparency by Authorizing Responses in IDR, and Reject Restrictions That Would Render IDR a Rubber Stamp for the QPA

The Departments should make the information that the parties disclose to one another in open negotiations admissible in IDR, require the parties to share their submissions to the IDR entity with one another, and make clear that the only mandatory exemptions of those materials from public disclosure are the ones established by the Freedom of Information Act (FOIA). Anything less than maximum transparency in the IDR process will enable parties to game the IDR system by withholding information from both the IDR entity and the public that is material to the decision-making process and integral to a fair resolution on the merits.

Fairness also requires an opportunity to respond to new information that a party withheld during open negotiations, and disclosed for the first time in its submission to the IDR entity. The Act imposes a 10-day statutory deadline for both sides to submit claims and supporting information to the IDR entity. But the Act authorizes the Secretary to modify that deadline for "extenuating circumstances." The Departments should include a provision in the Part II rule that defines "extenuating circumstances" to include a submitting party's presentation of information that was not disclosed during open negotiations, and that requires the IDR entity to grant the receiving party at least 5 days to respond to such information. A procedural right to respond to new information will encourage transparency during open negotiations and prevent unfair surprise.

The Departments should approach the batching of claims and management of the IDR entities in a manner that is consistent with policies underlying the Federal Rules of Civil Procedure. The Federal Rules facilitate the joinder of parties and claims to promote judicial economy and efficiency, avoid duplicative actions, and reduce costs. The Departments should liberally construe terms such as "the same provider or facility," the "same party," and items and services "related to the treatment of a similar condition" with the aim of enabling the batching of claims to the fullest extent (and thereby reducing the number of IDR proceedings). The Departments should authorize the batching of claims for periods of up to 180 days, and the Departments should not apply any caps on the total fees payable to the IDR entity for a single proceeding, as such caps would frustrate the ability of the IDR entity to adjudicate large batches of claims at reasonable hourly rates. Such an approach would create a strong incentive for settlement of large numbers of claims during open negotiations.

Finally, and perhaps most importantly, the Departments should not delay the availability of the IDR process past the effective date of the statutory ban on balance billing. Such a delay would contravene the text or structure of the Act, and would not be a valid exercise of any type of enforcement discretion. Moreover, the lack of a functional IDR process for any period of time after the effective date of the statutory ban on balance billing would prejudice air ambulance providers because it would disrupt their cash flow and put them at an unfair and material disadvantage in any informal payment negotiations with payers. The Departments should not begin the implementation of the Act with a delay that skews the playing field in favor of payers at the expense of air ambulance providers.

Unless IDR is available concurrent with the ban on balance billing, provides for the robust and

public exchange of information between the parties and the IDR entity, and allows for liberal batching of claims, without any requirement to afford the QPA special weight, IDR will be little more than a rubber stamp for the QPA and its many flaws. All parties deserve a fairer and more transparent process that allows for consideration of all relevant information.

***

Thank you for the opportunity to provide comments on the IFR. We believe it is critical to protect patients' use of air ambulance services, both in emergency and nonemergency situations. Air ambulance services are essential to our healthcare system and there must be a reliable mechanism in place to financially support these operations. We look forward to working with the Departments as the Act is implemented and hope to serve as a resource for addressing the provisions related to air ambulance services. If you have any questions, please contact AAMS Vice President of Public Affairs Christopher Eastlee at ceastlee@aams.org.

Sincerely,

Cameron Curtis, CMM, CAE
President & CEO
Association of Air Medical Services

Debbie Boudreaux MSN, RN, LP

Deborah Boudreaux, MSN, RN, CCRN, C-NPT, LP, CMTE
Chairman and Region IV Director, AAMS
Teddy Bear Transport, Cooks Children Medical Center

Exhibit 5

ASSOCIATION OF AIR MEDICAL SERVICES

December 6th, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Ave N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, DC 20220

Dear Secretaries Becerra, Walsh and Yellen:

I write to offer the views of the Association of Air Medical Services (AAMS) on the tri-departmental Interim Final Rule ("IFR"), *Requirements Related to Surprise Billing; Part II*, as prescribed by the No Surprises Act, Pub. L. No. 116-260 (2020) (the "Act"). AAMS is the international trade association that represents over 93 percent of air ambulance providers in the U.S. Together, our over 300 members operate nearly 1,000 helicopter air ambulances and 200 fixed wing air ambulance services across the U.S. AAMS represents every emergency air ambulance care model, including aircraft based at hospitals, independent aircraft at bases in rural areas far from hospitals, and many hybrid variations.

AAMS strongly supports the purpose of the Act, which is removing patients from payment disputes between healthcare providers and payers, through an independent dispute resolution ("IDR") process, while maintaining patient cost sharing at participating levels. However, we are gravely concerned about the negative consequences that will result from the implementation timeline, cost sharing and payment methodologies, and IDR process, as currently drafted.

We believe the IFR threatens the sustainability of air ambulance services and places traditionally underserved communities at risk of reduced access to care. The qualifying payment amount ("QPA") methodology and the Departments' presumption that the QPA is the appropriate out-of-network rate to be selected in IDR will create a race to the bottom in which existing contracts are destabilized and reimbursement drops to an unsustainable level. Instead of simply removing patients from payer-provider payment disputes, the Departments have put patients at risk by making it harder for air ambulance providers to sustain operations and deliver life-saving care. Air ambulance providers can only operate if they receive fair, adequate payments that cover the costs of delivering services. Fair payments are essential to preserving the emergency medical system that saves American lives every day.

Without adequate reimbursement, air ambulance providers may be forced to exit the market or reduce services, leaving patients in emergent situations with few options. This is not the outcome Congress intended when it passed the Act. We urge the Departments to consider the negative impacts the regulations will have on underserved communities and, instead, take a more equitable approach to ensure that access to care is possible, regardless of location.

In this comment letter, we offer several considerations that the Departments should take into account as you revise the regulation, including recommendations in the following key areas:

I. Navigating Implementation
II. Qualifying Payment Amount
III. Weighting of Factors in IDR
IV. Transparency in IDR
V. IDR Entity Certification
VI. Batching of Claims

* * *

I. Navigating Implementation

We appreciate the ambitious timeline that Congress prescribed in the Act and the Departments' efforts to achieve those milestones to protect consumers from surprise bills. However, the IFRs involve significant, industry-wide changes to day-to-day practices that require time, resources, and careful attention to implement correctly. These changes were initiated and adopted without notice and comment. And, where we engaged with Congressional Members during the design and passage of the Act, we have not seen the intent and vision of those Members, nor our discussions, carried through in the Departments' regulations.

We believe the Departments can achieve the goal of the Act if they provide stakeholders more time to understand, test, and provide thoughtful recommendations on the policies. We have just begun to identify the barriers to implementation and are anticipating many more hurdles ahead. To that end, the Departments should engage more deeply with the air ambulance provider community, so that concerns and solutions can be openly shared and addressed.

The Departments should also exercise enforcement discretion as stakeholders work to become compliant with the new requirements, which are far-ranging and complex (e.g., data reporting,

and more). The Departments have demonstrated a willingness to exercise enforcement discretion for group health plans and issuers. They should extend comparable regulatory relief to air ambulance providers that are making good faith, reasonable efforts to implement the Act. We urge the Departments to use their enforcement discretion as the IFRs are implemented; to work with the air ambulance provider community as obstacles are identified; and to provide reasonable and timely clarification, when needed.

II. Qualifying Payment Amount

The QPA methodology described in IFR Part I and reinforced in IFR Part II will have unintended consequences for access to emergency air ambulance services, especially in rural America. The Departments posit that the QPA is a median contracted rate that "generally reflect[s] market rates."[1] The QPA methodology, however, arbitrarily excludes from the median calculation certain types of contracts, like single case agreements and alternative payment arrangements (collectively, "SCAs"), that are commonplace in the air ambulance industry. The magnitude of the exclusion is material; AAMS members representing 236 air bases (approx. 25% of the national air bases) report that, in 2019, 38%-56% of out-of-network claims were resolved through SCAs. The result is that under the QPA methodology, the QPA does not reflect market rates.

The QPA methodology also treats all types of air ambulance providers the same – lumping together in the same category those providers that negotiate with insurers as part of a larger hospital system and those providers that negotiate independently Plus, if there is an insufficient number of contracted rates at the state level to determine a median, then IFR Part I requires the QPA to be determined using all metropolitan statistical areas ("MSAs") in a Census division or all other areas in the Census division. This means that an air ambulance provider's reimbursement may derive from amounts paid several states, or even an ocean, away.

This methodology will depress reimbursement. Congress tasked the Departments with implementing a framework that would remove patients from payment disputes and allow for the swift resolution of disagreements. Instead, the Departments have distorted the statutory framework to reduce payment on a national scale – something Congress considered and rejected. This is not a theoretical problem. We were alarmed to see a now widely-circulated letter by BlueCross BlueShield of North Carolina, which uses the QPA as a lever to immediately terminate and renegotiate provider contracts.[2] We are concerned that this is only the start of contract terminations and that, in straying from Congress's intent, the Departments have put patient access to care at risk. As payers terminate contracts and drive reimbursement to levels at or below the administratively depressed QPA, air ambulance providers will be forced to make difficult, but necessary, business decisions. Our members simply cannot operate where expenses exceed reimbursement. This means that transports may be reduced, including in rural, underserved areas. This is not what Congress intended in implementing the Act.

[1] 86 *Fed. Reg.* 55,980, 56,060.

[2] *See e.g.,* J. Lagasse, *American Society of Anesthesiologists Accuses BCBSNC of Abusing No Surprises Act*, Healthcare Finance (Nov. 23, 2021). Accessible at: https://www.healthcarefinancenews.com/news/american-society-anesthesiologists-accuses-bcbs-north-carolina-abusing-no-surprises-act.

For these reasons and more, we ask that the Departments fix the QPA methodology and we discuss each of the fundamental flaws below.

***The QPA Methodology Arbitrarily Excludes Relevant Data*:** The QPA methodology excludes contracted rates from a wide range of contracts, including SCAs, letters of agreement, arrangements used to supplement a payer's network, incentive-based and retrospective arrangements. Given these broad exclusions, the methodology will not produce QPAs that reflect all contracted rates, nor will it account for the cost of services. Rather, the QPA will reflect the comparatively smaller number of rates from in-network contracts, including contracts that were accepted without vigorous negotiation (as described below). This will exacerbate the historic market conditions that prompted the need for the Act in the first place.

Instead, all contracted rates should be included in the QPA calculation, especially since no reliable database presently exists to determine a median contracted rate for air ambulance services in the case of "insufficient information." There is no existing database that contains a representative number of the air ambulance transports in a given state. AAMS is interested in working with the Departments to create such a database. However, in the interim, the only avenue for generating a fair, reliable QPA is to include all contracted rates in the methodology.

***The QPA Methodology Should Differentiate Between Air Ambulance Provider Types*:** The QPA is the median contracted rate for the "same or similar item or service" rendered by a provider in "the same or similar specialty" in the geographic region. The Departments lump all air ambulance providers into "the same or similar specialty," and fail to draw critical distinctions between those that bill for services through a hospital system and those that do not, emergency rotor-wing and emergency and non-emergency fixed wing providers, and active and shuttered providers. Each of these distinctions can drive the costs of delivering the service, as well as any contracted rate negotiated between the provider and the payer.

This is an unreliable approach because it does not account for critical differences in an entity's structure and contracting practices. For example, a hospital may enter into an agreement with a payer based on a broad range of services, including rates for air ambulance services. In some instances, a hospital may agree to rates for air ambulance services without actually offering the services. Such rates may be far below market, and may be included in the contract without any negotiation because the hospital will never seek payment.

In contrast, providers of air ambulance services who only bill for air ambulance services must ensure that rates are sufficient to maintain services. Otherwise, they cannot cover their costs. It is not rational for the Departments to treat independent rates negotiated at arm's length the same as below-market, ghost rates that are passively accepted by hospitals because they will never be charged to payers.

The Departments acknowledge legitimate differences between independent and hospital providers elsewhere in IFR Part I. Notably, the Departments recognize that standalone emergency departments may have a different relationship to payers when compared to

emergency departments that bill through a hospital system.[3] The Departments should similarly recognize the distinctions between air ambulance providers.

***The Use of Census Divisions Will Produce Absurd Results*:** While we appreciate the Departments' efforts to base the QPA on sufficient information, the use of Census divisions in the context of air ambulance services means that a rate from Hawaii or Alaska may dictate the QPA for a pick-up in California. We believe this approach, again, reflects a misunderstanding of the unique nature of air ambulance services. Congress tied payment rates to geography because it understood that healthcare is local or regional and that the unique features of a market varies by geography and economy. The circumstances of a rural county in Alaska should not dictate payments for services in Los Angeles, California. There are better approaches to reaching a sufficient number of rates – such as including SCAs and historic payment rates established in the same market – that do not involve comparing markets that are thousands of miles apart.

***The Departments Should Mitigate the QPA's Unintended Consequences*:** Regardless of whether the Departments address flaws in the QPA methodology, the Departments should, at a minimum, work to mitigate the unintended consequences of the methodology. As a first step, payers should be required to disclose additional information about the limitations of the QPA to providers. As drafted, payers are required to communicate very little information about the QPA to providers and there is no opportunity for providers, or the Departments, to confirm that payers have taken the necessary and correct steps to reach the final amount. The Departments have placed a significant amount of trust in payers to understand and calculate this complex sum, with hardly any oversight or checks and balances.

To promote transparency and confidence in the QPA, payers should disclose: the number of contracts used to calculate the QPA; the rates, types of air ambulance providers, and volumes of claims in the QPA; out-of-network volume and payment amounts; volume and payment amounts for all other arrangements (e.g., SCAs); and a description of each contract omitted from the QPA methodology and the reasons for the omission. Disclosure of this information will allow providers to assess whether payers' calculations were performed correctly and will better equip both parties to evaluate the reasonableness of their positions. If providers have assurance that the amount is accurate and based on a sufficient number and range of contracts, the number of claims brought to IDR will likely be reduced.

In addition, the Departments should instruct IDR entities on the limitations of the QPA. IDR entities should evaluate payments to air ambulance providers with an open mind and with a clear-eyed understanding of what the QPA does and does not represent. The IDR entity should be able to consider the QPA in context and, based on all of the circumstances Congress articulated in the statute, make a sound selection of the appropriate out-of-network rate.

[3] 86 *Fed. Reg.* 36,872, 36,892 (July 13, 2021) ("[W]here a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute.")

III. Weighting of Factors in IDR

***IDR Entities Should be Free to Weigh the Circumstances that Congress Mandated for Payment Determinations*:** The Act establishes certain criteria that an IDR entity must weigh when determining which payment offer to select, including the QPA, the provider or facility's level of training, experience, and quality and outcomes measurements, and more. The IFR, however, ignores these factors and instead requires arbiters to "select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate [.]"[4] This approach directly conflicts with the process Congress designed.

The Act states that the IDR entity "shall consider" the list of circumstances enumerated, and the QPA is but one of those factors.[5] Congress likely designed the IDR process to consider multiple circumstances because no two patients are alike. The cost of services may vary from case to case based on the severity of the condition, the expertise of the provider/s involved, the patient's underlying conditions, and more. The presumption that the QPA is the appropriate out-of-network rate ignores these realities to the detriment of providers and their patients.

The Departments also add qualifying terms (i.e., "credible information" and "materially different") that are not included in the Act, further diminishing the relevance of the additional circumstances that Congress directed the IDR entities to consider. These qualifiers create a much higher bar for providers to meet and impose an additional step in the resolution process.

The result is that the Departments have transformed the IDR process enacted by Congress into a perfunctory rubber stamp for an administratively depressed QPA. Instead of considering all circumstances mandated by Congress, evaluating the parties' arguments, and reaching an independent conclusion, IDR entities must award the QPA in all but the most exceptional cases. This approach is inconsistent with the statute. If Congress had meant for the QPA to be the appropriate out-of-network rate, then it would have said so. Instead, Congress created an IDR in which the QPA is one of many factors that IDR entities must consider when determining the appropriate out-of-network rate.

Congress's design was to encourage payers and air ambulance providers to resolve their monetary disputes through negotiations between each other to avoid having to risk it all in an IDR determination with little guidance as to what a particular IDR entity would view as the reasonable payment amount. And, even if the parties could not reach an agreement through negotiations, final-offer dispute resolution creates strong incentives for both sides to put forth their most reasonable offer and then for the certified IDR entity to choose the one that it deems most reasonable. The need to make a reasonable offer is reinforced by the statute's obligation on the losing party to bear the costs of the IDR process.

Congress' design is effective because it offers a dispute resolution process that is *un*predictable. Despite this design, the Departments concluded that "emphasizing the QPA will allow for

[4] 86 *Fed. Reg.* 55,980, 55,984.
[5] Public Health Service Act (PHSA) § 2799A-2(b)(5)(C).

predictability."[6] The IFR states "[t]his certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor" and "may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period."[7] Therefore the express purpose of IFR Part II is to destabilize the foundation on which the dispute resolution is built and to render the process effectively meaningless. Congress created an independent dispute resolution process because it wanted an *independent* dispute resolution process, not one in which outcomes were predetermined.

The Departments should revise their regulations to align with the process Congress intended. IDR entities should have the discretion to weigh all of the circumstances mandated by Congress, consider the parties' arguments, and make independent decisions.

IV. Transparency in IDR

***The Departments Should Encourage Transparency in IDR*:** The Departments should make the information that the parties disclose to one another in open negotiations admissible in IDR, require the parties to share their submissions to the IDR entity with one another, and make clear that the only mandatory exemptions of those materials from public disclosure are the ones established by the Freedom of Information Act ("FOIA"). Anything less than maximum transparency in the IDR process will permit parties to game the IDR system by withholding information from both the IDR entity and the public that is material to the decision-making process and integral to a fair resolution on the merits.

Fairness also requires an opportunity to respond to new information that a party withheld during open negotiations, and disclosed for the first time in its submission to the IDR entity. The Act imposes a 10-day statutory deadline for both sides to submit claims and supporting information to the IDR entity. But the Act authorizes the Secretary to modify that deadline for "extenuating circumstances." The Departments should define "extenuating circumstances" to include a submitting party's presentation of information that was not disclosed during open negotiations, and that requires the IDR entity to grant the receiving party at least 5 days to respond to such information. A procedural right to respond to new information will encourage transparency during open negotiations and prevent unfair surprise.

V. IDR Entity Certification

***The Departments Should Require that IDR Entities Request Average Non-Contracted Paid Claims Amounts From the Parties*:** The IFR outlines a process for certifying IDR entities to ensure they carry out their responsibilities. The Act authorizes the Departments to revoke an IDR entity's certification if it demonstrates a pattern or practice of noncompliance. Separately, the Act requires the parties to submit to the IDR entity (i) an offer for a payment amount, and (ii) "such information as requested by the certified IDR entity." Together, these provisions authorize the Departments to require IDR entities to request specific information from parties in IDR as a

[6] 86 *Fed. Reg.* 55,980, 56,061.
[7] *Id.*

condition of IDR certification.

We recommend that the Departments require IDR entities to request that, with respect to a dispute regarding calendar year 2022, the provider submit the average non-contracted paid claims amount during calendar year 2019 (to be updated by an inflation factor with respect to a dispute regarding a future calendar year). This information is important because it reflects the amounts that payers were willing to offer before the Act was implemented. The information will provide the parties and the IDR entity with a more complete and transparent factual basis for assessing the dispute. The failure to request this information should result in decertification of the IDR entity.

VI. Batching of Claims

***The Departments Should Clarify the Definitions Associated with the Batching of Claims; Allow Air Ambulance Providers to Batch Base and Mileage Rates*:** The Act allows multiple qualified IDR dispute items and services to be considered jointly in one determination if they are: (i) furnished by the same provider or facility; (ii) payment is made by the same health plan or issuer; (iii) items or services rendered are related to the treatment of a similar condition; and (iv) items or services were furnished during the same 30-day period or an alternative period as determined by the Secretary. The IFR refines the definition of "same provider or facility" to include entities that bill with the same National Provider Identifier ("NPI") or Taxpayer Identification Number ("TIN").

However, the Act and IFR do not define "same health plan or issuer." We believe that the Departments intend to refer to a specific health plan in the market and not to a payer's parent organization, which may operate on a regional or national basis. If the Departments were to interpret the definition as applying at the parent organization level, it would create a significant backlog as every claim associated with a national payer is forced to wait out the cooling off period. This would be contrary to Congress's vision of establishing an "efficient" resolution process. We request confirmation of this understanding.

Next, the IFR adds a conflicting definition of "items or services." While the Act defines items or services as related to the treatment of a similar condition, the IFR defines items or services as "billed under the same service code, or a comparable code under a different procedural code systems [.]"[8] Service codes are defined according to CPT, HCPCS, or DRG codes. We believe that the Departments should apply the Act's broader definition, with the aim of enabling the batching of claims to the fullest extent (and thereby reducing the number of IDR proceedings).

Similarly, we request that the Departments clarify the ability to bundle air ambulance base rates and milage rates in one payment determination. Every air ambulance flight is billed with a base rate and loaded miles. Under the current structure, it is not clear whether these amounts may be batched in one resolution. It appears that payers may issue separate QPAs for the base rate and mileage and that these amounts will then the deemed separate items or services. This means that for each air transport, an air ambulance provider might need to initiate two IDR processes for: (i) base rates involving the same NPI, same payer, and in the same 30-day window; and (ii)

[8] 86 *Fed. Reg.* 55,980, 55,994.

milage rates involving the same NPI, same payer, and in the same 30-day window.

This approach would create tremendous inefficiencies and essentially double the IDR disputes involving air ambulance providers. Rather, the Departments should clarify that, given the nature of air ambulance services, base and mileage rates go hand-in-hand and should be considered in the same determination.

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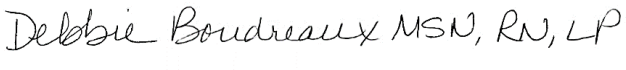
Thank you for the opportunity to provide comments on the IFR. We believe it is critical to protect patients' use of air ambulance services, both in emergency and nonemergency situations. Air ambulance services are essential to our healthcare system and there must be a reliable mechanism in place to financially support these operations. We are concerned that the IFR will have serious, unintended consequences, particularly for underserved and rural communities, and we urge the Departments to consider our recommendations. If you have any questions, please contact AAMS Vice President of Public Affairs Christopher Eastlee at ceastlee@aams.org.

Sincerely,



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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civ. No. 1:21-cv-3031 (RJL)

[PROPOSED] ORDER

Upon consideration of Plaintiff's Motion for Summary Judgment and any opposition and replies thereto, it is hereby

ORDERED that Plaintiff's Motion is **GRANTED**; and

ORDERED that the following portions of the interim final rules were issued in violation of the Administrative Procedure Act, and they are hereby vacated:

- 45 C.F.R. § 149.510(c)(4)(ii)(A), 26 C.F.R. § 54.9816-8T(c)(4)(ii)(A), and 29 C.F.R. § 2590.716-8(c)(4)(ii)(A)'s direction that "[t]he certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer."

- 45 C.F.R. § 149.520(b)(2), 26 C.F.R. § 54.9817-2T(b)(2), and 29 C.F.R. § 2590.717-2(b)(2)'s related direction limiting consideration of "Additional information submitted by a party" only to information that is "credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section," and "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate."
- 45 C.F.R. § 149.140(a)(1), 26 C.F.R. § 54.9816-6T(a)(1), and 29 C.F.R. § 2590.716-6(a)(1)'s direction that "[s]olely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract."
- 45 C.F.R § 149.140(a)(7)(ii)(B), 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B), and 29 C.F.R. § 2590.716-6(a)(7)(ii)(B)'s provision that "[i]f a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605)."

- 45 C.F.R. § 149.140(a)(12), 26 C.F.R. § 54.9816-6T(a)(12), and 29 C.F.R. § 2590.716-6(a)(12)'s provision that "except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty."

Dated: _____

_____
RICHARD J. LEON
UNITED STATES DISTRICT JUDGE