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)

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."

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Respectfully submitted,

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