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

LIFENET, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 6:22-cv-00162-JDK

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, FOR JURISDICTIONAL DISCOVERY, AND MEMORANDUM IN OPPOSITION TO PLAINTIFF'S SUMMARY JUDGMENT MOTION

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For the reasons stated below, the Defendants respectfully request that the Court award summary judgment in their favor. In the alternative, the Defendants respectfully request pursuant to Federal Rule of Civil Procedure 56(d) that the Court defer consideration of the cross-motions for summary judgment to allow for a limited period of jurisdictional discovery.

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. The cost difference between receiving care from an in-network versus an out-of-network 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, a patient may require an airlift to a hospital, with no way of knowing whether the air ambulance provider is in-network or not. 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 in-network 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 submits its proposed payment amount and an independent, private arbitrator, known as a "certified IDR entity," selects between the two offers. Congress also directed the Departments that are Defendants in this suit to create rules to establish this arbitration process.

The principal provisions of the Act went into effect on January 1 of this year, and the first arbitrations of payment disputes began 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, LifeNet, Inc., takes issue with portions of the September rule that instruct that the arbitrator, when choosing between the competing amounts proposed by the air ambulance provider and the group health plan or health insurance insurer, should look primarily 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. As an initial matter, Plaintiff lacks standing to advance this claim, as it does not and will not participate in the Act's arbitration process. In any event, Plaintiff is incorrect on the merits. The September 2021 rule comports with the statutory text. The rule, like the statute, sets forth a series of factors for the arbitrator to consider; the 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 the rule, which was promulgated in response to a Congressional assignment of authority to the Departments.

STATEMENT OF THE ISSUES

1. Has Plaintiff met its Article III burden to prove its standing to challenge the arbitration rule, given that it will not participate in arbitrations under that rule, and it receives a fixed fee for its services that does not depend on the outcome of arbitrations?

2. Did the Defendants reasonably exercise their rulemaking authority under the No Surprises Act to establish a framework for the arbitrator to adjudicate competing offers for the payment amount

for an out-of-network air ambulance service?

3. Did the Defendants properly exercise the authority that Congress has granted to them to issue interim final rules as they find to be appropriate?

4. Is the interim final rule arbitrary and capricious?

STATEMENT OF UNDISPUTED MATERIAL FACTS

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) (AR 330).

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.* For example, in an emergency, a patient may be unable to choose which emergency department he or she goes to (or is taken to). *Id.* "This scenario also plays out frequently for air ambulance services, where individuals generally do not have the ability to select a provider of air ambulance services, and, therefore, have little or no control over whether the provider is in-network with their plan or coverage." *Id.*

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. This inability to choose "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. *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions* ("*Examining Surprise Billing*"), 116th Cong. 40 (2019) (statement of Ilyse Schuman, Senior Vice-President, American Benefits Council) (AR 472).

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) (AR 1397). 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) (AR 2855).

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) (AR 1119). Air ambulance bills have "spiked over the past decade," with median charges for a fixed-wing transport "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) (AR 2845). Air Methods Corporation, in particular, took advantage of this market distortion by increasing its prices for medical transports by 283 percent from 2007 to 2016. Loren Adler et al., *High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers*, USC-Brookings Schaeffer on Health Policy (Oct. 13, 2020) (AR 4771).

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) (AR 1155-1157)); *see also* Joseph D. Bruch et al., *Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition*, 180 JAMA Intern. Med. 1428 (2020) (AR 1299). 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) (AR 1112-1113). 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) (AR 4103); *see also* Consumer Union, *Up in the Air: Inadequate Regulation of Emergency Air Ambulance Transportation* (Mar. 2017) (AR 3028) (discussing Air Methods' aggressive billing and collection strategies following its acquisition by private equity investors).

This has led to unexpected, and devastating, medical bills for patients. Air ambulance balance bills, for example, averaged 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) (AR 2960). "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 (AR 1067).

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 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 (AR 1397). 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 out-of-network rates. *See* Brown et al., *The Unfinished Business of Air Ambulance Bills* (AR 2845). 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 (AR 1068). 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," Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 AM. J. MANAGED CARE 401, 403 (2020) (AR 1385), placing a financial burden "on employer plan sponsors as well as individuals." *Examining Surprise Billing*, at 39 (2019) (AR 471) (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). Since becoming effective on January 1, 2022, the Act has protected patients with private health coverage from unexpected liabilities arising from the most common forms of balance billing. Air ambulance service providers, in particular, are prohibited from balance billing patients for the cost of out-of-network services, 42 U.S.C. § 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 provided by such a participating provider," *id.* § 300gg-112(a)(1).[1]

[1] The Act makes parallel amendments to the Public Health Service Act ("PHSA") (administered by HHS), the Employee Retirement Income Security Act ("ERISA") (administered by the Department

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 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 plan or issuer 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

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of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). In addition, the Act requires OPM 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.

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 an air ambulance provider within 30 calendar days after the provider submits a bill to it for an out-of-network service. *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-112(b)(1)(A). If those negotiations do not resolve the dispute, the parties may then proceed to an independent dispute resolution process. *Id.* § 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-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-

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 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 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-112(b)(7)(A)(iv), (B)(iv). The arbitrator is

required to submit such information to the Departments as they determine necessary to enable them to carry out these publication requirements. *Id.* § 300gg-112(b)(7)(C).

Congress thus selected an approach to the resolution of payment disputes that was "designed to reduce premiums and the deficit." H.R. REP. NO. 116-615, at 58; *see also id.* at 48 (IDR 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 in-network payment amounts; 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) (AR 781).[2] In total, the Act is expected to reduce the deficit by $16.8 billion, over ten years. *Id.* at 7 (AR 785).

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

[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) (AR 1757) ("[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 [the Joint Committee on Taxation] 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).

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). The Departments released their first set of interim final rules on July 1, 2021, *see Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021), and a second set of interim final rules on September 30, 2021, *see Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021).

The September rule exercised Congress's delegation of authority to the Departments to "establish by regulation one independent dispute resolution process," 42 U.S.C. § 300gg-112(b)(2)(A), for disputes between air ambulance providers and group health plans or insurers over payment for certain out-of-network services. In particular, the rule sets 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 rule also addresses the factors that the arbitrator should consider in deciding between the competing offers to be submitted by providers and payers in setting the out-of-network payment amount for a given medical service.

With regard to payment disputes involving air ambulance services, the rule instructed the arbitrator 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)(iii) 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)(ii)(A); *see id.* § 149.520(b)(1). After taking these considerations into account, the arbitrator was to "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 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.*

The considerations that the rule instructed 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.* § 149.520(b)(2). 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.* 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.*

Earlier this year, this Court vacated certain portions of 45 C.F.R. § 149.510, the regulation addressing the arbitration of payment disputes between non-air-ambulance providers and plans or issuers. *Texas Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 6:21-CV-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022).[3] The Departments have appealed that judgment, and the Fifth Circuit has granted their motion to stay proceedings on appeal during the pendency of ongoing rulemaking proceedings. *Texas Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, No. 22-40264, 2022 WL 1632580 (5th Cir. May 3, 2022). The Departments anticipate that they will issue a final rule by early summer that will address the arbitration process under the No Surprises Act both for air ambulance and non-air ambulance providers.

[3] The regulation addressing payment disputes involving out-of-network air ambulance services, 45 C.F.R. § 149.520(b)(1), incorporates "the requirements of § 149.510." Following this Court's judgment in *Texas Medical Association*—and pending new rulemaking proceedings—the Departments understand Section 149.520 to incorporate only those portions of Section 149.510 that have remained in place after this Court's order of vacatur. Section 149.520(b)(2) also independently requires a party submitting additional information in an IDR proceedings involving air ambulance services to show that this additional information clearly demonstrates that the qualifying payment amount is different from the appropriate out-of-network rate. In April 2022, the Departments released guidance explaining the operation of arbitration proceedings following this Court's order until new rulemaking proceedings are concluded. *See* Centers for Medicare & Medicaid Services, *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities* (Apr. 13, 2022), www.cms.gov/sites/default/files/2022-04/Revised-IDR-Process-Guidance-Certified-IDREs.pdf.

IV. This Litigation is Brought.

Plaintiff, LifeNet, Inc., provides air ambulance services in Texas, Arkansas, Oklahoma, and Louisiana. It brings this suit to challenge the September rule's establishment of the arbitration procedures with respect to payment disputes involving air ambulance providers. Compl., ECF No. 1. Plaintiff is paid for its services by Air Methods Corporation, a national air ambulance company provider that contracts with local partners. ECF No. 24-1 (Grimes Decl.), ¶ 5. The contract "sets an agreed amount of compensation for LifeNet's emergency air transport services, which amount is to be paid to LifeNet by Air Methods." ECF No. 27 (Pl.'s Mem.), 11. "According to the contract, Air Methods is responsible for collecting reimbursement from other payors (e.g., patients, health plans, health insurers) for LifeNet's services." *Id.* "But Air Methods owes the agreed amount to LifeNet, for a given transport, even if Air Methods is unsuccessful at collecting reimbursement for that transport from other payors." *Id.*

Air Methods is a member of the Association of Air Medical Services, a national association of air ambulance providers, and has been actively involved since December 2021 in the association's litigation in the U.S. District Court for the District of Columbia challenging the same rule that Plaintiff challenges here. *Ass'n of Am. Med. Servs. v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-3031 (D.D.C.).

Six months after the Departments issued the September rule, and five months after the Association of Air Medical Services filed its separate lawsuit in the District of Columbia, Plaintiff filed its two-count Complaint. ECF No. 1. In Count I, Plaintiff alleges that the portions of the September rule that instruct the arbitrator to look first to the qualifying payment amount when making a decision are inconsistent with the text of the Act. In Count II, Plaintiff alleges that the Departments were required to follow notice and comment rulemaking when promulgating the interim final rules.

STANDARD OF REVIEW

"As the party invoking federal jurisdiction, the plaintiffs bear the burden of demonstrating that they have standing." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207 (2021). That burden "becomes gradually stricter as the parties proceed through the successive stages of the litigation." *In*

re Deepwater Horizon, 739 F.3d 790, 799 (5th Cir. 2014). "[A]t the summary judgment stage, such a party can no longer rest on mere allegations, but must set forth specific facts that adequately support their contention." *California v. Texas*, 141 S. Ct. 2104, 2117 (2021).

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. 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'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

In evaluating an agency's decision to issue a rulemaking without first providing for a period of notice and comment, the Fifth Circuit "us[es] the APA's standard: agency action may be set aside if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)). This standard is "narrow and highly deferential." *Sierra Club v. U.S. Dep't of Interior*, 990 F.3d 909, 913 (5th Cir. 2021). "[T]he 'court is not to substitute its judgment for that of the agency." *Id.* (citation omitted). Rather, the court "consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation omitted). 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. Plaintiff Has Not Shown That It Has Standing to Challenge the Rule's Arbitration Procedures.

To prove Article III standing, Plaintiff must show that it has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *see also*

Ortiz v. Am. Airlines, Inc., 5 F.4th 622, 628 (5th Cir. 2021). In particular, to show an injury in fact, it must prove that it has "suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 459 (5th Cir. 2005). "Causation requires a 'traceable connection' between the plaintiff's injury and the defendant's conduct." *Arkansas Project v. Shaw*, 775 F.3d 641, 648 (5th Cir. 2014). Redressability requires "a likelihood that the requested relief will redress the alleged injury." *Id.*

On summary judgment, the Plaintiff must set forth "specific facts" in affidavits to support its claim of standing. *California v. Texas*, 141 S. Ct. at 2117; *see also Ortiz*, 5 F.4th at 628. This burden is not met by "a conclusory statement in [an] affidavit." *Kitty Hawk Aircargo*, 418 F.3d at 459; *see also Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990) (a plaintiff may not meet its burden at summary judgment through "conclusory allegations of an affidavit"). Plaintiff has failed to meet this burden.

To the contrary, Plaintiff's briefing and affidavits decisively rebut its claim to standing. Plaintiff does not participate in the No Surprises Act arbitration proceedings. Only Air Methods, not LifeNet, will pursue payment for out-of-network air ambulance services, and only Air Methods will submit its offers for decision to an arbitrator under the Act's procedures. *See* ECF No. 27-2 (Gaines Decl.), ¶ 9, ("The QPA Presumption adopted in the Departments' regulations will therefore make it more challenging for *Air Method's* offers … to win in the IDR proceeding") (emphasis added). And only Air Methods has a financial interest in the outcome of those arbitrations; Plaintiff is paid a fixed amount whether or not Air Methods is successful in obtaining reimbursement from other payors. Pl.'s Mem. 11. Plaintiff therefore is not an object of the regulation that it challenges, and it suffers no injury-in-fact from the operation of that regulation. *See Kitty Hawk Aircargo*, 418 F.3d at 459. The proper plaintiff to challenge the regulation instead would be Air Methods; and that corporation is in fact already doing so through its participation in the Association of Air Medical Services litigation.

Plaintiff has failed to prove causation and redressability as well, as its compensation is determined by its contract with Air Methods, not by the arbitrator or by the Departments. There is no "likelihood that the requested relief will redress the alleged injury" by motivating Air Methods to provide higher fees for LifeNet's services. *Arkansas Project v. Shaw*, 775 F.3d 641, 648 (5th Cir. 2014).

Plaintiff has entirely failed to show that even if Air Methods stands to do better under revised IDR regulations, it will pass that financial benefit on to Plaintiff in any way. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (rejecting a standing theory premised on a speculative chain of possibilities). In sum, Plaintiff has not shown that it has suffered or will suffer any injury traceable to the rule.

Plaintiff asserts that there is a "significant risk" that Air Methods will terminate its contract with Plaintiff absent judicial relief. Pl.'s Mem. 20 (quoting ECF No. 27-3 (2d Gaines Decl.), ¶ 4). In an attempt to support the utterly speculative assertion that Air Methods would seek to terminate its existing contract with Plaintiff, Plaintiff points to a contract provision permitting either party to terminate the agreement only in the event of a "financially unviable situation that is beyond the reasonable expectations of either [Air Methods or Plaintiff]," and only "upon at least 180 days prior written notice to the other Party." ECF No. 27-3, (2d Gaines Decl.), ¶ 3. But Plaintiff offers no proof—other than its conclusory speculation in its own affidavit, which is legally inadequate, *see Nat'l Wildlife Fed'n*, 497 U.S. at 888—that Air Methods would find its business relationship with Plaintiff to be unviable to a point that was "beyond the reasonable expectations" of the parties on the basis of the regulation at issue in this case.

Moreover, the fact that the Departments plan to issue a final rule in the near future superseding the interim regulation at issue here underscores how unlikely it is that Air Methods would invoke a contract termination provision that only takes effect upon 180 days' notice. And importantly, Plaintiff's claimed injury depends on the actions of a third party (Air Methods) "whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Inclusive Communities Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 655–56 (5th Cir. 2019) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992). In such a case, Plaintiff may not rely on its own speculation as to how Air Methods might react to the regulation, but instead it bears the burden "to adduce facts *showing* that those choices *have been or will be made* in such manner as to produce causation

and permit redressability of injury." *Id.* (quoting *Defenders of Wildlife*, 504 U.S. at 562). Plaintiff has failed to carry that burden.[4]

Nor does Plaintiff advance its claim to standing by asserting that it suffers a "procedural injury," Pl.'s Mem. 19, or an injury from purportedly "untrue and disparaging statements" as to the value of air ambulance services, *id.* 23. A "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." *Summers*, 555 U.S. at 496. As noted above, Plaintiff has failed to show that it suffers any concrete injury from the regulation. Plaintiff also asserts its will suffer an "intangible harm" if the IDR process values Plaintiff's services lower than Plaintiff does, and as a result "[c]ommercial health plans and insurers … will not agree to pay LifeNet any more than what they believe LifeNet can obtain through the IDR process." Pl's Mem. 22. But as Plaintiff itself has made clear, commercial health plans and insurers do not compensate Plaintiff for its services; instead, Air Methods does. As discussed above, Plaintiff has offered nothing more than sheer speculation as to how Air Methods will react to the regulation. For the foreseeable future, at least, Plaintiff's payment rates are guaranteed by contract.

If this Court remains doubtful about the nature of Plaintiff's arrangement with Air Methods, and whether Plaintiff stands to suffer any injury-in-fact as a result of the challenged rule, this Court should defer ruling on the cross-motions for summary judgment to allow for a period of targeted jurisdictional discovery. *See* Fed. R. Civ. P. 56(d); *Bailey v. KS Mgmt. Servs., L.L.C.*, No. 21-20335, --- F.4th ---, 2022 WL 1672850, at *2 (5th Cir. May 26, 2022). Plaintiff has described portions of its contract with Air Methods, but it has not produced that contract in its entirety. At the very least, further proof would be needed of the course of dealings between Plaintiff and Air Methods before Plaintiff could be held to have satisfied its burden of proof to show its standing.

[4] For this reason, this case is unlike *Texas Medical Association*. In that case, this Court held that the plaintiffs had "established that they will likely suffer financial harm" directly from the operation of an arbitration rule. 2022 WL 542879, at *5. Here, Plaintiff suffers no such direct harm, since it is held harmless by Air Methods. Plaintiff instead offers only speculation that it will indirectly suffer a harm because Air Methods might end up terminating its contract. This speculation does not suffice.

II. The Rule's Arbitration Procedures Are Consistent with the No Surprises Act.

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-112(b)(2)(A). The Departments fulfilled that responsibility by issuing the September rule, which comprehensively addresses the procedures for the parties to a dispute over payment for an out-of-network air ambulance service to invoke the arbitration process, to select an arbitrator, and to present their offers and their respective positions to that arbitrator, so that he or she may select one of the two offers under a "baseball" arbitration process. *See* 45 C.F.R. § 149.520(b). This exercise of the Department's statutory authority is governed by the *Chevron* standard.

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 the party's offer, and "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate." *Id.* § 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, the air ambulance type, and the training, experience, and quality of the medical personnel furnishing the service. *Id.* 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 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.*

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 the information shows 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 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-112(a)(1). For air ambulance services, these cost-sharing obligations are calculated by using the qualifying payment amount. *See id.*; *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.

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 payment amount 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 primarily 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, "there 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). 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 Initiative for Health Policy (Feb. 4, 2021) (AR 1372)); *see also* H.R. Rep. No. 116-615, at 57 (AR 334) (predicting "double digit billions" of dollars in increases in the federal deficit if the arbitration process were designed to increase payments systematically above median in-network 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.

Plaintiff faults the Departments for purportedly violating a statutory command that the arbitrator consider each of the factors in every case. Pls.' Mem. 13. The September rule, however, requires just that. *See* 45 C.F.R. § 149.510(c)(4)(ii)(A) (instructing the arbitrator to "tak[e] into account" each of the statutory considerations); *id.* § 149.520(b)(2). Plaintiff also contends that the September rule improperly treats the QPA differently from the other statutory factors. Pl.'s Mem. 13. But the No Surprises Act itself directs the arbitrator first to the qualifying payment amount, and then instructs the arbitrator next to consider "additional information" or "additional circumstances" that may warrant the award of a different 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.

Indeed, the September rule plainly satisfied the deferential *Chevron* 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. 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 addresses the market distortion caused by surprise billing practices, by diminishing the discrepancy between out-of-network payments for air ambulance services and the in-network payments for the same services that are negotiated at arm's length in a free market. *See id.*

The Departments recognize that this Court reached a contrary conclusion with respect to the provisions of 45 C.F.R. § 149.510 that were at issue in *Texas Medical Association*. For the reasons stated above, the Departments respectfully disagree with that decision.

III. The Departments Were Not Required to Issue the Rule through Notice-and-Comment Rulemaking.

A. The Governing Statutes Authorize the Departments to Issue Interim Final Rules as They Deem to Be Appropriate.

An agency ordinarily is required to publish a notice of proposed rulemaking, and to provide for a period of public comment, before issuing a substantive rule. *See* 5 U.S.C. § 553(b), (c). But an agency may forgo notice and comment, and instead issue an interim final rule, when Congress sets forth its "clear intent that APA notice and comment procedures need not be followed." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994); *see also Asiana Airlines v. FAA*, 134 F.3d 393, 397-98 (D.C. Cir. 1998); *Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 105 (D.D.C. 2006) (statute providing that "[t]he Secretary may promulgate interim final regulations" "granted the [agency] some discretion to issue an interim rule without first providing notice and comment in order to ensure that a rule was in place by" a statute's effective date). This is the case here.

The No Surprises Act amends the PHSA, ERISA, and the Internal Revenue Code. Each of these statutes authorizes the Secretary of each of the Departments to "promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter," 42 U.S.C. § 300gg-92; *see also* 26 U.S.C. § 9833; 29 U.S.C. § 1191c, and the Departments found it to be appropriate to issue interim final rules so as to allow regulated parties to prepare for the Act's new legal regime. The statutory authorization to issue interim final rules as the Departments "determine[] are appropriate"

is an express grant of authority to issue rules without an advance period of public notice and comment, and to do so applying a standard that is different from the ordinary APA standards for interim final rules. *Cf. Kisor v. Wilkie*, 139 S. Ct. 2400, 2448-49 (2019) (Kavanaugh, J., concurring) ("[S]ome cases involve regulations [or, here, statutes] that employ broad and open-ended terms like 'reasonable,' 'appropriate,' 'feasible,' or 'practicable.' Those kinds of terms afford agencies broad policy discretion, and courts allow an agency to reasonably exercise its discretion to choose among the options allowed by the text of the rule [or, here, statute].").

The Departments recognize that some out-of-circuit authority has reasoned that 42 U.S.C. § 300gg-92 does not authorize a departure from ordinary APA rulemaking procedures. *See Pennsylvania v. President*, 930 F.3d 543, 566 (3d Cir. 2019), *rev'd*, 140 S. Ct. 2367 (2020); *California v. Azar*, 911 F.3d 558, 578 (9th Cir. 2018). And the Departments acknowledge, of course, that this Court followed the reasoning of those cases in its *Texas Medical Association* opinion. The Departments respectfully disagree, however, with the reasoning of those cases, which failed to account for the point that the Departments already had the authority under the APA to issue interim final rules even in the absence of Section 300gg-92. The specific grant of authority to the Departments to issue interim final rules as they "determine[] are appropriate" adopts a standard that is different from the ordinary APA procedures. Otherwise, Section 300gg-92 would be mere surplusage, an outcome contrary to the canons of statutory construction. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001).

Because the Secretaries were entitled to rely on their statutory authority to issue interim final rules as they "determine[d] appropriate," the Secretaries were not required to adhere to the APA's notice and comment requirement. Plaintiff's claim of a procedural violation should be rejected.

B. The Defendants Had Good Cause to Issue the Interim Final Rule.

Even if the September interim final rule were subject to the APA's notice and comment requirement, the Departments properly invoked the "good cause" exception to this requirement. *See* 5 U.S.C. § 553(b)(B). The Departments respectfully disagree with this Court's contrary conclusion with respect to this issue in its *Texas Medical Association* opinion.

Although the good cause exception to the notice and comment requirement is narrow, it does permit agencies to depart from the default APA rulemaking procedures where the circumstances so warrant. This "good cause inquiry is inevitably fact- or context-dependent." *Mid-Tex Elec. Co-op., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987). "[D]eviation from APA requirements has been permitted where congressional deadlines are very tight and where the statute is particularly complicated." *Methodist Hosp. of Sacramento*, 38 F.3d at 1237; *see also United States v. Cain*, 583 F.3d 408, 422 (6th Cir. 2009) ("A deadline imposed by Congress before which an agency must regulate may support a finding of good cause, which makes sense because Congress can implicitly set aside the APA when it specifically requires rapid action."). A statutory deadline "is a factor to be considered" in evaluating good cause. *U.S. Steel Corp. v. EPA*, 595 F.2d 207 (5th Cir. 1979).

The Departments properly invoked the good cause exception by including in the Federal Register their finding that notice and comment would be impracticable and contrary to the public interest. 86 Fed. Reg. at 56,043. The Departments noted that the major provisions of the No Surprises Act would go into effect on January 1, 2022, barely twelve months after these provisions were enacted, and that regulated entities would need months of lead time to prepare for the new legal regime. *Id.* at 56,043-56,044. First, the Departments found that health plans and health insurance issuers would have to account for the provisions of the September rule "in establishing premium or contribution rates and in making other changes to benefit designs," and would "need time to secure approval for required changes in advance of plan or policy years." *Id.* at 56,044; *see also, e.g.*, Letter from Katy Johnson, Senior Counsel, Health Policy, American Benefits Council, to Carol Weiser, Benefits Tax Counsel, U.S. Dep't of Treasury, et al., at 28 (June 11, 2021) (AR 2533) (noting that the forthcoming rules on the arbitration process "will, by necessity, be incredibly complicated" and will "require significant time and effort [for employers, health plans, and insurers] to implement"). Without sufficient lead time, insurers would be forced to guess at the possible content of a rule governing out-of-network payments. There is a close correlation between the amounts that insurers anticipate that they will need to pay providers for out-of-network services and the amounts that insurers set as premiums, and any lingering uncertainty over the particulars of the new legal regime

would increase premiums further. *See, e.g.*, Duffy et al., 26 AM. J. MANAGED CARE at 403 (AR 1385). The Departments thus properly found that prompt rulemaking was required to avoid increasing health care premiums, a result that would defeat the Act's purpose of reducing health care costs.

Second, the Departments found that providers would need lead time to respond to the September rule's new standards "regarding how they must initiate open negotiation and the Federal IDR process, as well as what information they must provide to certified IDR entities when engaging in the Federal IDR process." 86 Fed. Reg. at 56,044. For many out-of-network medical services furnished on or after January 1, 2022, the Act prohibits certain health care providers from balance billing patients, and it directs those providers to the new statutory process for dispute resolution. But to present claims for payment to group health plans and health insurers after that date, providers needed advance notice of the types of information and the nature of the information that they would need to develop contemporaneously to support those claims. Given that an arbitrator will be empowered to rule against a provider for its failure to provide contemporaneous information supporting the provider's payment claim, *see* 42 U.S.C. § 300gg-112(b)(5)(B)(i)(II), it was vitally important for the Departments to set the arbitration rules well in advance of the Act's effective date.

On this score, the Departments recognized that they did not have the option of deferring the date on which the arbitration process would go into effect. The Act's prohibitions on balance billing went into effect on January 1. For providers who are now statutorily prohibited from balance billing patients, the absence of a functional arbitration process would mean that they could not recover full payment for out-of-network services either from patients or from insurers, resulting in "the possibility that [these providers] will be undercompensated for their services," 86 Fed. Reg. at 56,044, potentially threatening their viability and patients' access to medical care, *id.* As a coalition of providers warned the Departments, "if the IDR process [were] not ready on the backend by January 1 when the balance billing protections are implemented, then providers [would] be at the mercy of the insurer for reimbursement." Centers for Medicare & Medicaid Servs., *Report: No Surprises Act Listening Session with Providers* at 3 (Apr. 14, 2021) (AR 2492). These circumstances "constitute[] the 'something specific' required to forgo notice and comment." *Biden v. Missouri*, 142 S. Ct. 647, 654 (2022).

Third, the Departments found that prompt rulemaking was required to allow time for arbitrators to "acquire the necessary expertise and evidence of qualification to apply for certification in order to be prepared to conduct payment determinations for plan years beginning on or after January 1, 2022." *Id.* Upon issuing the interim final rule, the Departments gave arbitrators one month to review the rule's certification procedures and to submit applications for certification, leaving the Departments only two months to review applications and to complete the process of approving or rejecting those applications, in order for an approved list of arbitrators to be in place by the beginning of 2022. *See* Centers for Medicare & Medicaid Services, *Apply to become a certified Independent Dispute Resolution Entity*, cms.gov/nosurprises/help-resolve-payment-disputes/apply. Any further delay would not have left the Departments with sufficient time to ensure that certified arbitrators meet the Act's standards for expertise and integrity. *See* 42 U.S.C. § 300gg-111(c)(4)(A).

These circumstances establish good cause for the Departments' determination that an interim rule was needed in advance of a final rule to be issued after notice and comment. It generally takes federal agencies more than a year to complete the process of preparing a proposed rule; submitting a proposed rule to OMB for that agency's review; publishing a proposed rule; allowing for a comment period; reviewing the comments that are submitted; preparing a final rule; submitting the final rule again to OMB; and publishing the final rule. *See* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 N.W. L. Rev. 471, 513-19 (2011) (on average, even routine rulemakings take 1.3 years to complete, and significant rulemakings on average take four months longer). The Departments did not have the option to wait that long to issue these rules, given the need for advance planning shared by insurers, providers, and arbitrators alike.

Congress recognized this need for prompt action by directing the Departments to "establish by regulation" the arbitration process no later than December 27, 2021. 42 U.S.C. § 300gg-112(b)(2)(A). *See Petry v. Block*, 737 F.2d 1193, 1200-01 (D.C. Cir. 1984) (upholding interim final rule given the statute's complexity and the short time frame to issue implementing regulations). Given "the regulated industry's need for guidance" in advance of the Act's effective date, the Departments had good cause to take the steps needed to create an arbitration system that would be able to function

effectively from the outset. *See Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 20 (D.D.C. 2010) (upholding interim rule issued under Section 300gg-92 to implement new statutory requirements); *see also Am. Transfer & Storage Co. v. ICC*, 719 F.2d 1283, 1293 (5th Cir. 1983).

C. Any Error in Promulgating the Interim Final Rule Was Harmless.

In any event, any procedural error was harmless. *See City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013); *see also* 5 U.S.C. § 706 (in reviewing agency action, "due account shall be taken of the rule of prejudicial error"). The Departments respectfully disagree with this Court's contrary conclusion with respect to this issue in its *Texas Medical Association* opinion. "The harmless error rule requires the party asserting error to demonstrate prejudice from the error." *City of Arlington*, 668 F.3d at 243 (internal quotation omitted). Although Plaintiff makes a cursory attempt to allege that it suffered prejudice, Pl.'s Mem. 15, it does not explain what harm it believes it has suffered. To the best of the Departments' knowledge, Plaintiffs did not submit a comment on the rulemaking record in response to the September rule. This forecloses any possible claim that it suffered prejudice from the Departments' rulemaking procedures. *See Am. Bankers Ass'n v. NCUA*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (finding harmless error where the plaintiff "did not explain what it would have said had it been given an opportunity to respond").

Plaintiff cannot meet its burden to show prejudice. "In conducting the harmless error inquiry, [the court informs its] analysis with a number of potentially relevant factors, including (1) 'an estimation of the likelihood that the result would have been different'; (2) 'an awareness of what body (jury, lower court, administrative agency) has the authority to reach that result'; (3) 'a consideration of the error's likely effects on the perceived fairness, integrity, or public reputation of judicial proceedings'; and (4) 'a hesitancy to generalize too broadly about particular kinds of errors when the specific factual circumstances in which the error arises may well make all the difference.'" *City of Arlington*, 668 F.3d at 244 (quoting *Shinseki v. Sanders*, 556 U.S. 396, 411-12 (2009)). Each of these factors points toward a finding that any error was harmless here.

First, there is no indication that the Departments' conclusions would have been materially different had they first engaged in notice and comment. Plaintiffs does not contend that the

Departments failed to consider any relevant factual or policy issues in resolving statutory ambiguities at Step Two of the *Chevron* inquiry; instead, it raises a purely legal argument that the rule is foreclosed by the language of the statute. The Departments were aware of Plaintiff's legal argument, and simply arrived at a different reading of the statutory language. *See* 86 Fed. Reg. at 55,995-55,997. Second, Congress expressly entrusted the Departments with the authority to establish the arbitration process under the No Surprises Act, *see* 42 U.S.C. § 300gg-111(c)(2), and it did so by amending existing statutes that themselves expressly give the Departments interim final rulemaking power, *see* 42 U.S.C. § 300gg-92. Third, there is no reason to believe that the "error" will have any effect on the "perceived fairness, integrity, or public reputation of judicial proceedings." *City of Arlington*, 668 F.3d at 244.

Finally, the "specific factual circumstances in which the [alleged] error arises" also point against finding any prejudice here. *Id.* Although Plaintiff has not participated in the rulemaking proceedings, the Association of Air Medical Services has robustly done so. It advocated its construction of the statutory language with regard to air ambulance arbitrations in numerous instances in correspondence and meetings with the Departments, in advance of the issuance of the September rule. AR 2501; AR 4989; AR 4985; AR 5782. The Departments thus have been presented with the air ambulance providers' statutory arguments, and they simply disagreed with their reading of the statute. Moreover, the September rule invited comments from the public, *see* 86 Fed. Reg. at 55,980, and the Departments are considering these comments as they formulate final rules for the arbitration process, which they anticipate will be issued by early summer. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020).

IV. The Rule Is Not Arbitrary and Capricious.

Plaintiff contends that 45 C.F.R. § 149.520 is now arbitrary and capricious, in light of the *Texas Medical Association* decision, insofar as it now treats the arbitration of air ambulance providers' payment disputes differently from the arbitration of payment disputes involving other providers. Pl.'s Mem. 15. This argument misconstrues the nature of arbitrary-and-capricious review of a rulemaking under the Administrative Procedure Act.

"Agency action is to be upheld, if at all, on the basis of the record before the agency at the time it made its decision." *Louisiana v. Verity*, 853 F.2d 322, 327 n.8 (5th Cir. 1988) (emphasis added); *see also Texas v. United States*, 300 F. Supp. 3d 810, 851 (N.D. Tex. 2018) (A "[c]ourt determines whether an agency action is arbitrary and capricious 'solely on the basis of the agency's stated rationale at the time of its decision.'") (quoting *Luminant Generation Co. v. EPA*, 675 F.3d 917, 925 (5th Cir. 2012)), *aff'd in part, rev'd in part on other grounds sub nom. Texas v. Rettig*, 987 F.3d 518 (5th Cir. 2021). This is because "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *see also Sierra Club v. U.S. Fish & Wildlife Serv.*, 245 F.3d 434, 444 (5th Cir. 2001).

If a party believes that changed circumstances warrant a different rule, "[t]he proper procedure for pursuit of [that] grievance is set forth explicitly in the APA: a petition to the agency for rulemaking, § 553(e), denial of which must be justified by a statement of reasons, § 555(e), and can be appealed to the courts, §§ 702, 706." *Auer v. Robbins*, 519 U.S. 452, 459 (1997). In the absence of such a petition, "there is no basis for the court to set aside the agency's action prior to any application for relief addressed to the agency itself." *Id. See also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (a "party cannot challenge [an] agency's failure to amend its rule in light of changed circumstances without first seeking relief from the agency").

As noted, the Departments are currently preparing a final rule that will address the procedures for the arbitration of payment disputes involving both air ambulance service providers and other types of health care providers. They are thus already engaged in the new rulemaking process that would be the proper forum to address Plaintiff's claim under *Auer* and *Encino Motorcars*. In the meantime, Plaintiff's arguments do not cast doubt on the rationale underlying the September rule.

V. Any Relief Should Be Appropriately Limited.

In the event the Court disagrees with the Departments, any relief should be no broader than necessary to remedy the demonstrated harms of the specific, identified plaintiffs 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). For this reason, "[a] valid Article III remedy 'operates with respect to specific parties,' not with respect to a law 'in the abstract.'" *Arizona v. Biden*, 31 F.4th 469, 483 (6th Cir. 2022) (Sutton, J., concurring) (quoting *California v. Texas*, 141 S. Ct. at 2115) (internal alterations omitted). "That is why courts generally grant relief in a party-specific and injury-focused manner." *Id.* at 483 (Sutton, J., concurring). This limit on the judicial role is particularly important where, like here, other litigation is pending challenging the same rule. As the Fifth Circuit recently instructed, "[p]rinciples of judicial restraint control here," *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021), to preclude broad relief that would interfere with other courts' consideration of the same challenge.

At most, the Court should remand the matter to the Departments without vacatur of the challenged provisions because there is "at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so." *Tex. Ass'n of Mfrs. v. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 389-90 (5th Cir. 2021) (remanding without vacatur to permit an agency to cure a notice-and-comment violation). "'Only in 'rare circumstances' is remand for agency reconsideration not the appropriate solution.'" *Id.* (quoting *O'Reilly v. U.S. Army Corps of Eng'rs*, 477 F.3d 225, 238-39 (5th Cir. 2007)). A remand without vacatur is particularly appropriate here, given that the Departments are already in the process of formulating a final rule that will supersede the portions of the September rule that Plaintiff challenges, and they anticipate that they will issue that rule by early summer. In the meantime, vacatur would disrupt the dispute resolution process and threaten the interests of patients, business groups, benefit administrators, insurers, and the public at large, each of whom have a stake in a rule that aims to provide stability and predictability to the arbitration process. These interests counsel heavily against vacatur. *See Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000).

CONCLUSION

For the foregoing reasons, the Defendants' motion for summary judgment should be granted, and the Plaintiffs' motion for summary judgment should be denied. In the alternative, this Court should defer consideration of the summary judgment motions to allow for a limited period of jurisdictional discovery.

Dated: June 1, 2022

Respectfully submitted,

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Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify on this 1st day of June, 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ Joel McElvain
JOEL McELVAIN

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

LIFENET, INC., Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 6:22-cv-00162-JDK

DECLARATION OF JOEL McELVAIN

Pursuant to 28 U.S.C. § 1746, I, Joel McElvain, declare and state as follows:

1. I am counsel of record for the Defendants in this action. I make this declaration based on my personal knowledge and on information I have received in my official capacity.

2. Plainitff, LifeNet, Inc., filed a motion for summary judgment in this action on May 18, 2022, ECF No. 27, twenty-one days after it filed its complaint, *see* ECF No. 1. The Defendants have not yet had the opportunity to conduct discovery in this action.

3. In that summary judgment motion, Plaintiff asserts that it has standing to bring this action, relying on two declarations of its general counsel, James L. Gaines. *See* ECF No. 27-2 (1st Gaines Decl.); ECF No. 27-3 (2d Gaines Decl.). These declarations describe a contract in force between Plaintiff and Air Methods Corporation.

4. In its summary judgment motion, Plaintiff concedes that "[t]his contract sets an agreed amount of compensation for LifeNet's emergency air transport services,

which amount is to be paid to LifeNet by Air Methods. According to the contract, Air Methods is responsible for collecting reimbursement from other payors (e.g., patients, health plans, health insurers) for LifeNet's services. But Air Methods owes the agreed amount to LifeNet, for a given transport, even if Air Methods is unsuccessful at collecting reimbursement for that transport from other payors." ECF No. 27, p. 11.

5. Plaintiff asserts that Air Methods may terminate or seek to renegotiate its contract with Plaintiff, citing a portion of the contract. *See* ECF No. 27-3, ¶ 3. Plaintiff has not produced a full copy of the contract.

6. The cited portion of the contract purportedly permits either party to terminate the contract in the event that revenue drops to a "financially unviable situation that is beyond the reasonable expectations of either Party," and only "upon at least 180 days prior written notice to the other Party." *See id.*

7. Plaintiff has produced no evidence that would permit an evaluation as to how likely it is that Air Methods would invoke this termination provision. For example, the record lacks evidence as to the course of dealing between Plaintiff and Air Methods; the revenues that either of those parties realized under this contract and/or any other previous contract between the parties; the reasonable expectations of either party at the time the contract was executed; or the presence or absence of any communications between the parties relating to plans to invoke the contract's termination procedures.

8. The Defendants contend that Plaintiff has failed to carry its burden on summary judgment to demonstrate its standing, and have moved for summary judgment in their favor on this ground. In the alternative, the Defendants contend pursuant to

Rule 56(d) of the Federal Rules of Civil Procedure that further discovery is needed before Plaintiff could carry its burden to prove its standing. The Defendants contend that discovery that is directed toward elucidating the evidence described in paragraph 7 above would be necessary to evaluate any evidence purportedly supporting Plaintiff's claim of standing.

9. For example, the production of a complete copy of the contract between Air Methods and LifeNet may reveal additional conditions on either party's invocation of the termination provision. Discovery into the course of dealings between Air Methods and Plaintiff may reveal information regarding each party's understanding of the meaning of the phrase "financially unviable situation," as that phrase is used in the cited passage of the contract; this discovery may reveal that it is unlikely that arbitrations under the No Surprises Act could create a "financially unviable situation," within the meaning of the contract, for either party. Discovery into the revenues realized by either party could reveal information with regard to each party's expectation of their financial performance under the contract, and the reasonableness of those expectations. In the absence of discovery into these topics, however, Plaintiff has not carried its burden to prove its standing.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief. Executed this 1st day of June, 2022 in Washington, D.C.

/s/ Joel McElvain
JOEL McELVAIN

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

LIFENET, INC.,

Plaintiff,

v.

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

Defendants.

No. 6:22-cv-00162-JDK

ORDER

Before the Court is the Plaintiff's Motion for Summary Judgment and the Defendants' Cross-Motion for Summary Judgment or, in the Alternative, for Jurisdictional Discovery. Having fully considered both motions, and finding that the Plaintiffs have not carried their burden in this case, the Plaintiffs' Motion is DENIED and the Defendants' Cross-Motion is GRANTED, and summary judgment is awarded to the Defendants.

IT IS SO ORDERED.

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

LIFENET, INC.,

Plaintiff,

v.

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

Defendants.

No. 6:22-cv-00162-JDK

ORDER

Before the Court is the Plaintiff's Motion for Summary Judgment and the Defendants' Cross-Motion for Summary Judgment or, in the Alternative, for Jurisdictional Discovery. Having fully considered both motions, and finding that a dispute of fact remains with respect to Plaintiff's standing, the Court's consideration of the Motions is STAYED pending a period of discovery limited to the question whether Plaintiff has Article III standing to pursue its claim.

IT IS SO ORDERED.