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.	No. 1:21-cv-03031-RJL Consolidated with No. 1:21-cv-03231-RJL

DEFENDANTS' SUPPLEMENTAL BRIEF

Pursuant to this Court's instructions at the hearing that it held in these consolidated cases on March 21, 2022, and this Court's minute order entered on the same day, the Defendants respectfully submit this supplemental brief to address issues raised during that hearing.

I. THE DEPARTMENTS ADOPTED A REASONABLE METHODOLOGY TO CALCULATE THE QUALIFYING PAYMENT AMOUNT.

The No Surprises Act defines the "qualifying payment amount," or QPA, in general, to be "the median of the contracted rates recognized by the plan or issuer, respectively … as the total maximum payment … under such plans or coverage, respectively, on 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," subject to an inflation adjustment. 42 U.S.C. § 300gg-111(a)(3)(E)(i). Because the statute bases the calculation of a patient's cost-sharing obligation for an out-of-network medical service (in the absence of a statutory exception) on the qualifying payment amount, the statutory definition "ensur[es] that any coinsurance or deductible is based on rates that would apply for the services if they were furnished by a participating provider, given that the QPA is generally based on median contracted rates, as opposed to rates charged by nonparticipating providers[.]" 86 Fed. Reg. 36,872, 36,884 (July 13, 2021).

The Act instructs the Departments to develop the methodology under which the qualifying payment amount is set for a given medical service. 42 U.S.C. § 300gg-111(a)(2)(B)(i). The Departments exercised this authority to fulfill Congress's purpose "to protect participants, beneficiaries, and enrollees from excessive bills," 86 Fed. Reg. at 36,884, by adopting a methodology under which the qualifying payment amount stands in for the payment rate that would have applied if the provider and the plan or issuer had negotiated an in-network rate before the service was furnished to the patient. The Departments' methodology is reasonable, and should be upheld by this Court.

1. In particular, the Departments interpreted the statutory phrase "contracted rates," 42 U.S.C. § 300gg-111(a)(3)(E)(i), to refer "only to the rate negotiated with providers and facilities that are contracted to participate in any of the networks of the plan or issuer under generally applicable terms of the plan or coverage and [to] exclude[] rates negotiated with other providers and facilities," 86 Fed. Reg. at 36,889. The Association of Air Medical Services (AAMS) protests that this definition excludes payment amounts that are set in "single case agreements" that are negotiated after the fact between plans and issuers and out-of-network providers.

AAMS's approach would defeat a central purpose of the No Surprises Act, which is to protect patients from excessive charges claimed by out-of-network providers. Some providers—including air ambulance service providers in particular—have adopted a business strategy to remain out of network and to demand higher prices after a service is furnished, rather than to negotiate an in-network payment rate for the service in advance. Because the "very high costs" of air ambulance services that result from this business strategy can be financially devastating for patients, plans and issuers have paid the full amounts charged by out-of-network air ambulance providers about half of the time, even in the absence of any legal requirement to do so. *See* Erin C. Fuse Brown et al., *The Unfinished Business of Air Ambulance Bills*, Health Affairs Forefront (Mar. 26, 2021) (JA 367). This has created a "market failure" that private equity has exploited in recent years, resulting in a spiral of increasing prices for out-of-network air ambulance services that do not bear any reasonable relationship to the actual cost of furnishing those services. *See* Loren Adler et al., *High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers*, USC-Brookings Schaffer on Health Policy (Oct. 13, 2020) (JA 596). The No

Surprises Act addresses this market failure by reducing the economic incentive for providers to remain out of network. And the Departments' rule furthers this statutory goal by ensuring that the qualifying payment amount is calculated on the basis of in-network payment rates, so as to "ensur[e] that the QPA reflects market rates under typical contract negotiations." 86 Fed. Reg. at 36,889. But if the QPA were calculated by reference to single case agreements, as AAMS proposes, the result would be to lock in the inflated charges that air ambulance service providers have demanded recently.

The No Surprises Act does not require such a self-defeating result. A payment amount established by a single case agreement is not a "contracted rate" that is recognized "under such plans or coverage." 42 U.S.C. § 300gg-111(a)(3)(E)(i). A payment arises "under" a plan or coverage if it is "governed by," or is owed "by reason of the authority of," the terms of the plan or policy. *Ardestani v. INS*, 502 U.S. 129, 135 (1991) (defining "under"). A plan or an issuer obligates itself to pay in-network payment rates to providers that are in the network of the plan or policy. Single case agreements, by definition, set payment rates that are not dictated under the generally applicable terms of the plan or policy. If such a payment were so dictated, after all, the provider would be in-network, and no single case agreement would be necessary. The Departments therefore reasonably interpreted the statute to direct them to look to in-network payment rates, rather than payment rates for out-of-network services, to set the qualifying payment amount, and *Chevron* deference is owed to that interpretation.

2. The Departments also reasonably interpreted the No Surprises Act to conclude that all air ambulance service providers are "provider[s] in the same or similar specialty," 42 U.S.C. § 300gg-111(a)(3)(E)(i), without regard to their ownership structure. *See* 86 Fed. Reg. at 36,891. AAMS contends that its members—independently-owned air ambulance operators—should have been treated as a separate "specialty" from hospital-owned air ambulance operators, because as a general rule they have higher contracted rates for the same services than hospital-owned providers do. A particular provider's ownership structure or business practices, however, are not relevant considerations in determining which providers perform "the same or similar specialty." The statutory phrase refers instead to providers who perform the same or similar medical services, that is, providers

in the same "practice specialty," 86 Fed. Reg. at 36,891. All air ambulance service providers perform the same service—medical transportation—no matter their business model.

3. The Departments also reasonably exercised their rulemaking power under 42 U.S.C. § 300gg-111(a)(2)(B)(iii) to define the geographic regions that are used to set the qualifying payment amount. For air ambulance service providers, the Departments primarily defined a "geographic region" as "one region consisting of all MSAs [metropolitan statistical areas] in the state, and one region consisting of all other portions of the state." 86 Fed. Reg. at 36,893; *see* 45 C.F.R. § 149.140(a)(7)(ii)(A). AAMS does not object to this primary definition.

The Departments also prescribed a secondary definition of "geographic region" for air ambulance services, to be used in circumstances where this primary definition leaves the plan or issuer without enough data to calculate a median of contracted rates. Under this secondary definition, the relevant geographic region is "based on Census divisions—that is, one region consisting of all MSAs in each Census division and one region consisting of all other portions of the Census division." 86 Fed. Reg. at 36,893; *see* 45 C.F.R. § 149.140(a)(7)(ii)(B). This backup definition accounts for the "lower prevalence of participating providers of air ambulance services." 86 Fed. Reg. at 36,893. Air ambulance transports are relatively rare to begin with, and at least 70% of these transports have been performed by out-of-network providers in recent years. *See* Brown et al., *The Unfinished Business of Air Ambulance Bills* (JA 367). The Departments accordingly needed to draw regions broadly enough to capture sufficient data on in-network prices so as to allow for a meaningful calculation of the qualifying payment amount. *See* 86 Fed. Reg. at 36,893.

AAMS argues that the Departments should have relied on a commercial database instead of setting a secondary definition for geographic regions. But "[t]here is no existing database that contains a representative number of the air ambulance transports in a given state." Letter of Cameron Curtis, Pres., AAMS, et al., to Xavier Becerra, Secretary, U.S. Dep't of Health and Human Servs., et al., at 4 (Dec. 6, 2021), ECF No. 5-8. AAMS has proposed to develop a database for the Departments, but its proposal contemplates the collection of claims data, not in-network contracted rates. *See* Letter of Cameron Curtis, Pres., AAMS, et al., to Xavier Becerra, Secretary, U.S. Dep't of Health and Human

Servs., et al., at 4-5 (June 15, 2021) (JA 291-292). The Departments reasonably chose to rely on existing market data, rather than developing a database from scratch that, even when completed, would lack data on in-network contracted rates.

II. THIS COURT MAY EXERCISE ITS DISCRETION TO DEFER A DECISION ON THE ARBITRATION RULE.

The Departments have taken comments from the public on the interim final rules that they have issued under the No Surprises Act. They have begun the preparation of a final rule that will address the procedures for arbitrations under the Act, and that will address the provisions of the interim final rule that were vacated by the Eastern District of Texas. *See Texas Med. Ass'n v. U.S. Dep't of Health & Human Servs.*, No. 6:21-cv-425-JDK. 2022 WL 542879 (E.D. Tex. Feb. 23, 2022). Although the Departments had initially anticipated that this final rule would be issued no later than May 2022, they have reassessed this timeline and now anticipate that the rule will be issued by early summer of 2022.

In light of the forthcoming issuance of this final rule, this Court may wish to exercise its discretion to defer ruling on the challenges to the arbitration rule. A ruling on these challenges would be of limited utility, given that the parties will very likely be in a different posture in the near future. *See, e.g.*, *Nat'l Wildlife Fed'n v. EPA*, 925 F.2d 470, 472 (D.C. Cir. 1991) (staying proceedings to permit agency to complete new rulemaking).

If the Court does elect to proceed with a decision, it should hold that the Plaintiffs in the *American Medical Association* case lack standing to proceed with their challenge. In contrast to AAMS, which has challenged a second regulation (45 C.F.R. § 149.520) with independent operative effect, the AMA Plaintiffs challenge the same regulation (45 C.F.R. § 149.510) that was at issue before the Eastern District of Texas, and that Court's order of vacatur fully addresses the injuries that these Plaintiffs have claimed.

The AMA Plaintiffs contend that they still have a live dispute because they challenge two additional provisions in 45 C.F.R. § 149.510 that the Eastern District of Texas did not address. They do not have standing to challenge either provision. The first provision, 45 C.F.R. § 149.510(a)(2)(v),

directs the arbitrator to rely only on "credible information," which the regulation defines to be "information that upon critical analysis is worthy of belief and is trustworthy." The second provision, the third sentence of 45 C.F.R. § 149.510(c)(4)(ii)(A), instructs the arbitrator to select the offer that "best represents the value" of an out-of-network medical service. The AMA Plaintiffs have not alleged that they suffer any injury from an inability to present arbitrators with information that is not worthy of belief, or information that is not trustworthy. Nor have they alleged that they suffer any injury from an inability to recover payment awards that exceed the fair value of their medical services. They accordingly lack standing to challenge these provisions. *See California v. Texas*, 141 S. Ct. 2104, 2119 (2021) (requiring a plaintiff to trace an injury to the specific provision of law that is challenged).

If the Court addresses these provisions on the merits, it should uphold them. Congress entrusted the Departments with the authority to "establish by regulation" the process for arbitrators to determine out-of-network payment amounts. 42 U.S.C. § 300gg-111(c)(2)(A). This rulemaking authority plainly encompasses the power to establish a process under which arbitrators aim to ensure that providers are paid for the actual value of their services, and that in doing so arbitrators base their decisions only on credible evidence. *See, e.g.*, *Nat'l Min. Ass'n v. Dep't of Labor*, 292 F.3d 849, 868 (D.C. Cir. 2002) (according deference to agency's adoption of evidentiary rules for adjudications).

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Respectfully submitted,

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