IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, Plaintiff, v.

No. 1:21-cv-03031-RJL

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure and Local Civil Rule 7(h), the

Defendants respectfully request that the Court award them summary judgment with respect to all

claim presented by the Plaintiff in this action. The grounds for this motion are set forth more fully in

the accompanying memorandum of law.

Dated: January 18, 2022

Respectfully submitted,

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

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DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S SUMMARY JUDGMENT MOTION

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INTRODUCTION

Millions of Americans, at one time or another, may face a critical decision whether to seek health care services "in network" or "out of network"—that is, from a provider that is under contract with the patient's health plan, or from a provider that is not. As anyone familiar with private health coverage can attest, the cost difference between receiving care from an in-network versus an out-ofnetwork provider can be substantial. And, in many cases, a patient might not be able to avoid these costs by choosing an in-network provider.

For example, in an emergency, the patient might be given care by a provider that turns out not to be in their network, or may require an airlift to a hospital with no way of knowing whether the air ambulance provider is in-network or not. Or the patient might carefully schedule a procedure at an in-network facility but, unbeknownst to him or her, a portion of the service could be performed by an out-of-network provider. Cases like these have often led to staggering, and sometimes ruinous, medical bills. What is more, this phenomenon of surprise billing has also inflated the cost of innetwork care, because many providers—air ambulance providers in particular—have simply refused to negotiate for fair in-network payment rates, with the awareness that they could fall back on the option of demanding much higher out-of-network payments.

In late December 2020, Congress enacted the No Surprises Act ("NSA," or "the Act"). The principal aim of the NSA is to address this "surprise billing" problem. The NSA limits a patient's share of the cost of emergency services delivered by out-of-network providers, including air ambulance providers, and of the cost of non-emergency services provided by out-of-network providers in certain in-network facilities absent patient consent. The Act also addresses how a payment dispute in these situations between an out-of-network provider and a group health plan or health insurance issuer will be resolved. The Act creates an arbitration mechanism whereby each party will submit its proposed payment amount and an independent, private arbitrator, known as a "certified IDR entity," will select between the two offers. Congress also directed the Departments that are Defendants in this suit to create rules to establish this arbitration process, and to do so within one year of the NSA's enactment.

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The principal provisions of the Act went into effect on January 1 of this year, and the first arbitrations of payment disputes will likely begin in April. But providers, as well as insurers and group health plans, needed to prepare in advance for their new obligations and responsibilities under the Act. To accommodate this need, the Defendants—the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (the Departments), along with the Office of Personnel Management (OPM)—released two interim final rules, one in July 2021, and a second one in September 2021.

The Plaintiff here, the Association of Air Medical Services, takes issue with portions of each rule. The July rule establishes the methodology for determining a figure that is known in the Act as the "qualifying payment amount," or QPA. This amount is based on the calculation of the median contracted rate for a given medical service—that is, what an insurer or group health plan typically would have paid for the service, if it had been performed by an in-network provider. The determination of this amount plays a central role in the statute, as both patients' cost-sharing responsibilities for out-of-network services and the ultimate determination of the payment owed by a group health plan or health insurance issuer to an air ambulance provider turn, in whole or in part, on this calculation. The Plaintiff contends that the Departments acted arbitrarily in setting the methodology for determining this amount for air ambulance services. It is incorrect; the Departments reasonably determined, and reasonably explained, each of their decisions that went into the calculation of a qualifying payment amount that approximates what the in-network rate for air ambulance services would have been, if that rate had been negotiated in advance.

The Plaintiff also objects to portions of the September rule that instruct the arbitrator, when choosing between the competing amounts proposed by the provider and the group health plan or health insurance insurer, to look first to the qualifying payment amount. It contends that these instructions depart from the text of the Act, which on the Plaintiff's reading leaves it to the arbitrators' virtually unfettered discretion to rely on any information he or she may wish to consider in choosing one of the parties' competing offers. This, again, is incorrect. The September rule comports with the statutory text. The rule, like the statute, sets forth a series of factors for the arbitrator to consider; the

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arbitrator begins with the qualifying payment amount, and then proceeds to consider what the statute describes as "additional" circumstances. The rule leaves ample room for the arbitrator to incorporate these additional circumstances into his or her decision, in accordance with the statute. And *Chevron* deference is owed to both rules, which were promulgated in response to Congressional assignments of authority to the Departments to set the methodology for the qualifying payment amount and to establish the Act's arbitration process.

For all these reasons, the Defendants' motion for summary judgment should be granted, and the Plaintiff's motion for summary judgment should be denied.

BACKGROUND

I. Providers' Surprise Billing Practices Have Imposed Devastating Financial Consequences on Patients and Have Driven Up the Overall Cost of Health Care.

Congress enacted the No Surprises Act to address a "market failure" that gave certain health care providers little incentive to negotiate fair prices in advance for their services, resulting in exorbitant bills to patients and "highly inflated payment rates" for those services. H.R. REP. NO. 116-615, pt. I, at 53 (Dec. 2, 2020).

Most group health plans and health insurance issuers "have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services." *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872, 36,874 (July 13, 2021). "By contrast, providers and facilities that are not part of a plan or issuer's network (nonparticipating providers) usually charge higher amounts" than the in-network rates negotiated between insurers and providers. *Id.* When an individual receives care out of network, the insurer could decline to pay for the services, or could pay an amount lower than the provider's billed charges, leaving the patient responsible for the remainder of the bill. *Id.*

"A balance bill may come as a surprise for the individual." *Id.* Surprise billing occurs, for example, when a patient receives care from a provider whom the patient could not have chosen in advance, or whom the patient did not have reason to believe would be outside the network of the patient's insurance plan. *Id.* These bills frequently arise in the following circumstances. First, in

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emergency situations, a patient may be unable to choose which emergency department he or she goes to (or is taken to); even if the patient goes to an emergency department that is in-network, he or she may still receive care from nonparticipating providers working at that facility. *Id.* Second, a patient may schedule a medical procedure in advance at an in-network hospital or facility, but may not be aware that providers of ancillary services, such as radiologists, anesthesiologists, or pathologists, are out-of-network. *Id.* "Unlike most medical services, for which patients have an opportunity to seek in-network providers, patients generally are not able to choose these emergency and ancillary providers." Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 AM. J. MANAGED CARE 401, 401 (2020). Third, "[t]his scenario also plays out frequently for air ambulance services, and, therefore, have little or no control over whether the provider is in-network with their plan or coverage." 86 Fed. Reg. at 36,874.

In these circumstances, the patient's inability to choose an in-network provider has created a distortion in the market wherein these providers have little incentive to negotiate fair prices in advance for their services, or to moderate their charges for out-of-network care. "Emergency physicians and anesthesiologists receive a flow of patients based on individuals electing care at the hospital in which they practice. And that volume will be the same regardless of whether the physician is in- or out-of-network. Because volume does not depend on prices set by providers in these no choice specialties, going out-of-network frees them to bill patients at essentially any rate they choose. And, as would be expected, we see that physician specialties that are able to bill out-of-network have extraordinarily high charges compared to other doctors." *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions*, 116th Cong. 8 (2019) (statement of Christen Linke Young, Brookings Inst.). "A lack of choice also defines the massive costs associated with" out-of-network air ambulance service providers, as these providers have had powerful incentives "to remain out-of-network" with the awareness that they could instead balance bill their patients. *Id.* at 40 (statement of Ilyse Schuman, Senior Vice-President, American Benefits Council).

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This market distortion has led to a widespread phenomenon of surprise billing. More than 20 percent of in-network emergency department visits involve care from out-of-network physicians. See Zack Cooper et al., Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians, 39 HEALTH AFFAIRS 24, 24 (Jan. 2020). Similarly, elective surgeries, even at in-network facilities, result in an out-of-network bill from providers of ancillary services in more than 20 percent of cases. See Karan R. Chhabra et al., Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery with In-Network Primary Surgeons and Facilities, 323 JAMA 538, 540 (2020). And air ambulance services are even more likely to involve out-of-network care; in total, about 77 percent of air ambulance transports are performed by out-of-network providers. Erin C. Fuse Brown et al., Out-of-Network Air Ambulance Bills: Prevalence, Magnitude, and Policy Solutions, 98 Milbank Quarterly 747, 751 (2020).

Before the enactment of the No Surprises Act, this phenomenon of out-of-network billing had been rapidly growing, "becoming more common and potentially more costly in both the emergency department and inpatient settings." Eric C. Sun et al., *Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals*, 179 JAMA INTERN. MED. 1543, 1544 (2019). From 2010 to 2016, "the incidence of out-of-network billing increased from 32.3% to 42.8% of emergency department visits, and the mean potential liability to patients increased from \$220 to \$628. For inpatient admissions, the incidence of out-of-network billing increased from 26.3% to 42.0%, and the mean potential liability to patients increased from \$804 to \$2040." *Id.* Air ambulance bills also have "spiked over the past decade, nearly tripling from \$12,500 to \$35,900 between 2008 and 2017." Erin C. Fuse Brown et al., *The Unfinished Business of Air Ambulance Bills*, Health Affairs Forefront (Mar. 26, 2021).

One factor leading to the recent explosion in out-of-network billing practices has been the increasing participation of private equity groups in the health care market, through the acquisition of physician practices and of air ambulance operators. *See Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980, 56,046-56,047 (Oct. 7, 2021) (citing Jane M. Zhu et al., *Private Equity Acquisitions of Physician Medical Groups Across Specialties, 2013-2016*, 323 JAMA 663, 663-665 (2020)); *see also* Joseph D. Bruch et al., *Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition*, 180

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JAMA Intern. Med. 1428 (2020). 'These investors have made a conscious business decision to forgo joining insurance networks in order to be able to charge higher prices out of network. See Zack Cooper et al., Surprise! Out-Of-Network Billing for Emergency Care in the United States, 128 J. POL. ECON. 3626, 3672-3673 (2020). "Research on one large private equity-owned firm showed that when it entered a hospital network, out-of-network billing rates increased by more than 81 percentage points." H.R. REP. NO. 116-615, pt. I, at 54. For air ambulance services in particular, private equity investors have adopted a business model of "avoidance of insurance network participation combined with aggressive collection practices." Missouri Dep't of Insurance, Policy Brief: Health Coverage for Ambulance Transport: Missourians Caught in the Middle 6 (Jan. 2019). As a result, air ambulance operators owned by private equity investors charge almost twice as hospital-owned operators do for the same service. See Loren Adler et al., High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers, USC-Brookings Schaeffer on Health Policy (Oct. 13, 2020).

This has led to unexpected, and devastating, medical bills for patients. "[B]alance bills can be substantial. ... [T]he mean potential balance bills for anesthesiologists, pathologists, radiologists, and assistant surgeons were \$1,171, \$177, \$115, and \$7,420, respectively." Cooper et al., 39 HEALTH AFFAIRS at 27; see also Erin L. Duffy et al., Prevalence and Characteristics of Surprise Out-Of-Network Bills from Professionals in Ambulatory Surgery Centers, 39 HEALTH AFFAIRS 783, 785 (2020) (finding 81 percent increase in average amounts of surprise bills at ambulatory surgical centers from 2014 to 2017). Air ambulance balance bills were even higher, averaging over \$27,000 in 2017. Karan R. Chhabra et al., Most Patients Undergoing Ground And Air Ambulance Transportation Receive Sizable Out-Of-Network Bills, 39 Health Affairs 777, 779 (2020). "Given that nearly half of individuals in the US do not have the liquidity to pay an unexpected \$400 expense without taking on debt, these out-of-network bills can be financially devastating to a large share of the population and should be a major policy concern." Cooper et al., 128 J. POL. ECON. at 3627.

Beyond these financial consequences in individual cases, the market distortion created by surprise billing has had the broader effect of driving up health care costs for all parties. This is because "the ability to bill out of network allows [emergency department] physicians to be paid in-network

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rates that are significantly higher than those paid to other specialists who cannot readily bill out of network. These higher payments get passed along to all consumers (including those who do not even access care) in the form of higher insurance premiums." Cooper et al., 39 HEALTH AFFAIRS at 24. For example, anesthesiologists (who have generally been able to remain out-of-network and balance bill patients) have been able to command in-network payment at rates more than twice as high as orthopedists (who have generally lacked that ability), when their payment rates are measured as a percentage of Medicare reimbursement rates. *See id.* at 26.

Likewise, air ambulance providers have secured inflated in-network rates for their services, given that the group health plan's or insurance issuer's alternative would be to pay even higher outof-network rates. *See* Brown et al., *The Unfinished Business of Air Ambulance Bills*. Emergency room physicians have also been able to command higher in-network payment rates, a phenomenon "caused not by supply or demand, but rather by the ability to 'ambush' the patient." Cooper et al., 128 J. POL. ECON. at 3628. Because emergency department care is so common, this practice "raise[s] overall health spending." *Id.* This has resulted in "commercial health insurance premiums as much as 5% higher than they otherwise would be in the absence of this market failure," Duffy et al., 26 AM. J. MANAGED CARE at 403, placing a financial burden "on employer plan sponsors as well as individuals." *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions*, 116th Cong. 39 (2019) (statement of Ilyse Schuman, Senior Vice-President, American Benefits Council).

II. Congress Enacted the No Surprises Act to Protect Patients from Surprise Billing Practices and to Control Health Care Costs.

To address these surprise billing practices and to rein in the cost of health care, Congress enacted the No Surprises Act in December 2020. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758-2890 (2020). Beginning on January 1, 2022, the Act protects patients with private health coverage from unexpected liabilities arising from the most common forms of balance billing. If such a patient receives emergency care in an emergency department of a hospital or an independent freestanding emergency department, or if he or she

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receives care that is scheduled at certain types of in-network facilities, providers are generally prohibited (absent, in certain circumstances, the patient's consent) from balance billing the patient for any part of his or her care that is furnished by an out-of-network provider. *See* 42 U.S.C. §§ 300gg-131, 300gg-132.¹ Likewise, the patient's cost-sharing responsibilities for out-of-network services may not exceed his or her financial responsibilities "that would apply if such services were provided by a participating provider or a participating emergency facility." *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(A). For example, if the patient's health insurance policy would require him or her to pay coinsurance of 20% of the cost of an in-network service, the patient's responsibility for any out-of-network service would be limited to the same 20% co-insurance. *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(A), (B). Similarly, air ambulance service providers are prohibited from balance billing patients for the cost of out-of-network services, *id.* § 300gg-135, and the patient's cost-sharing responsibilities for out-of-network services furnished by an air ambulance provider may not exceed his or her financial responsibilities "that would apply if such services were provider," *id.* § 300gg-112(a)(1).

With respect to health care facilities, the patient's cost-sharing responsibilities are calculated "as if the total amount that would have been charged for such services by such participating provider or participating emergency facility were equal to the recognized amount[.]" *Id.* § 300gg-111(a)(1)(C)(ii), (b)(1)(B). The "recognized amount" is a term of art under the statute. If an All-Payer Model Agreement is in place in a given State, or a specified State law applies with respect to a particular medical service, then the Agreement or the State law will determine the recognized amount. Otherwise, the "recognized amount" is the "qualifying payment amount (as defined in subparagraph (E)) for such year and determined in accordance with rulemaking described in paragraph (2)(B)) for

¹ The Act makes parallel amendments to the Public Health Service Act ("PHSA") (administered by the Department of Health and Human Services ("HHS")), the Employee Retirement Income Security Act ("ERISA") (administered by the Department of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). In addition, the Act requires the Office of Personnel Management to ensure that that its contracts with Federal Employees Health Benefits Program carriers require compliance with applicable provisions in the same manner as group health plans and health insurance issuers. 5 U.S.C. § 8902(p). For ease of reference, except where otherwise noted, this brief cites only to the Act's amendments to the PHSA.

such item or service." *Id.* § 300gg-111(a)(3)(H)(ii); *see also id.* § 300gg-111(a)(2)(B) (directing the Departments to issue rules by July 1, 2021 that set the methodology for determining the qualifying payment amount). With respect to air ambulance services, the patient's cost-sharing responsibilities are calculated on the basis of the rates that would apply for these services if they were furnished by such a participating provider, which the Departments understand to be the lesser of the billed amount or the qualifying payment amount. *See* 42 U.S.C. § 300gg-112(a)(1); 86 Fed. Reg. at 36,884.

The "qualifying payment amount," in turn, is also a statutory term of art. It is generally defined, for a given item or service and for a given group health plan or insurer, as "the median of the contracted rates recognized" by the plan or insurer, measured with respect to the payment rates 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," under all the plans offered by that insurer in a given insurance market. *Id.* §§ 300gg-111(a)(3)(E)(i)(I), 300gg-112(c)(2). The qualifying payment amount is generally based on the insurer's or group health plan's calculation of the median for its plans as of January 31, 2019; this amount is subject to an inflation adjustment under a methodology established by the Departments. *Id.* § 300gg-111(a)(3)(E)(i)(I). The statute thus textually treats the "qualifying payment amount," calculated in this manner, as a reasonable proxy for what the in-network payment rate would have been for a given out-of-network service, for the purposes of calculating an insured patient's cost-sharing responsibilities.

In addition to setting the rules to determine a patient's payment obligations for a particular out-of-network medical service, the Act also establishes a procedure to resolve disputes between health care providers and group health plans or insurers over the amount of payment for such a service, in which the "qualifying payment amount" again plays a central role. The Act specifies that the insurer or plan will issue an initial payment, or notice of a denial of payment, to a provider within 30 calendar days after the provider submits a bill to it for an out-of-network service. *Id.* § 300gg-111(a)(1)(C)(iv), (b)(1)(C); *see also id.* § 300gg-112(a)(3)(A). If the provider is not satisfied with this amount, it may initiate a 30-day period of open negotiation with the insurer or group health plan over the claim. *Id.* §§ 300gg-111(c)(1)(A), 300gg-112(b)(1)(A). If those negotiations do not resolve the

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dispute, the parties may then proceed to an independent dispute resolution process. *Id.* §§ 300gg-111(c)(1)(B), 300gg-112(b)(1)(B).

The Act specifies that the Departments "shall establish by regulation," no later than December 27, 2021, "one independent dispute resolution process … under which" an arbitrator, known in the statute as a "certified IDR entity," "determines, … in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by" an out-of-network provider. *Id.* §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A). The Act further instructs the Departments to "establish a process" to certify arbitrators, *id.* § 300gg-111(c)(4)(A), under which such an entity "meets such other requirements as determined appropriate by the Secretary," *id.* § 300gg-111(c)(4)(A)(vii); *see also id.* § 300gg-112(b)(4)(A). The Departments are also instructed to "provide for a method" under which the parties to a dispute either jointly select an arbitrator or defer to the Departments' selection, *id.* § 300gg-111(c)(4)(F); *see also id.* § 300gg-112(b)(4)(B).

The Act establishes a system of "baseball" arbitration under which both the provider and the insurer or group health plan will each submit a proposed payment amount, with an explanation, and the arbitrator will select one or the other offer as the amount of payment for the item or service that is in dispute, "taking into account the considerations specified in subparagraph (C)." *Id.* §§ 300gg-111(c)(5)(A)(i); 300gg-112(b)(5)(A)(i). Subparagraph (C) begins by instructing the arbitrator, with respect to payment disputes involving air ambulance services, to consider "the qualifying payment amounts (as defined in section 300gg-111(a)(3)(E) of this title) for the applicable year for items or services that are comparable to the qualified IDR air ambulance service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR air ambulance service." *Id.* § 300gg-112(b)(5)(C)(i)(I).

Subparagraph (C) then goes on to set forth several examples of "additional information" and "additional circumstances" for the arbitrator to consider. *Id.* § 300gg-112(b)(5)(C)(i)(II), (C)(ii). The "additional circumstances" include: the quality and outcome measurements of the air ambulance service provider; the acuity of the individual receiving the service or the complexity of furnishing the service to the individual; the training, experience, and quality of the medical personnel that furnished

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the service; the type of ambulance vehicle; the population density of the patient's pick up location; and a demonstration of the provider's or the insurer's good faith efforts to enter into network agreements for the service, or the lack of such efforts. *Id.* § 300gg-112(b)(5)(C)(ii). The "additional information" for the arbitrator to consider includes any "information as requested by the certified IDR entity relating to such offer," and "any information relating to such offer submitted by either party." *Id.* § 300gg-112(b)(5)(B)(i)(II), (B)(ii). The arbitrator is prohibited from considering the provider's usual and customary charges for an item or service, the amount that the provider would have billed for the item or service in the absence of the Act, or the reimbursement rates for the item or service under the Medicare or Medicaid programs. *Id.* § 300gg-112(b)(5)(C)(iii). The arbitrator's decision is binding on the parties, and is not subject to judicial review, except under the circumstances described in the Federal Arbitration Act. *Id.* §§ 300gg-111(c)(5)(E), 300gg-112(b)(5)(D).

The No Surprises Act requires the Departments to publish a report for each calendar quarter that states, among other things, "the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount, specified by items and services," and for each dispute decided by an arbitrator, "the amount of such offer so selected expressed as a percentage of the qualifying payment amount." *Id.* §§ 300gg-111(c)(7)(A)(v), (B)(iv); 300gg-112(b)(7)(A)(iv), (B)(iv). The arbitrator shall submit such information to the Departments as they determine necessary to enable them to carry out these publication requirements. *Id.* §§ 300gg-111(c)(7)(C); 300gg-112(b)(7)(C).

Congress thus selected an approach to the resolution of provider-insurer payment disputes that was "designed to reduce premiums and the deficit." H.R. REP. NO. 116-615, at 58; *see also id.* at 48 (arbitration process is structured "to reduce costs for patients and prevent inflationary effects on health care costs"). The Act would not succeed in this goal, however, if arbitrations were to result routinely in payments greater than median contracted rates; such a process would *increase* both federal deficits and health insurance premiums. *See id.* at 57. The Congressional Budget Office ("CBO") scored the Act on the understanding that Congress had avoided this pitfall, finding that the Act's arbitration procedures will result in "smaller payments to some providers [that] would reduce premiums by between 0.5 percent and 1 percent. Lower costs for health insurance would reduce federal deficits because the federal government subsidizes most private insurance through tax preferences for employment-based coverage and through the health insurance marketplaces established under the Affordable Care Act." CBO, *Estimate for Divisions O Through FF H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260 Enacted on December 27, 2020*, at 3 (Jan. 14, 2021).² In total, the Act is expected to reduce the deficit by \$16.8 billion, over ten years. *Id.* at 7.

III. The Departments Issued Rules to Implement the Act's Framework to Protect Patients and to Control Health Care Costs.

As noted above, Congress instructed the Departments to issue one set of rules no later than July 1, 2021, to "establish ... the methodology ... to determine the qualifying payment amount," 42 U.S.C. § 300gg-111(a)(2)(B)(i), and to issue a second set of rules no later than December 27, 2021, to "establish ... one independent dispute resolution process" for an arbitrator to determine the payment owed by a group health plan or health insurance issuer to an out-of-network provider, *id.* §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A).

A. The July Rule Established a Methodology to Determine the Qualifying Payment Amount.

The Departments released their first set of interim final rules on July 1, 2021. *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). As relevant here, these rules specified that a patient's cost-sharing responsibilities for out-of-network air ambulance services are calculated by reference to the qualifying payment amount, *id.* at 36,886, and established the methodology for determining the qualifying payment amount, *id.* at 36,888. This methodology begins with a calculation of "the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar

² See also CBO, H.R. 5826, the Consumer Protections Against Surprise Medical Bills Act of 2020, as Introduced on February 10, 2020: Estimated Budgetary Effects at 1 (Feb. 11, 2020) ("[Under] H.R. 5826 ..., dispute resolution entities would be instructed to look to the health plan's median payment rate for in-network rate care. ... [U]nder the bill, ... average payment rates for both in- and out-of-network care would move toward the median in-network rate, which tends to be lower than average rates. CBO and JCT estimate that in most affected markets in most years, lower payments to some providers would reduce premiums by between 0.5 percent and 1 percent," also lowering federal deficits).

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specialty and provided in a geographic region in which the item or service is furnished, increased for inflation." *Id.*

For the purposes of calculating the median of a plan's or issuer's contracted rates, the rule looks to the contracted payment rate for a particular service under each of the plans or policies that the payer has negotiated in advance with providers of that service. 45 C.F.R. § 149.140(a)(1).³ The Departments recognized that, in some cases, plans or issuers may not have a contract in place with a particular provider for a given service, and that the plan or issuer may enter into a "single case agreement" to govern payment for that service. 86 Fed. Reg. at 36,889. The Departments excluded payment rates under these single case agreements from the calculation of the median, because "[t]he term 'contracted rate' refers 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 excludes rates negotiated with other providers and facilities." *Id.* The Departments found that "this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." *Id.*

The statute requires the qualifying payment amount for a particular service to be calculated as the median of a plan's or issuer's contracted rates for that service "that is provided by a provider in the same or similar specialty." 42 U.S.C. § 300gg-111(a)(3)(E)(i). For the purpose of this calculation, the Departments concluded that all providers of air ambulance services "are considered to be a single provider specialty." 86 Fed. Reg. at 36,891. The Departments considered whether to treat hospitalbased air ambulance providers as a separate specialty from non-hospital-based air ambulance providers, but concluded that it would not be appropriate to treat these providers differently solely on the basis of their differing ownership structures. *Id.* Although the Departments recognized that "hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers," they reasoned that patients "frequently do not have the

³ The interim final rules set forth parallel regulations implemented by HHS, the Department of Labor, and the Department of the Treasury. For ease of reference, except where otherwise noted, this brief cites only to the HHS regulations.

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ability to choose their air ambulance provider," and so they should not be required to pay higher costsharing amounts simply "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." *Id.*

The Act also directs that the qualifying payment amount for a given service be calculated on the basis of the median of contacted rates for the service "provided in the geographic region in which the item or service is furnished," 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I), and instructs the Departments to issue regulations defining these geographic regions, *id.* § 300gg-111(a)(2)(B)(iii). For air ambulance services, the Departments defined a "geographic region" as "one region consisting of all [metropolitan statistical areas] MSAs 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). Alternatively, if the group health plan or issuer lacks sufficient information to calculate the median of contracted rates for the service using that definition, then it should "apply broader regions 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).

The Departments determined not to apply a narrower definition of geographic regions for air ambulance services because smaller regions would be more likely to "result in more instances of insufficient information" to calculate a median of contracted rates, "[g]iven the nature of air ambulance services, the infrequency with which they are provided relative to the other types of items and services subject to the No Surprises Act, and the lower prevalence of participating providers of air ambulance services." 86 Fed. Reg. at 36,893. Although the Act, in instances where a plan or issuer has insufficient information to calculate a qualifying payment amount based on median contracted rates, creates a fallback mechanism for the calculation to be based instead on allowed payment amounts found in a third-party database, 42 U.S.C. § 300gg-111(a)(3)(E)(iii), the Departments sought to minimize the use of this mechanism. 86 Fed. Reg. at 36,888. They interpreted the Act to envision that this fallback "will be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region." *Id.* In addition, "[u]sing larger geographic regions, for which plans and issuers are likely to have more information, is

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expected to reduce the likelihood that the median of contracted rates would be skewed by contracts under which the parties have agreed to particularly high or low payment amounts." *Id.* at 36,892.

B. The September Rule Established the Arbitration Process.

The Departments released a second set of interim final rules on September 30, 2021. *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021). These rules implemented the Act's provisions requiring health care providers to furnish good-faith estimates of the cost of medical services to uninsured individuals; establishing a procedure for these individuals to dispute bills that exceed these good-faith estimates; extending the Affordable Care Act's external review requirements to adverse benefit determinations under the Act's surprise billing provisions; and clarifying that carriers under the Federal Employees Health Benefits Program generally are subject to the Act's terms. *See id.* at 55,984-55,987.

These rules also exercise Congress's delegation of authority to the Departments to "establish by regulation one independent dispute resolution process," 42 U.S.C. §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A), for the resolution of disputes between providers, group health plans, and insurers over the amount of payment for certain out-of-network services. In particular, the rules set forth procedures for arbitrators to be certified, and for providers, group health plans, and insurers to invoke the Act's independent dispute resolution system. *See* 86 Fed. Reg. at 55,985. The interim final rules also address the factors that the arbitrator should consider in deciding between the competing offers to be submitted by providers and payors and setting the out-of-network payment amount for a given medical service.

With regard to payment disputes involving air ambulance services, the arbitrator is instructed to "[s]elect as the out-of-network rate ... one of the offers submitted [by the provider and the insurer], taking into account the considerations specified in paragraph (c)(4)(ii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section)." 45 C.F.R. 149.510(c)(4)(i)(A); *see id.* 149.520(b)(1). After taking these considerations into account, the arbitrator "must select the offer closest to the qualifying payment amount unless [it] determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the

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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." 45 C.F.R. 149.510(c)(4)(i)(A).

The considerations that the rule instructs the arbitrator to take into account are: the qualifying payment amount; any information that the arbitrator requests the parties to submit, so long as that information is credible; and any additional information submitted by a party, provided that information is credible, relates to certain specified circumstances as described in the regulation, and "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate." *Id.* § 149.510(c)(4)(iii)(C). Mirroring the statute, the rule describes these specified circumstances, with respect to air ambulance services, as: the provider's quality and outcomes measurements; the patient's acuity, or the complexity of the service that is furnished to the patient; the training, experience, and quality of the medical personnel that furnished the service; the type of ambulance vehicle; the population density of the point at which the patient was picked up; and the good faith efforts, or the lack thereof, by the provider or by the insurer to enter into in-network agreements for the service, and contracted rates, if any, for the service. *Id.* § 149.520(b)(2). The arbitrator must also consider any "[a]dditional information submitted by a party," so long as the information is credible, relates to the party's offer, and does not include information on the factors that the arbitrator is prohibited from considering under the statute. *Id.* § 149.510(c)(4)(iii)(D).

For these purposes, the rule defines "credible information" as "information that upon critical analysis is worthy of belief and is trustworthy," *id.* § 149.510(a)(2)(v), and "material difference" as "a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate," *id.* § 149.510(a)(2)(viii).

STANDARD OF REVIEW

When evaluating a challenge to an agency's interpretation of a statute, a court should first ask "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Nat.*

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Res. Def. Council, Inc., 467 U.S. 837, 842 (1984). If it has, "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.* at 842-43. Where Congress has not spoken directly to the issue at hand, the court should defer to the agency's interpretation so long as it is "based on a permissible construction of the statute." *Id.* at 843. That is true "even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

The APA provides a "narrow standard of review" to "assess only whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1905 (2020) (internal quotations omitted). Under this standard, "[a]n agency's action must be within its lawful authority, and the process by which it reaches that result must be logical and rational." *Farrell v. Blinken*, 4 F.4th 124, 137 (D.C. Cir. 2021) (internal quotations omitted). Where an agency "adequately explain[s] why" it took an action, the court "must uphold its decision." *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 730 (D.C. Cir. 2016). In short, the arbitrary-and-capricious standard simply "requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).

ARGUMENT

I. THE RULE'S ARBITRATION PROCEDURES ARE CONSISTENT WITH THE NO SURPRISES ACT.

A. The Departments Reasonably Exercised Their Statutory Authority to Guide the Discretion of Arbitrators.

The No Surprises Act instructs the Departments to "establish by regulation ... one independent dispute resolution process" for arbitrators to resolve payment disputes between providers and insurers involving out-of-network medical services. 42 U.S.C. 300gg-111(c)(2)(A), 300gg-112(b)(2)(A). The Departments fulfilled that responsibility by issuing the September rule, which comprehensively addresses the procedures for the parties to invoke the arbitration process, to select an arbitrator, and to present their offers and their respective positions to that arbitrator, so that

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he or she may select one of the two offers under a "baseball" arbitration process. *See* 45 C.F.R. §§ 149.510(c)(4)(ii)(A), 149.520(b). This exercise of the Department's statutory authority is governed by the *Chevron* standard, as the Plaintiff appears to acknowledge. Mem. of P. & A. in Supp. of Pl.'s MSJ (Pl.'s Mem.) at 15, ECF No. 5-1.⁴

The rule directs the arbitrator, in making the payment decision, to "tak[e] into account" several considerations, namely, (1) the qualifying payment amount; (2) any information that the arbitrator requests the parties to submit, if that information is credible; (3) and any additional information submitted by a party, if the information is credible, relates to certain specified circumstances as described in the regulation, and "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate." 45 C.F.R. §§ 149.510(c)(4)(ii)(A), (iii), 149.520(b).

The specified circumstances, in turn, are the specific qualitative factors that are listed in the Act itself, such as the providers' quality and outcome measurements, the patient's acuity or the complexity of providing services to the patient, and the training, experience, and quality of the medical personnel furnishing the service. *Id.* § 149.520(b)(2). The arbitrator is also instructed to consider any "[a]dditional information submitted by a party," so long as the information is credible, relates to the party's offer, and does not include information on the factors that the arbitrator is prohibited from considering under the statute. *Id.* § 149.510(c)(4)(iii)(D).

After taking these considerations into account, the arbitrator "must select the offer closest to the qualifying payment amount unless [it] determines that credible information submitted by either

⁴ The Plaintiff appears to retract that acknowledgment, alluding in a footnote to an argument that the Departments' authority to establish the arbitration process does not include an authority to address the arbitration factors. Pl.'s Mem. at 15 n.6. This "perfunctory and undeveloped argument[]," referenced only in a footnote, is waived. *See Gold Rsrv. Inc. v. Bolivarian Republic of Venezuela*, 146 F. Supp. 3d 112, 126 (D.D.C. 2015). In any event, Congress has specifically delegated to the Departments the authority to establish the arbitration process under 42 U.S.C. §§ 300gg-111(c) and 300gg-112(b). Under *Chevron*, that delegation of authority empowers the Departments to resolve ambiguities as to which arbitration rules would be "in accordance with" the remainder of the paragraph, 42 U.S.C. §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A), including that paragraph's discussion of the considerations for the arbitrator to take into account in setting an out-of-network payment amount, *id.* §§ 300gg-111(c)(5), 300gg-112(b)(5). Deference is thus owed to the Departments' niterpretation of those considerations. *See City of Arlington v. FCC*, 569 U.S. 290, 296 (2013).

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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." *Id.* § 149.510(c)(4)(iii)(A).

For these purposes, information is "credible" if "upon critical analysis [it] is worthy of belief and is trustworthy," *id.* § 149.510(a)(2)(v), and information shows a "material difference" if there is "a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate," *id.* § 149.510(a)(2)(viii).

Taking Section 149.510(c)(4) and Section 149.520(b) together with the regulatory definitions, the rule thus instructs the arbitrator to: (1) begin with the qualifying payment amount; (2) consider each of the additional factors identified in the statute and regulation, including "any additional information" that the arbitrator or a party may consider to be relevant; (3) apply his or her expertise to assess whether there is a "substantial likelihood" that the information would show that the qualifying payment amount is not the appropriate out-of-network rate; and, after completing that analysis, then (4) select one of the offers as the payment rate, with the offer that is closest to the qualifying payment amount being the offer selected, unless the arbitrator finds that the additional statutory factors point in favor of a different decision.

The Departments thus reasonably exercised their authority under the Act to establish an independent dispute resolution process that sets forth these guidelines to structure the arbitrator's decision-making. Although the Plaintiff faults the Departments for structuring this analysis to begin with the qualifying payment amount, the Act itself is structured in the same way. The statute lists the qualifying payment amount as the first factor for the arbitrator's consideration; the other factors listed for the arbitrator to consider are described as "additional circumstances" or "additional information." 42 U.S.C. § 300gg-112(b)(5)(C)(i)(II), (ii). These circumstances could only be "additional," of course, if there were some other circumstance already in place that they could be added to—here, the qualifying payment amount. The statute thus textually informs the reader that the analysis should

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begin with the qualifying payment amount, and then should move on to take into account the other statutory factors. *See In re Border Infrastructure Env't Litig.*, 915 F.3d 1213, 1223 (9th Cir. 2019) ("In simple terms, 'additional' means 'supplemental.").

Moreover, "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 666 (2007) (internal quotation marks omitted); see also Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 321 (2014) ("reasonable statutory interpretation must account for both the specific context in which ... language is used and the broader context of the statute as a whole" (internal quotation marks omitted)). The overall statutory scheme here shows Congress's expectation that-in the ordinary case at least-the qualifying payment amount is a proxy for the in-network price that a given medical service would command in a functional health care market. As noted above, the qualifying payment amount plays a central role in the Act's limitations on a patient's cost-sharing responsibilities for out-of-network care. Where the Act applies, the patient's cost-sharing obligation may not be greater than the requirement that would apply if such services were provided by a participating provider, 42 U.S.C. §§ 300gg-111(a)(1)(C)(i), (b)(1)(A), 300gg-112(a)(1). For air ambulance services, these cost-sharing obligations are calculated by using the qualifying payment amount. See id. § 300gg-112(a)(1); see also 86 Fed. Reg. at 36,884. The text and structure of the statute thus equates the qualifying payment amount with the reasonable amount of payment for a given medical service.

What is more, many of the statutory factors would already have played a role in the calculation of the qualifying payment amount in the first place. Recall that this amount is generally defined, for any given medical service, as "the median of the contracted rates recognized" by the insurer or group health plan, measured with respect to the payment rates 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," under all of the plans offered by that insurer or plan in a given insurance market. 42 U.S.C. § 300gg-111(a)(3)(E)(i). The arm's-length negotiations underlying these contracted rates, ordinarily, would have taken into account the typical provider's level of training,

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experience, and quality. *Id.* § 300gg-112(b)(5)(C)(ii). Likewise, one would expect these negotiations to take into account the typical provider's quality and outcome measurement, and the typical patient's acuity and the complexity of providing a service to that patient, and any other factors that might be relevant in setting an arm's-length price. *Id.*

Outliers are possible, of course. In any particular case, for example, an ambulance transport might be abnormally complex (or unusually simple), or a provider might have unusually positive or negative quality and outcome measurements. The qualifying payment amount is a "median" amount, *id.* § 300gg-111(a)(3)(E)(i), and so might not reflect the appropriate payment amount in these unusual cases. But it can be expected to reflect—indeed, it textually is assigned the role of—the appropriate payment rate in the typical case. The rule thus properly instructs the arbitrator to consider whether there is a "substantial likelihood" that any factor might show that the qualifying payment amount is higher or lower than the appropriate out-of-network payment rate.

Indeed, it is difficult to imagine how the arbitrator could go about the decision-making process without starting with the qualifying payment amount. The arbitrator's analysis begins with one number—the qualifying payment amount, *i.e.*, the median contracted rate for the medical service in the geographic region where the service in question was performed. And it ends with another number—the payment amount for the service that is in dispute. What comes in between are a series of qualitative, not quantitative, factors. The clear implication is that Congress intended the arbitrator to consider these qualitative factors to determine whether a departure from the first number was warranted in arriving at the second number. At all events, "[t]here is no canon against using common sense in construing laws as saying what they obviously mean." *Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 63 (2004).

This common-sense understanding is confirmed when one considers the reporting obligations that Congress imposed on the Departments. They are to publish a report, each calendar quarter, that states the number of times the arbitrator determines a payment amount that is greater than the qualifying payment amount, 42 U.S.C. § 300gg-112(b)(7)(A)(iv), and the amount of each payment award, expressed as a percentage of the qualifying payment amount, *id.* § 300gg-112(b)(7)(B)(iv).

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These reporting obligations are not mere technical details. Instead, Congress was focused on ensuring that the Act's dispute resolution mechanism would "reduce premiums and the deficit." H.R. REP. NO. 116-615, at 58. But if arbitrators were to systematically set out-of-network payment rates higher than the qualifying payment amount, "this could result in a potential increase in costs and premiums." 86 Fed. Reg. at 56,060 (citing Loren Adler et al., *Understanding the No Surprises Act*, USC-Brookings Schaeffer on Health Policy (Feb. 4, 2021)); *see also* H.R. REP. NO. 116-615, at 57 (predicting "double digit billions" of dollars in increases in the federal deficit if the arbitration process were designed to increase payments systematically above median contracted rates). Congress thus set forth these reporting obligations so that it could carefully monitor whether the Act was working as intended, to bring out-of-network payments in line with payments negotiated in a free market for in-network reimbursement.

B. The Plaintiff's Contrary Arguments Are Premised on a Misreading of the Rule.

The Plaintiff challenges the validity of the September rule, arguing that the rule violates the statute by "tying [the arbitrator's] hands" and rendering the arbitration process "effectively meaningless," because the qualifying payment amount "will inevitably be the outcome" of that process. Pl.'s Mem at 17, 20. But the Plaintiff is attacking a straw man of its own devising. The rule that the Departments actually published does not make the qualifying payment amount determinative. Instead, as discussed above, the rule instructs the arbitrator to begin with the qualifying payment amount, and then to consider each factor to determine if there is a "substantial likelihood" that the factor would be "significant" in showing that the appropriate out-of-network payment rate is materially different from the median contracted rate for a given medical service. 45 C.F.R. § 149.510(a)(2)(viii). The rule thus leaves ample room for the arbitrator to apply his or her expertise to consider each of the factors that the parties bring to his or her attention.

The Plaintiff's arguments lose force, then, when they are considered against the rule as it actually exists. The Plaintiff faults the Departments, for example, for purportedly violating a statutory command for the arbitrator to consider each of the factors in every case, Pl.'s Mem. at 17-18, but the rule itself requires just that. *See* 45 C.F.R. § 149.510(c)(4)(ii)(A) (instructing the arbitrator to "tak[e]

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into account" each of the statutory considerations). It also contends that the rule violates the statute by prohibiting the parties from submitting categories of information to the arbitrator. Pl.'s Mem at 17. This, again, flatly misreads the rule. Apart from certain factors that the Act itself forbids the arbitrator from considering, the rule permits the parties to submit any information that they wish to offer to the arbitrator, 45 C.F.R. § 149.510(c)(4)(i)(B), and instructs the arbitrator to consider that information, *id.* § 149.510(c)(4)(iii)(D).

The Plaintiff also attempts, Pl.'s Mem at 18, to analogize the rule to the Clean Air Act rule that was at issue in *American Corn Growers Association v. EPA*, 291 F.3d 1 (D.C. Cir. 2002). In that case, the court invalidated an EPA rule that "extract[ed] one of the five statutory factors listed in [the Clean Air Act] and treat[ed] it differently than the other four." *Id.* at 6. The statute at issue in that case listed five statutory factors together in a single clause, without any indication that any one factor should be treated differently. *See* 42 U.S.C. § 7491(g)(2). Here, in contrast, the No Surprises Act directs the arbitrator first to the qualifying payment amount, and then instructs the arbitrator to consider "additional information" or "additional circumstances" that may warrant an upward or downward departure from that amount. 42 U.S.C. § 300gg-112(b)(5)(C)(i)(II), (ii). Congress, of course, may "prescribe a structure" for an agency to go about addressing a set of statutory factors, *Ramirez v. ICE*, 471 F. Supp. 3d 88, 176 (D.D.C. 2020), and one way it can do so is by setting forth a sequence in which the agency is to address various factors, *id.* at 177. Congress did just that in enacting the No Surprises Act. At the very least, the Departments reasonably read the Act to prescribe this structure, and deference is owed to their reading of the statute.

The Plaintiff also relies on *American Corn Growers* for the proposition that the Departments unlawfully interfered with arbitrators' "complete discretion" to decide cases any way that they wished. Pl.'s Mem. at 19. But, as noted above, the statute assigns to the Departments, not to individual arbitrators, the responsibility to "establish by regulation ... *one* independent dispute resolution process" to resolve payment disputes. 42 U.S.C. §§ 300gg-111(c)(2)(A), 300gg-112(b)(2)(A) (emphasis added). The Act thus assigns to the Departments, not individual private arbitrators, the responsibility to resolve any ambiguities with regard to how the statutory factors are to be applied. Thus, if there

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was any gap to fill in the Act in how to treat the various factors that go into setting out-of-network payment amounts, the job of filling that gap belongs to the Departments that are charged with administering the Act, not private arbitrators. *See New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992); *Cent. Vt. Ry., Inc. v. ICC*, 711 F.2d 331, 336 (D.C. Cir. 1983); *see also Am. Hosp. Ass'n v. NLRB*, 499 U.S. 606, 612 (1991) (recognizing agency authority to use rulemaking to establish "general principles to guide the required case-by-case ... determinations").

It is implausible that Congress intended to enact the Plaintiff's alternative approach, in which private arbitrators would enjoy "complete discretion" to weigh any of the statutory factors in any way they choose.⁵ Recall that two of the factors for the arbitrator to consider are any "information as requested by the certified IDR entity relating to such offer," and "any information relating to such offer submitted by either party." 42 U.S.C. § 300gg-111(c)(5)(B(i)(II), (B)(ii)). Under the Plaintiff's approach, then, the arbitrator would be free to take essentially any information he or she wishes—either information that it requests one or both parties to provide, or information that either party takes it upon itself to furnish—accord that information dispositive weight, and then decide as he or she wishes. Congress is unlikely to have intended such a free-for-all. *Cf. Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 399 (1940) (applying the private non-delegation doctrine to prohibit a standardless delegation of authority to a private entity without supervision by a federal agency).

The Plaintiff also refers to alternative versions of surprise-billing legislation that were under consideration in Congress. Pls.' Mem. at 18 n.8. It notes that Congress rejected an alternative bill that would have set the qualifying payment amount as an unrebuttable benchmark for out-of-network reimbursement. But that doesn't describe the Departments' rule. As noted above, the rule leaves ample room for arbitrators to depart from the qualifying payment amount when they find a

⁵ The Plaintiff purports to find a textual hook for this claim in the Act's label for the "*independent* dispute resolution" process; it contends that this phrase means that the arbitrator must be free from any guidance from the Departments, or from any statutory constraints on his or her decision-making power. Pl.'s Mem. at 17-18 (emphasis in original). It is apparent from the context of the statute, however, that Congress intended the arbitrator to be "independent" in the sense that he or she would not have any conflicts of interest with the provider or the group health plan or health insurance issuer who are the parties to the payment dispute. *See* 42 U.S.C. §§ 300gg-111(c)(4)(A)(ii), (iv), (vi), (c)(4)(F)(i); 300gg-112(b)(4)(B).

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"substantial likelihood" that evidence is "significant" in showing that the qualifying payment amount is not the appropriate out-of-network payment rate for a particular service. And, in any event, Congress also considered and rejected bills that would have adopted the Plaintiff's preferred approach of a standardless delegation of authority to private arbitrators to set payment rates at any level they choose. *See* S. 1266, 116th Cong. (2019); H.R. 4223, 116th Cong. (2019). The Plaintiff's "argument highlights the perils of relying on the fate of prior bills to divine the meaning of enacted legislation. 'A bill can be proposed for any number of reasons, and it can be rejected for just as many others."" *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 422 (2012) (quoting *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 170 (2001)).

The Plaintiff goes further astray by citing to post-enactment letters from members of the current Congress, which purport to describe the last Congress's intent in enacting the No Surprises Act. But "[post-enactment legislative history (a contradiction in terms) is not a legitimate tool of statutory interpretation." *Bruesenitz v. Wyeth LLC*, 562 U.S. 223, 242 (2011); *see also Carlson v. Postal Reg. Comm'n*, 938 F.3d 337, 350 (D.C. Cir. 2019). In any event, the letters that the Plaintiff cites do not accurately describe the intent of the enacting legislators. The Chairs of the Senate Committee on Health, Education, Labor and Pensions and the House Energy and Commerce Committee—who played central roles in the enactment of the statute—have "express[ed] their strong support" for the September rule, which they describe as "consistent with Congress' intent when it enacted the No Surprises Act." Letter from Sen. Patty Murray and Rep. Frank Pallone to Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., at 1 (Jan. 7, 2022), <u>https://perma.cc/5HKC-9ZFU</u>. In particular, they noted their understanding that "every bill considered by the committees" during the legislative process "included the [qualifying payment amount] as the primary rate that IDR entities should consider when making decisions." *Id.* at 4.⁶

⁶ See also Letter from Sen. Murray and Rep. Pallone to Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., et al., at 2 (Oct. 19, 2021), <u>https://perma.cc/UC5M-BKQC</u> (describing the September rule as "consistent with our intent and our determination that the QPA, which reflects standard market rates arrived at through private contract negotiations, represents a reasonable rate for services in a vast majority of cases"); Letter from Robert C. Scott, Chair, and Virginia Foxx, Ranking

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Finally, the Plaintiff briefly disputes whether the September rule satisfies Step Two of the *Chevron* analysis. PL's Mem. at 20-21. But the rule plainly satisfies that deferential inquiry. The rule furthers the Congressional purpose for the Act's arbitration mechanism to "reduce premiums and the deficit," H.R. REP. NO. 116-615, at 58, a goal that could only be accomplished if that mechanism were to be structured to focus the arbitrator's decision-making initially around the qualifying payment amount, *see id.* at 57; *see also* 86 Fed. Reg. at 55,996, 56,061. The rule also promotes predictability and regularity in the arbitration process. This is an important goal in its own right, contrary to the Plaintiff's claim that Congress deliberately sought to create an arbitration process that is "*uncertain*" and "*un*predictable," PL's Mem. at 20 (emphasis in original). Each arbitration will carry with it its own transaction costs, and patients ultimately bear those costs in the form of increased premiums. A rule that generally promotes the predictability of arbitration outcomes will thus encourage earlier settlements and help to lower premiums. *See* 86 Fed. Reg. at 55,996. And, perhaps most fundamentally, the rule will address the market distortion caused by surprise billing practices, by diminishing the discrepancy between out-of-network payments for health services and the in-network payments for the same services that are negotiated at arm's length in a free market. *See id*.

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

As noted, the No Surprises Act defines the "qualifying payment amount" generally as "the median of the contracted rates recognized by the plan or issuer ... 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 under paragraph (2)(B)," as of January 31, 2019, subject to an inflation adjustment. 42 U.S.C. § 300gg-111(a)(3)(E)(i); *see also id.* § 300gg-112(c)(2). The Act further instructs the Departments to issue regulations that establish the "methodology ... to determine the qualifying payment amount,"

Member, House Committee on Education and Labor, to Martin J. Walsh, Secretary, U.S. Dep't of Labor, at 3 (Nov. 19, 2021), <u>https://perma.cc/CWH9-D2UD</u> (describing the September rule as "consistent with the plain language of the No Surprises Act, which makes clear the primacy of the QPA through its textual structure").

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including the definition of the geographic regions used to make that determination. *Id.* § 300gg-111(a)(2)(B)(i), (iii). The Departments reasonably exercised their statutory authority to set this methodology, and reasonably explained their decision. The APA requires nothing more. *See Prometheus Radio Project*, 141 S. Ct. at 1158.

A. The Departments Reasonably Established a Methodology for the Calculation of the Median of Contracted Rates.

As noted above, the July rule directs group health plans and health insurance issuers, for the purposes of calculating the median of a plan's or issuer's contracted rates, to look to the contracted payment rate for a particular service under each of the contracts that the plan or issuer has negotiated in advance with providers of that service. 45 C.F.R. § 149.140(a)(1). By limiting the calculation to contracts that have been negotiated in advance, the Departments decided to exclude "single case agreements" that may be negotiated between a provider and a health plan or issuer, either at the time that a service is performed, or after the fact. *See* 86 Fed. Reg. at 36,889. The Departments excluded these agreements from the calculation of the median because they understood the statutory term "contracted rate" 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 excludes rates negotiated with other providers and facilities." *Id.* The Departments found that "this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." *Id.*

The Plaintiff challenges the Departments' decision to exclude single case agreements from the calculation of the median. It argues that Section 300gg-111(a)(3)'s use of the term "contracted rate" unambiguously refers to the rate of payment for a health service under any contractual arrangement that a provider may enter into with a payor. Pl.'s Mem. at 23. It incompletely quotes the statute, however. The qualifying payment amount is "the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market ... as the plan or coverage) as the total maximum payment ... under such plans or coverage, respectively, on January

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31, 2019," adjusted for inflation. 42 U.S.C. § 300gg-111(a)(3)(E)(i). "Plans" and "coverage" are terms of art under the PHSA and ERISA. A "group health plan" is an employee welfare benefit plan that provides medical care for employees and their dependents. *Id.* § 300gg-91(a)(1). And "health insurance coverage" means benefits consisting of medical care under a policy offered by a health insurance issuer. *Id.* § 300gg-91(b)(1).

The plain text of the statute, then, does not direct the Departments to include all contracts in the calculation of the median; it instead instructs them to include the payment rates that are contracted for *under* the generally applicable terms of a health plan or health insurance policy. Moreover, the statute refers to plans or coverage that are offered in a particular insurance market, *id.* § 300gg-111(a)(3)(E)(i), and "insurance market" is itself a defined term of art, *see id.* § 300gg-111(a)(3)(E)(iv). Single case agreements do not set the rates of payment under the generally applicable terms of plans or coverage offered in a particular market, any more than the settlement of a particular payment dispute under the Act's arbitration procedures would. *See id.* §§ 300gg-111(c)(1)(A), 300gg-112(b)(1)(A). The Departments thus properly determined that any payment arrangements made under single case agreements do not figure into the calculation of the median. *Cf. Ass'n for Cmty. Affiliated Plans v. U.S. Dep't of Treasury*, 966 F.3d 782, 785 (D.C. Cir. 2020) (discussing definition of individual health insurance coverage).⁷

The Plaintiff also contends that the Departments acted arbitrarily in excluding single case agreements from the calculation of the median of contracted rates for air ambulance services, given that air ambulance providers rarely enter into agreements in advance to establish in-network rates for their services. Pl.'s Mem. at 25. But that precisely describes the problem that Congress sought to resolve in enacting the No Surprises Act. Congress recognized that a substantial majority of air ambulance services are furnished by out-of-network providers, and that these providers' ability to remain out-of-network has created a "market failure" that has permitted them to charge far more than

⁷ It is, moreover, highly unlikely that Congress would have intended the Departments to include only those single case agreements that were in place on a single day, January 31, 2019, in the calculation of the median. *See* 42 U.S.C. § 300gg-111(a)(3)(E)(i).

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the price that they would be able to command in a fair and functioning market. H.R. REP. NO. 116-615, at 52-53. Congress accordingly sought to limit patients' cost-sharing responsibilities for air ambulance services to an amount based on the rate that would apply if the service were provided innetwork, and it based the calculation of the provider's payment on the same amount. *See* 42 U.S.C. § 300gg-112(a)(1). If anything, the in-network payment amounts for air ambulance services are themselves highly inflated, since they reflect the ability that these providers have had until now to refuse to join provider networks and to rely instead on balance billing. *See* Brown et al., *The Unfinished Business of Air Ambulance Bills*. The Act thus reduces some of the upward pressure on air ambulance payment rates, and the Departments reasonably chose a methodology that honored Congress's intent on this score. *See, e.g., Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1049 (D.C. Cir. 1997) (deferring to rule that is "reasonable and consistent with the statutory purpose and legislative history").

The Plaintiff also asserts that the Departments acted inconsistently by excluding single case agreements from the calculation of the median contracted rate, but including the same agreements as contracts for purposes of determining whether a health care facility is "participating" for the purposes of some of the Act's balance-billing rules. Pl.'s Mem. at 26. The Act does not ban balance billing in all contexts; for example, under certain circumstances, the Act protects a patient from balance billing from out-of-network providers only if he or she receives care from such a provider during a scheduled visit to a facility that is otherwise a "participating" facility under the patient's plan or policy. 42 U.S.C. § 300gg-132. The definition of whether a particular facility is "participating" thus can be important for determining whether a particular service is subject to the Act's protections or not. For this purpose, the Act defines a "participating health care facility" as, "with respect to an item or service and a group health plan or health insurance issuer offering group or individual health insurance coverage, a health care facility ... that has a direct or indirect contractual relationship with the plan or issuer, respectively, with respect to the furnishing of such an item or service at the facility." Id. § 300gg-111(b)(2)(A)(i). This definition is different from that of the qualifying payment amount, and it serves a different purpose in the statutory scheme. The Departments reasonably determined that a single case agreement could constitute a contractual relationship that would cause a facility to be a

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"participating facility," thereby triggering the Act's balance-billing protections for other services performed at that facility in that single case, *see* 86 Fed. Reg. at 36,882, even though that agreement is excluded from the calculation of the median of contracted rates under a different statutory definition.

B. The Departments Reasonably Treated All Air Ambulance Providers as in the Same or Similar Specialty.

The No Surprises Act instructs that the qualifying payment amount for a particular service is to be calculated as the median contract rate for the service "that is provided by a provider in the same or similar specialty." 42 U.S.C. § 300gg-111(a)(3)(E)(i). For the purposes of this calculation, the Departments concluded that all providers of air ambulance services "are considered to be a single provider specialty." 86 Fed. Reg. at 36,891. They considered whether to treat hospital-based air ambulance providers as a separate specialty from independent air ambulance providers, but concluded that it was inappropriate to treat these providers differently solely on the basis of their ownership structures. *Id.* Even though "hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers," the Departments noted that patients "frequently do not have the ability to choose their air ambulance provider," and so they should not be required to pay higher cost-sharing amounts simply "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." *Id.*

The Plaintiff challenges the Departments' reasoning on this score, arguing that hospital-based air ambulance services must be in a different "provider specialty" because hospitals frequently negotiate rates for air ambulance services together with rates for other services, leading to lower air ambulance rates than those demanded by independent providers. Pl.'s Mem at 27. This argument casts no doubt on the Departments' rule. The term "specialty" refers to the "practice specialty of a provider," 86 Fed. Reg. at 36,891, such as cardiology or urology. *See* 42 U.S.C. § 300gg-139(d) (No Surprises Act provision requiring provider directories to list provider specialties). All air ambulance providers perform the same service for patients who require emergency transportation, no matter what their business model may be. Because a patient has no opportunity to consider what the

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particular business model might be of the air ambulance provider that provides him or her with transportation, the Departments reasonably considered the provider's ownership structure to be irrelevant for the purposes of determining the "provider specialty" of air ambulance providers.

The Plaintiff protests that the Departments acted inconsistently by treating hospital-based emergency departments separately from freestanding emergency departments, while at the same time treating all air ambulance providers as part of the same specialty. Pl.'s Mem. at 28. The rule's treatment of emergency departments did not turn on the definition of "specialty," however. Instead, with respect to emergency departments, the Departments exercised their rulemaking authority to account for "relevant payment adjustments that take into account quality or facility type (including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities." 42 U.S.C. § 300gg-111(a)(2). The rule thus defers to the practices of group health plans and health insurance issuers, and permits (but does not require) them to calculate the qualifying payment amount separately for the two types of emergency departments, if the plan or issuer has contracted rates that vary based on the type of facility. 86 Fed. Reg. at 36,891. The Departments drew this distinction on the basis of evidence that there are material differences in the case mix and level of patient acuity in the two types of emergency facilities. Id. at 36,892 (citing Medicare Payment Advisory Comm'n, Report to the Congress: Medicare and the Health Care Delivery System 246 (June 2017)). The Plaintiff does not suggest that there are similar differences in case mix or patient acuities between different types of air ambulance providers, nor does it provide any reason to think that such differences would exist. And air ambulance service providers, in any event, are not "facilities" for the purpose of the Department's payment adjustment authority. See 42 U.S.C. § 300gg-111(b)(2)(A)(iii); 45 C.F.R. § 149.30. The Departments, then, were not obligated to draw a distinction between different types of ownership structures for air ambulance providers in defining which "specialty" these providers perform.

C. The Departments Reasonably Defined Geographic Regions for Use in Calculating the Qualifying Payment Amount.

The Act also directs that the qualifying payment amount for a given service to be calculated

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on the basis of the median of contacted rates for the service "provided in the geographic region in which the item or service is furnished," 42 U.S.C. § 300gg-111(a)(3)(E)(i), and instructs the Departments to issue regulations defining these geographic regions, *id.* § 300gg-111(a)(2)(B)(iii). The Departments exercised this authority by defining a "geographic region," for air ambulance services, as "one region consisting of all [metropolitan statistical areas] MSAs 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). If this definition leaves the group health plan or health insurance issuer with insufficient information to calculate a median of contracted rates, then a broader definition is applied of "regions 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).

The Plaintiff contends that the Departments abused their discretion in adopting this definition, because, in its view, Congress would not have intended for the Departments to use regions of this size. Pl.'s Mem. at 30. Contrary to this claim, Congress deferred to the Departments' selection of geographic regions, see 42 U.S.C. § 300gg-111(a)(2)(B)(iii), and the Departments reasonably explained their decision to exercise their statutory discretion in this way. They determined that geographic regions should not be defined overly narrowly for air ambulance services, given that such an approach would be more likely to "result in more instances of insufficient information" to calculate a median of contracted rates, "[g]iven the nature of air ambulance services, the infrequency with which they are provided relative to the other types of items and services subject to the No Surprises Act, and the lower prevalence of participating providers of air ambulance services." 86 Fed. Reg. at 36,893. The Departments recognized that the Act permits the use of a third-party database of allowed amounts in cases where there is otherwise insufficient information to calculate a qualifying payment amount. 42 U.S.C. § 300gg-111(a)(3)(E)(iii). They sought, however, to minimize the use of this stop gap, as they read the statute to envision that this mechanism "will be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region." 86 Fed. Reg. at 36,888. In addition, "[u]sing larger geographic regions, for which plans and

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issuers are likely to have more information, is expected to reduce the likelihood that the median of contracted rates would be skewed by contracts under which the parties have agreed to particularly high or low payment amounts." *Id.* at 36,892.

The Departments thus reasonably explained their decision to define geographic regions in this way. See Prometheus Radio Project, 141 S. Ct. at 1158. The Plaintiff protests that air ambulances, on average, transport a patient only 56 miles. Pl.'s Mem. at 30. But this misunderstands the basis for the Departments' rule; they set the definition of geographic regions not on the basis of how far air ambulances travel, but instead on the relative infrequency of the service and the low prevalence of innetwork air ambulance providers. 86 Fed. Reg. at 36,893. A broader definition of geographic regions thus was needed to ensure that there would be sufficient information to calculate a median of contracted rates. See Matthew Fiedler et al., Recommendations for Implementing the No Surprises Act, USC-Brookings Schaeffer on Health Policy (Mar. 16, 2021). The Plaintiff also notes that the Departments could have chosen to use third-party payment databases in the first instance, Pl.'s Mem. at 30, but, again, the Departments reasonably explained their decision not to adopt this alternative. They sought to establish a methodology under which the qualifying payment amount is calculated on the basis of actual information from market negotiations between air ambulance providers and health plans or health insurance issuers, and to develop enough of that information on market negotiations so that the qualifying payment amount would not be skewed by outliers with unusually high or low payment amounts. 86 Fed. Reg. at 36,888, 36,892. The Act did not foreclose the Departments from exercising their discretion in this way.

D. The Departments Reasonably Interpreted the Act to Base Patients' Cost-Sharing for Air Ambulance Services on the Qualifying Payment Amount.

Finally, the Plaintiff contends that the Departments gave patients an unjustified windfall by basing their cost-sharing obligations for air ambulance services on the qualifying payment amount. Pl.'s Mem. at 31-32. It notes that Section 300gg-112(a)(1), which governs air ambulance services, bases the patient's cost-sharing responsibilities for this service on the amount "that would apply if such services were provided by such a participating provider." The Plaintiff contends that this

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language is "unambiguous" in foreclosing the use of the qualifying payment amount to determine a patient's financial liability for an air ambulance encounter, and it argues that patients should be forced to pay a share of the (presumably higher) amount that may be negotiated after the fact between an air ambulance provider and a group health plan or health insurance issuer in a single case agreement. Pl.'s Mem. at 32.

Contrary to the Plaintiff's claim, the statute does not unambiguously foreclose the Departments' approach. The Act specifies that the patient's cost-sharing obligations should be calculated on the basis of the amount that would apply if the out-of-network air ambulance service had been provided instead in-network. 42 U.S.C. § 300gg-112(a)(1). It does not specify, however, how the Departments should go about determining what that amount would have been in the counterfactual scenario where the air ambulance provider had joined the network of the patient's health plan or insurance policy before the time that the service was provided. As the Departments reasonably explained in the July rule, they filled this gap by looking to the Act's parallel structure for services performed by health facilities and other providers, under which the patient's cost-sharing obligations ultimately turns (absent a statutory exception) on the qualifying payment amount. 86 Fed. Reg. at 36,884. This use of the qualifying payment amount "is one method of ensuring 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, and is one basis used for determining the cost-sharing amount in the context of emergency services and items and services furnished by nonparticipating providers at participating health care facilities." Id. This methodology thus reasonably promoted the statutory purposes of protecting patients from "excessive bills," and removing patients "as much as possible" from payment disputes between providers and group health plans or health insurance issuers. Id.

Under the Plaintiff's alternative approach, in contrast, a patient would not be able to meaningfully determine his or her financial responsibility for an air ambulance transport, as he or she would owe a percentage of a potentially much larger amount that might later be agreed upon between the air ambulance provider and the payer. The central purpose of the No Surprises Act, however, is to "take the consumer out of the middle" of these payment disputes. H.R. REP. NO. 116-615, at 57. The Departments reasonably rejected a reading of the statute that would have placed patients squarely back into the center of these disputes.

III. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED.

In the event the Court disagrees with the Departments' arguments, any relief should be no broader than necessary to remedy the demonstrated harms of the specific, identified plaintiff in this case. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018). So "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *id.* at 1934, and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). Moreover—as the Plaintiff properly acknowledges, Pl.'s Mem. at 33-34—any relief should be limited to the particular provisions that the Plaintiff has challenged. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (severing provisions of a regulation found to be invalid).

At most, the Court should remand the matter to the Departments without vacatur of the challenged provisions. "The decision whether to vacate depends on the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. Nuclear Regul. Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993) (internal quotation marks omitted). Both factors counsel in favor of remand without vacatur here. First, the Departments have begun the preparation of a final rule in response to the comments that they invited from the public on the July and September rules, and they intend to address those comments in publishing final rules. Thus, if the Departments committed any error, "there is at least a serious possibility that [they] will be able to substantiate [their rules] given an opportunity to do so." *Radio-Television News Directors Assn v. FCC*, 184 F.3d 872, 888 (D.C. Cir. 1999). Second, vacatur would be highly disruptive, as it would leave arbitrators with no

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guidance as to how to proceed with their decision-making, just as arbitrations are set to begin operating under the Act this spring. Patients, business groups, benefit administrators, insurers, group health plans, and the public at large have a stake in a rule that will prohibit balance billing and that will reduce upward pressure on health care costs. These interests counsel heavily against vacatur. *See, e.g., Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002).

CONCLUSION

For the foregoing reasons, the Defendants' motion for summary judgment should be granted, and the Plaintiff's motion for summary judgment should be denied.

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Respectfully submitted,

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