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

TEXAS MEDICAL ASSOCIATION, et al.,	)	
	)	
Plaintiffs,	)	
	)	Case No.: 6:22-cv-00450-JDK
v.	)	
	)	Lead Consolidated Case
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
	)	
Defendants.	)	
	)	

AIR AMBULANCE PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT

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The Air Ambulance Plaintiffs—LifeNet, Inc., East Texas Air One, LLC, Rocky Mountain Holdings, LLC, and Air Methods Corporation ("Air Ambulance Plaintiffs")—respectfully move the Court for summary judgment on Counts I through IV of their Complaint.

INTRODUCTION

The Air Ambulance Plaintiffs join the motion filed by the Texas Medical Association Plaintiffs ("TMA"), *see Motion for Summary Judgment*, ECF 25 (Jan. 17, 2023). Here, Air Ambulance Plaintiffs seek summary judgment on two additional claims, and also give two additional reasons why the Departments' QPA calculation methodology must be set aside.

First, the "July Rule," *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021),[1] contravenes the clear statutory deadline governing when an insurer must send its initial payment, or notice of denial, to the provider. This is a crucial gatekeeping event: the provider cannot move forward to an IDR determination until the insurer does this. Congress required the insurer to send its initial payment, or notice of denial, 30 calendar days after "the bill" is "transmitted" to it. 42 U.S.C. § 300gg-112(a)(3)(A).[2] Congress did *not* give the Departments power to change this deadline through rulemaking. But the Departments did so anyway, replacing Congress's clear deadline with an amorphous standard that allows the insurer to delay this critical

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[1] The Air Ambulance Plaintiffs' Complaint also referred to this rule as "*IFR Part I*." This brief uses "July Rule" in order to be consistent with the TMA Brief.

[2] The relevant statutory and regulatory provisions at issue in this case generally appear in triplicate and are identical in all material respects. For ease of reference, this brief—like TMA's brief—cites the relevant Public Health Services Act ("PHSA") provisions in Title 42, United States Code (42 U.S.C. §§ 300gg, *et seq.*) and the relevant PHSA implementing regulations in Title 45, Code of Federal Regulations (45 C.F.R. §§ 149, *et seq.*), which are enforced by the Department of Health and Human Services ("HHS"). The NSA made parallel amendments to the Employee Retirement Income Security Act ("ERISA"), enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), enforced by the Department of the Treasury. The relevant provisions are also codified at 29 U.S.C. §§ 1185e, 1185f (ERISA), and 26 U.S.C. §§ 9816, 9817 (IRC). The implementing regulations are also codified at 29 C.F.R. §§ 2590.716–2590.717 *et seq.* (ERISA) and 26 C.F.R. §§ 54.9816–54.9817 *et seq.*

step until 30 calendar days after the insurer "receives" all of the "information" it believes to be "necessary to decide the claim"—an effectively unenforceable deadline that allows insurers to delay paying what they owe. *See* 45 C.F.R. § 149.130(b)(4)(i). The Departments took no steps to forestall the "abuse" and "gaming" by insurers that they foresaw would result, and that has in fact resulted, from their unauthorized re-write of Congress's deadline. *See* July Rule, 86 Fed. Reg. at 36,901.

Second, the Departments' informal guidance, first issued in August 2022, now requires air ambulance providers to submit *two* separate IDRs for a *single* air ambulance transport. Overnight, this new two-IDRs-per-transport rule has doubled the costs, the fees, and the administrative burdens on everyone involved in the IDR process. The Departments have never articulated a reason for this new rule. It is contrary to common sense and to Congress's express statutory command, which was to create rules permitting IDR entities to consider services "jointly as part of a single determination" in order to "encourage[] the efficiency (including minimizing costs) of the IDR process." 42 U.S.C. § 300gg-111(c)(3)(A); *id.* § 300gg-112(b)(3).

Third, the Departments' QPA calculation methodology must be set aside as contrary to the statute, and as arbitrary and capricious, for two additional reasons not discussed in TMA's brief. The July Rule excludes, from the QPA, tens of thousands of rates that were agreed to in so-called "case-specific" agreements, which were agreed to by insurers and out-of-network providers in specific cases. "Case-specific" agreements are particularly common in the air ambulance industry, where in-network agreements are relatively rare. The Departments base this exclusion on their erroneous assertion that case-specific agreements are not "contracts," *see* 45 C.F.R. § 149.140(a)(1), even though they meet the black letter definition of that word, and even though

the Departments expressly found that case-specific agreements constitute a "contractual relationship" for other purposes, *see* 45 C.F.R. § 149.30.

The QPA methodology is also irrationally over-inclusive, because the Departments arbitrarily include contracted rates agreed to across an enormous geographic area. The Departments' rules permit an insurer to use a rate agreed to in Anchorage, Alaska to be used to calculate the QPA for a transport in San Diego, California. *See* 45 C.F.R. § 149.140(a)(7)(ii)(B). This expansion is irrational and contrary to the statutory goal of ensuring viable services in rural areas.

STATEMENT OF THE ISSUE

The Air Ambulance Plaintiffs respectfully incorporate TMA's statement of the issue. *See* ECF 25 at 2.

STATEMENT OF UNDISPUTED MATERIAL FACTS

The Air Ambulance Plaintiffs respectfully incorporate TMA's statement of undisputed material facts. *See* ECF 25 at 2–15. In addition, the Air Ambulance Plaintiffs add the following undisputed material facts relating to the separate claims and arguments made herein.

A. The Statutory and Regulatory Provisions Applicable to Air Ambulance Providers Are Substantially the Same

In the No Surprises Act ("NSA"), Congress enacted a separate—and much shorter—statutory provision that governs air ambulance IDRs: 42 U.S.C. § 300gg-*112*. For the most part, that separate provision is either identical to, or incorporates by reference, the statutory provision that governs *non*-air ambulance IDRs: 42 U.S.C. § 300gg-*111*.

One difference is that the "out-of-network rates" for *air ambulance* services are *never* determined by an All-Payer Model Agreement or specified state law. *Contra* ECF 25 at 3–4. That is because such state laws are preempted by the federal Airline Deregulation Act. *See* July Rule,

86 Fed. Reg. at 36,884. As a practical matter, this means that the IDR process is *the* central mechanism for ensuring that air ambulance providers receive adequate payment from insurers for their emergency services.

B. The July Rule Permits Insurers to Use "Ghost Rates" In Calculating the QPA

One example of "ghost rates" is described by the expert analysis firm of Dobson DaVanzo. *See* Compl. ECF 1 at ¶ 54–55; Compl. Ex. A, ECF 1-1 (DaVanzo Decl.). Their analysis of data made public by Aetna of Texas, pursuant to the Transparency in Coverage Act,[3] demonstrates that this payor's data includes many contracted rates, for air ambulance services, agreed to by providers that do not typically operate air ambulances. *See* Compl. Ex. A, ECF 1-1 (DaVanzo Decl.). For example, the data shows contracted rates, for air ambulance transport, which were agreed to by social workers, optometrists, and psychologists. *Id.*

The Dobson DaVanzo analysis is confirmed by another independent analysis firm, Avalere Health. According to Avalere Health, insurers' QPAs are routinely based on contracts with providers who "rarely or never provide" the service in question. Avalere Health, *PCP Contracting Practices and Qualified Payment Amount Calculation Under the No Surprises Act*, 1, (August 15, 2022) https://www.acr.org/-/media/ACR/Files/Advocacy/2022-8-15-Avalere-QPA-Whitepaper_Final.pdf [available at: https://perma.cc/6NJN-ZULQ].

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[3] *See* Transparency in Coverage Act Final Rules, 45 C.F.R. § 147.211(b)(1)(iii); *see also FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 29*, Dep'ts (Aug. 20, 2021) (https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf) [available at https://perma.cc/B7L7-QEKM].

C. The July Rule Re-Writes the Insurers' Deadline for Making an Initial Payment or Notice of Denial

The IDR process cannot even begin until the provider first obtains, from the insurer, an "initial payment" or a "notice of denial of payment." *See* 42 U.S.C. § 300gg-112(b)(1)(B) (IDR can only be "initiate[d]" "during the 4-day period beginning on the day after [the] open negotiation period"); *id.* § 300gg-112(b)(1)(A) (the "open negotiation period," in turn, can only be "initiate[d]" "during the 30-day period beginning on the day the provider receives an initial payment or a notice of denial of payment"); *see also* 45 C.F.R. §§ 149.510(b)(1)(i), (b)(1)(ii)(B), (b)(2)(i) (regulatory provisions implementing these statutory deadlines); 45 C.F.R. § 149.520(b)(1) (incorporating these provisions and deadlines for air ambulance IDRs).

Congress set a clear deadline in the NSA for when the insurer must provide its "initial payment" or "notice of denial of payment": 30 calendar days after the provider "transmit[s]" its "bill" to the insurer. *See* 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(I); *id.* § 300gg-111(b)(1)(C); *id.* § 300gg-112(a)(3)(A) (same, for air ambulances). This is the only statutory deadline in the NSA that is measured in *calendar* days, which underscores its importance.[4]

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[4] *Compare* 42 U.S.C. §§ 300gg-111(a)(1)(C)(iv)(I), 300gg-111(b)(1)(C) (the "initial payment" or "notice of denial of payment" is due within "30 *calendar* days" after the provider submits the bill) (emphasis added), and *id.* § 300gg-112(a)(3)(A) (same, for air ambulances), *with id.* § 300gg-111(c)(1)(A) ("the *30-day period*" to initiate open negotiations and the "*30-day-period*" which open negotiation lasts after initiation) (emphasis added), *id.* § 300gg-112(b)(1)(A) (same, for air ambulances), *id.* § 300gg-111(c)(1)(B) (the IDR process must be initiated "during the *4-day period*" after the open negotiation period closes) (emphasis added), *id.* § 300gg-112(b)(1)(B) (same, for air ambulances), *id.* § 300gg-111(c)(3)(A)(iv) ("*30[-]day period*" applicable to certain batched submission requirements) (emphasis and alteration added), *id.* § 300gg-112(b)(3) (same, for air ambulances), *id.* § 300gg-111(c)(4)(F) (deadlines to select IDR entities based on "*business days*") (emphasis added), *id.* § 300gg-112(b)(4)(B) (same, for air ambulances), *id.* 300gg-111(c)(5)(A), (B) ("*10 day[]*" offer deadline in IDR and "*30 day[]*" decision deadline in IDR) (emphasis added), *id.* § 300gg-112(b)(5)(A), (B) (same, for air ambulances), *id.* § 300gg-111(c)(5)(E)(ii) ("*90-day period*" applicable for "cooling-off period") (emphasis added), *id.* § 300gg-112(c)(5)(D) (same, for air ambulances), *id.* § 300gg-111(c)(6) ("*30*

In the July Rule, the Departments changed the deadline as follows: "the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services." 45 C.F.R. § 149.130(b)(4)(i).[5] The Departments acknowledged that this regulation created the possibility for "abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim." July Rule, 86 Fed. Reg. at 36,901. But the Departments made no effort to prevent the "abuse" and "gaming" they foresaw. The July Rule does not define what "information" an insurer can demand from the provider (or from others), does not require the insurer to take any affirmative steps to obtain the "information" it claims to need, and does not place any limits whatsoever on how long an insurer can delay. *See generally id.*

The "abuse and gaming" by insurers, which the Departments foresaw, has come to pass. Approximately 53% of the bills that Plaintiff Air Methods transmits do not receive an initial payment or denial within 30 calendar days of the bill being transmitted by Air Methods to the insurer. Ex. A (Brady Decl.), ¶ 2. Sometimes the delays are extreme: Air Methods' records show claims that have languished in the insurer's hands, without any initial payment or denial, for more than 325 days. *Id.* ¶ 3. Currently, Air Methods' records indicate an average of 104 calendar days between the time it submits a bill to the date insurers make initial payments. *Id*. Insurers commonly state their claims systems were not ready to process initial payments pursuant to the NSA's requirements. *Id.* ¶ 4. But the majority of the time, insurers have attributed their late payments to not being educated on the NSA. *Id*.

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day[]" post-determination deadline for additional payments) (emphasis added), and *id.* § 300gg-112(c)(6) (same, for air ambulances).

[5] Similar provisions apply to non-air-ambulance providers. 45 C.F.R. §§ 149.110(b)(3)(iv)(A); 149.120(c)(3).

Plaintiff East Texas Air One's experience is similar: Approximately 67% of the bills that it transmits do not receive an initial payment or denial within 30 calendar days. Ex. B (Mariani Decl.), ¶ 5. Here again, some delays are extreme: East Texas Air One's records show claims that have languished in the insurer's hands, without any initial payment or denial, for 253 days, with some claims still pending from March 2022. *Id.* ¶ 4.

These delays have important real-world consequences. Providers cannot initiate the federal IDR process, to force insurers to make a payment, until after the insurer provides its initial payment or notice of denial. *See supra,* at p. 5. So, if the insurer can find any means to delay sending its initial payment or notice of denial, the insurer is immediately rewarded by a delay of all other relevant dates, allowing the insurer to hang on to the provider's money for as long as possible. That benefits the insurer not only because of the time-value of money (the insurer can invest the money and the NSA does not provide for interest to compensate the provider for the delay) but also because the lack of cash flow to providers imperils providers' businesses and may even force providers to accede to unreasonably low payment or to an unfair in-network contract, simply for the sake of getting *some* cash in the door in time to meet payroll and keep the lights on. The practical effect of the challenged regulation, therefore, is to deprive providers of their right to reimbursement for an undefined length of time.

In a world in which inflation exceeds 7% a year, these delays cause significant monetary harm. To illustrate: suppose the insurer owes $100 to the provider for the out-of-network service. Suppose further that the insurer would have paid that money on July 1, 2022, if not for the "abuse and gaming" that the Departments' regulation enabled. Thanks to the Departments' regulation, the insurer holds on to that money for an extra year, during which time the insurer invests it and receives a 5% rate of return, such that by July 1, 2023, the insurer has $105. On that date, the

insurer finally pays the $100 it owes to the provider (but keeps the $5 investment gain for itself). By that point, thanks to inflation, the $100 paid to the provider on July 1, 2023, has a real purchasing power equivalent to just $93.50 in 2022. Delay means more money for the insurer and less money for the provider.

D. The Departments' August 2022 Informal Guidance Directs IDR Entities to Require Two IDRs For a Single Air Ambulance Transport

A single medical air transport is billed using two HCPCS codes,[6] which are: (a) a base or "lift" rate; and (b) a per-mile rate.[7] Air ambulance providers use those two codes to bill for the *same service* related to the *same patient encounter*. In other words, a single medical air transport of a patient will always result in a bill, from the provider, containing charges for each of these two codes, even though the provider rendered only one service: the transport.

For the first half of 2022, there was broad agreement among providers, IDR entities, and insurers that a single air transport should result in a single IDR process, in which the same IDR entity determined the appropriate payment amounts for both HCPCS codes for the one air transport service. Indeed, Air Methods' records indicate approximately 109 IDRs were resolved between approximately April 2022 and August 2022 in which the IDR entity rendered a single decision on both codes. Ex. A (Brady Decl.), ¶ 7.

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[6] HCPCS stands for Healthcare Procedure Coding System. *See HCPCS—General Information*, Centers for Medicare & Medicaid Services, *available at* https://www.cms.gov/medicare/coding/medhcpcsgeninfo (last visited January 13, 2023).

[7] A fixed-wing air ambulance transport incurs two HCPCS codes: one, a flat fee for the transport (A0430: Ambulance service, conventional air services, transport, one way (fixed wing) (FW)), and a per-mile rate that is calculated based on the number of miles flown with the patient onboard (A0435: Fixed-wing air milage, per statute mile). A rotary-wing air ambulance (i.e., a helicopter) has two similar codes: a flat fee (A0431: Ambulance service, conventional air services, transport, one way (a rotary wing) (RW)), and a per-mile fee (A0436: Rotary wing air milage, per statute mile). *See HCPCS A-Codes,* HCPCS.codes, https://hcpcs.codes/a-codes/ (last visited January 13, 2023).

Beginning in late August 2022, however, the Departments began to interpret their regulations to require *two separate* IDR processes for the *same* transport: one for each of the two HCPCS codes billed for each air ambulance transport. On August 18, 2022, the Departments issued an informal document entitled *Technical Guidance for Certified IDR Entities,* Center for Medicare and Medicaid Services (Aug. 18 2022), https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf [available at: https://perma.cc/R2G9-DW5L] ("*Technical Guidance*"). The *Technical Guidance* states that "multiple qualified IDR items or services" may only be "batched" together if, among other things, the services were "billed under the same service code." *Id.* at 2.

The *Technical Guidance*'s reference to "batching" is an interpretation of 45 C.F.R. § 149.510(c)(3), which states:

> (i) In general. Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). ….
>
> > (C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code ….

45 C.F.R. § 149.510(c)(3).[8]

The Departments have informed IDR entities on phone calls that the August 2022 *Technical Guidance* requires IDR entities to mandate two separate IDRs for each air ambulance transport: one for each HCPCS code. *See* Ex. C (Shepard Decl.) ¶ 3–7; Ex. D (Arters Decl.) ¶ 2–4. The IDR entities are obeying that directive. *See* Ex. C (Shepard Decl.) ¶ 3–7; Ex. D (Arters

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[8] This regulation was promulgated in the second Interim Final Rule, referred to in this and prior litigations as *IFR Part II* or as the "October Rule." *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021).

Decl.) ¶ 2–4. The Air Ambulance Plaintiffs have complied with this directive. Ex. D (Arters Decl.) ¶ 2–4.

On September 13, 2022, in a letter to the Director of Consumer Information and Insurance Oversight (CCIIO) at CMS, undersigned counsel pointed out the absurdity of requiring two separate IDR processes for a single air ambulance transport, and requested that the Departments instruct the IDR entities to return to prior practice of one IDR per air transport. *See* Ex. C (Shepard Decl.) ¶ 2–4. On September 15, 2022, this same counsel had a Zoom meeting with the Deputy Director of CCIIO, and other CMS employees, during which counsel re-iterated this request. *See id.* at ¶ 5. CMS has not responded to counsel's September 13 letter, nor provided any explanation of, or justification for, its new "two IDRs per single transport" requirement. *See id.* at ¶ 7.

On September 28, 2022, an IDR entity informed undersigned counsel that there had been a conference call "that morning" with CMS representatives and representatives of all of the certified IDR entities, during which CMS representatives re-iterated their previous directive: a single air ambulance transport requires two IDRs, one for each billing code. *See id.* ¶ 6.

In-house counsel for Air Methods sent a similar letter pointing out the inefficiencies and duplication occasioned by CMS's *Technical Guidance* on October 21, 2022, but has yet to receive any response. Ex. B (Brady Decl.), ¶ 11–13.

LEGAL STANDARDS

The Air Ambulance Plaintiffs incorporate TMA's statement of the legal standards. *See* ECF 25 at 15–17.

ARGUMENT

I. The Air Ambulance Plaintiffs Incorporate TMA's Arguments

The Air Ambulance Plaintiffs respectfully incorporate by reference all of TMA's arguments except for Subsection I.A.2 of the TMA Brief ("Including rates for providers in

different specialties violates the Act"), *see* ECF 25 at 19–20, which section is not relevant to the Air Ambulance Plaintiffs' Complaint.[9]

II. The Court Should Strike Down the Departments' Regulation (45 C.F.R. § 149.130(b)(4)(i)) That Extends Indefinitely the 30-Day Deadline that Congress Imposed on Insurers to Make Payment Determinations

The NSA unambiguously requires a plan or issuer to send its initial payment (or notice of denial of payment) to the provider "not later than 30 calendar days after the bill for such services is transmitted by such provider." 42 U.S.C. § 300gg-112(a)(3)(A). The "transmi[ssion]" of the provider's "bill" thus starts the 30-calendar-day payment-or-denial clock. *Id.* The statute does not provide any exceptions to this clear deadline.

The insurer's initial payment (or notice of denial of payment) is a critically important date in the NSA's carefully designed scheme. The provider is *unable* to move forward with the IDR process until the insurer provides this initial payment or notice of denial. *See supra*, at p. 5.

A. The Regulation Is Contrary to the Statute's Unambiguous Text

The regulation deviates from the statute's unambiguous mandate. Rather than start the payment clock when the provider "transmit[s]" its "bill," as Congress required, the regulation instead states: "[T]he 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services." 45 C.F.R. § 149.130(b)(4)(i). This creates an enormous regulatory loophole that contravenes the statutory text in two ways.

First, the regulation replaces the statute's clear starting date (i.e., the date when the provider "transmit[s]" the "bill") with an undefined later date (the date on which the insurer unilaterally

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[9] The regulations state that all air ambulance providers belong to the same "specialty." 45 C.F.R. § 149.140(a)(12).

determines that it has received all of "the information necessary to decide a claim"). It is very clear what a "bill" is; it is deeply *unclear* to everyone involved (and especially to the providers waiting to be paid) what is meant by "the information necessary to decide a claim." *See id.* Agencies routinely translate vague statutory standards into specific rules; this regulation does the opposite, by replacing Congress's clear rule with a hopelessly vague standard.

Second, this regulation contravenes the statute because it empowers the insurer to delay paying the provider based on inactions by *third parties* over whom the provider exercises no control. Congress deliberately started the deadline based on an action *by the provider*, namely: the "transmi[ssion]" of the provider's "bill." *See* 42 U.S.C. § 300gg-112(a)(3)(A). The regulation, by contrast, starts the deadline when the insurer "receives" "information"—without specifying *from whom* the insurer might be expecting to receive that information. *See* 45 C.F.R. § 149.130(b)(4)(i). There are many third parties from whom an insurer might want to receive information. What treatment did the patient receive at the emergency room to which the air ambulance transported her? Will the patient's auto insurance pick up any of the tab? Did the other driver cause the wreck, and if so will his insurance pick up the tab? *See* Ex. B (Mariani Decl.), ¶ 6 (describing the most common reasons that insurers have given East Texas Air One for their delays in making initial payments or sending notices of denial). An air ambulance provider does not have the answers to these questions, and does not have any way to compel third parties to provide the answers. The Departments' regulation thus contravenes the statute by delaying the provider's right to commence the IDR process (and thus its right to finally receive payment), based on inactions by third parties whom the provider does not control.

Section 149.130(b)(4)(i)'s departure from the statute is even more obvious when the NSA's provision is considered in the context of the other nearby statutory provisions. As previously

discussed, the NSA's statutory commands are codified in three statutes: ERISA, the PHSA, and the IRC.[10] Prior to the NSA, those statutes did not contain any specific claim-processing deadlines. Instead, the pre-NSA versions of these statutes contained very broad mandates that the claims process be "adequate," "full and fair," or "effective."[11] Those statutory standards were interpreted, by the Departments, to allow insurers to toll the claims-processing deadlines in ways that are similar to the regulation challenged here, albeit with some differences.[12]

In stark contrast to the pre-existing statutory standards for claims processing contained in the ERISA, PHSA, and IRC, Congress in the NSA made the deliberate choice to enact a very specific deadline. *See* 42 U.S.C. § 300gg-112(a)(3)(A). The contrast between the NSA's specific deadline, and these preexisting statutory standards, is further evidence that Congress deliberately intended something different here, since "[d]ifferent words within the same statute should, if possible, be given different meanings." *Cascabel Cattle Co., L.L.C. v. United States*, 955 F.3d 445,

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[10] This brief cites the PHSA codification, where the statutory deadline appears at 42 U.S.C. § 300gg-112(a)(3)(A). The same command also appears in ERISA, at 29 U.S.C. § 1185f(a)(3)(A), and in the IRC, at 26 U.S.C. § 9817(a)(3)(A).

[11] ERISA required group health plans to "provide adequate notice" of any denial and "a reasonable opportunity . . . for a full and fair review" of the denial. 29 U.S.C. § 1133. The PHSA broadly required group health plans and health insurance issuers to "implement an effective appeals process for appeals of coverage determinations and claims." 42 U.S.C. § 300gg-19(a)(1). The PHSA further required group health plan and issuers of group health coverage to follow the ERISA claims processing rules in 29 C.F.R. § 2560.503-1 (as amended). *See* 42 U.S.C. § 300gg-19(a)(2)(A). The PHSA simply required issuers of individual health insurance to "provide an internal claims and appeals process" that met "standards established by the Secretary of Health and Human Services." *Id.* at § 300gg-19(a)(2)(B). The IRC incorporated the PHSA's requirement by reference. *See* 26 U.S.C. § 9815(a).

[12] The Secretary of Labor has interpreted ERISA's broad claims-processing mandate to require the determination of post-service claims "not later than 30 days after receipt of the claim," but the regulation also allows insurers to extend and then toll this deadline, for a discrete period of time, due to "a failure of the claimant to submit the information necessary to decide the claim." 29 C.F.R. §§ 2560.503-1(f)(2)(iii)(B), (f)(4). This ERISA deadline was then incorporated by the Secretaries of HHS and of the Treasury in the corresponding PHSA and IRC regulations. *See* 45 C.F.R. § 147.136(b)(3)(i); 26 C.F.R. § 54.9815-2719(b)(2)(i); 26 C.F.R. § 54.9815-2719T(b)(2)(i).

451 (5th Cir. 2020). The NSA's explicit statutory deadline contains entirely "different words," *id.*, from the vague claims-processing standards contained in the pre-existing statutes into which the NSA's deadline provisions were inserted. The textual differences prove that the Departments cannot be correct when they interpret the NSA's very specific text to be *even vaguer and less specific* than the vague pre-existing statutory standards.[13]

B. Congress Did Not Delegate Rulemaking Authority to the Agencies to Rewrite the Deadline

Congress did not grant the Departments any rulemaking authority to alter the clear deadline that Congress established. "Courts recognize an implicit delegation of rulemaking authority *only* when Congress has not spoken directly to the extent of such authority, or has 'intentionally left [competing policy interests] to be resolved by the agency charged with administration of the statute.'" *Texas v. United States*, 497 F.3d 491, 503 (5th Cir. 2007) (quoting *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 865–66 (1984)) (alternation in original) (emphasis added). "It stands to reason that when Congress has made an explicit delegation of authority to an agency, Congress did not intend to delegate additional authority *sub silentio*." *Id.*

In the NSA, Congress expressly limited and defined its delegations of rulemaking authority.[14] None of those delegations of rulemaking authority gives the Departments any power

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[13] As previously discussed, the Departments' NSA regulation permits the insurer to toll the deadline based on supposed failures by *third parties* to provide information—something that not even the Departments' own prior regulations, implementing the previous broad standards, would allow. *See supra*, nn. 10, 11, 12.

[14] *See* 42 U.S.C. § 300gg-111(a)(2)(A) (audits of QPAs); *id.* § 300gg-111(a)(2)(B) (calculation of QPA, required disclosures, and complaints against insurers); *id.* § 300gg-111(a)(3)(C)(ii)(II)(cc)-(dd) (conditions for waiving NSA protections); *id.* § 300gg-111(b)(2)(B) (services included in medical "visit"); *id.* § 300gg-111(c)(1)(A) (date IDR process deemed to have begun); *id.* § 300gg-111(c)(2)(A) ("establish[ing]" the IDR process for non-air ambulance services); *id.* § 300gg-111(c)(2)(A) (criteria for batching IDR disputes); *id.* § 300gg-111(c)(4) (certification and selection of IDR entities); *id.* § 300gg-111(c)(8) (IDR fees); *id.* § 300gg-

to rewrite the 30-calendar-day deadline that appears in statutory subsection 300gg-112(a). The 30-calendar-day deadline has nothing to do with QPA audits or QPA calculations, and it has nothing to do with the IDR process, which cannot even begin until after the initial payment or notice of denial is received.

Congress's express delegation of rulemaking authority to the Departments regarding *different* subject matters, but *not* regarding the 30-calendar-day deadline, is powerful evidence that Congress deliberately chose not to empower the Departments to alter that deadline. Therefore, the Departments' promulgation of 45 C.F.R. § 149.130(b)(4)(i) exceeded the scope of Congress's delegation of rulemaking authority.

C. The Regulation Is Arbitrary and Capricious

In addition to being contrary to the clear statutory text and beyond the scope of the Departments' delegated powers, the regulation is also arbitrary and capricious for an additional reason: It is, in practice, unenforceable. Neither the providers nor the Departments themselves have any way to know even what the deadlines are, much less to determine whether the deadlines are being followed.

What is the "information necessary to decide the claim" under 45 C.F.R. § 149.130(b)(4)(i)? Since the Departments don't define that vague phrase, it is in practice left open for each insurer to interpret as broadly as it pleases. Necessity is in the eye of the insurer. By adopting ever more expansive views about what information is "necessary" for it to receive before

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111(c)(2)(A) (extension of certain IDR deadlines, *i.e.*, not deadline for initial payment or notice of denial); *id.* § 300gg-111(f)(2) (deadline to provide advanced explanation of benefits); *id.* § 300gg-111(c)(2)(A) (confidentiality of patient information); *id.* § 300gg-112(b)(1)(B) (date IDR process deemed to have begun); *id.* § 300gg-112(b)(2)(A) ("establish[ing]" the IDR process for air ambulance services); *id.* § 300gg-112(b)(8) (IDR fees); *id.* § 300gg-112(b)(9) (extension of certain IDR deadlines, *i.e.*, not deadline for initial payment or notice of denial).

parting with its money, an insurer may delay indefinitely the date on which the 30-calendar-day period begins to run. The insurer is not even required to tell the providers, or the Departments, how it is choosing to interpret the vague phrase, "information necessary to decide the claim." *Id.*

Even if the Departments or the providers were able to learn how insurers are defining this phrase (and they won't learn this, since the insurers aren't required to teach them), the Departments and providers would still be unable to tell whether the insurers are actually abiding by the deadline. The Departments and providers have no way to know whether an insurer has actually received whatever information it claims to need. The regulation does not even require the insurer to inform the Departments or the provider of the date on which it has finally received all this information (whatever it is). In practice, therefore, there is no way for providers or the Departments to tell whether any insurer is obeying this deadline, since no one but the insurer can possibly determine what information is required or when it has been received.

The Departments' failure to provide any way for providers or regulators to tell when the deadline has run is particularly outrageous because these problems were foreseen by the Departments when promulgating the July Rule. Even without the benefit of public comment, the Departments realized the potential for "abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim." July Rule, 86 Fed. Reg. at 36,900. The Departments rewrote the statutory deadline anyway, despite foreseeing this problem, and despite not making any effort to prevent the problem from occurring. As described above, the Air Ambulance Plaintiffs have experienced this "abuse and gaming" first-hand, and have suffered the real-world consequences to their cash flows. *Supra*, at pp. 6–7.

III. The Court Should Strike Down the Departments' New Rule Requiring Two Separate IDR Processes to Adjudicate Payment for a Single Air Transport

The Departments' recent interpretation of their own regulations to require *two separate* IDR processes for the same medical air transport—just because a single transport necessarily includes two different billing codes—is contrary to the statute and arbitrary and capricious.

A. Requiring Two IDRs Per Transport Is Contrary to the Statutory Text

The unambiguous text of the NSA requires that a single dispute, over the amount of payment for a single medical air transport (and its two billing codes), must be resolved in a *single* IDR process. The statute repeatedly refers to a single IDR process for each "service"; the statute does not require two separate IDR processes where, as here, a single service involves two HCPCS codes. *See* 42 U.S.C. §§ 300gg-112(b)(1)(B) (if negotiations fail, the provider may "initiate the independent dispute resolution process . . . with respect to such *item or service*") (emphasis added); *id.* § 300gg-112(b)(2)(A) ("*a* [single] certified IDR entity" shall determine "the amount of payment . . . for such *services*") (alteration and emphasis added); *see also id.* § 300gg-112(c)(1) ("The term 'air ambulance service' means medical *transport* by helicopter or airplane for patients.") (emphasis added).

The Departments' regulations recognize that the term "air ambulance service" means a single "medical *transport* by a rotary wing air ambulance . . . or fixed wing air ambulance," 45 C.F.R. § 149.30 (emphasis added), and further recognize that one air transport is a single "qualified IDR [i]tem or [s]ervice," *id.* § 149.510(a)(2)(xi)(A). *See also id.* § 149.520(a) (regulation governing air ambulance IDRs stating that, unless otherwise provided, the definitions in 45 C.F.R. § 149.30 apply).

The Department's August 2022 *Technical Guidance* broke with the statute's clear directive, and informally directed the arbitrators (the IDR entities) to insist upon two IDR processes for each air ambulance transport. *Supra,* at pp. 8–10.

The Departments' informal guidance is apparently based on the concept of "batching." "Batching" applies where the provider first performs a series of different services over time, often for different patients, and then later seeks to combine ("batch") those distinct services together into a single IDR. The Departments' regulation states that a provider may only "batch" services together in this way if, among other things, those services were "*billed under the same service code*." 45 C.F.R. § 149.510(c)(3); *see also* 42 U.S.C. § 300gg-111(c)(3)(A) (NSA statutory provision on "batching" for non-air ambulance services); *id.* § 300gg-112(b)(3) (same, for air ambulance services).

It is irrational for the Departments to apply the "batching" concept, and its implementing regulation, to a single air transport. A single air transport is, by its nature and its statutory definition, a *single* "service." *See id.* § 300gg-112(c)(1) ("The term 'air ambulance service' means medical *transport* by helicopter or airplane for patients." (emphasis added)). An air transport is quite obviously *not* a series of repeated but similar services provided over time. The "batching" concept thus does not apply when the air ambulance provider initiates a single IDR process to determine the payment due for a single transport.

B. The Departments' New Two-IDRs-Per-Transport Rule Is Directly Contrary to Congress's Rulemaking Directive

The two-IDRs-per-transport rule flouts Congress's express instruction, which directed the Departments to adopt rules that will permit IDR entities to consider items and services "jointly as part of a single determination" whenever the services "*are related to the treatment of a similar condition*"—an instruction that Congress gave in order to "encourage[] the efficiency (including

minimizing costs) of the IDR process." 42 U.S.C. § 300gg-111(c)(3)(A) (non-air ambulance IDRs) (emphasis added); *id.* § 300gg-112(b)(3) (these provisions "shall apply" to air ambulance IDRs). The two air-transport HCPCS codes obviously involve "the treatment of a similar condition," *id.* § 300gg-111(c)(3)(A), because they arise from the same service: transporting a critically ill or injured patient. Therefore, Congress's statutory directive required the Departments to promulgate rules that would allow the payments due, under both codes, to be decided "jointly as part of a single determination." *Id.* At first, the Departments appeared to have complied with that directive despite themselves, since IDR entities managed to adjudicate many disputes, between May and August 2022, that resolved both billing codes in a single IDR. *Supra*, at p. 8–10. But the August 2022 *Technical Guidance* then destroyed that sensible state of affairs.

C. The Regulation Is Arbitrary and Capricious

The Departments never responded to undersigned counsel's letter asking to know *why* this change was implemented in August 2022. *See supra*, at pp. 9–10. The Departments have never explained anywhere, to anyone, why this new two-IDRs-per-transport rule makes sense.

The two-IDRs-per-transport rule is arbitrary and capricious because it bears no rational relation to any legitimate purpose. An air ambulance transport is one service for the patient. It is provided by one air ambulance, with one crew. The provider's submission to the IDR entities, in two IDR processes, will therefore be exactly the same regarding all but one of the nine statutory factors that are relevant to the IDR entity's determination. *See* 42 U.S.C. § 300gg-112(b)(5)(C) (setting forth the considerations relevant to air ambulance IDR determinations). The only differing factor will be the QPA—there will be one QPA based on the insurer's contracted base code rates, and a different QPA based on the insurer's contracted mileage code rates, although both sets of

rates should be contained in the same set of underlying agreements.[15] There is no practical reason why a single IDR entity could not make both determinations (the appropriate base-code rate and the appropriate mileage-code rate) as part of the same IDR process.

The two-IDRs-per-transport rule has doubled the workload of all persons involved in the IDR process, without benefitting anyone. The rule doubles the administrative costs for providers and insurers, who must prepare twice the number of submissions; has doubled the fees that providers and insurers must pay; and has doubled the burden on IDR entities, who have already fallen far behind their statutory deadlines due to the high volume of IDRs.[16] *See supra* at pp. 8–10. This is an illogical waste of everyone's time and resources that serves no useful purpose.

IV. The Court Should Strike Down the July Rule's QPA Calculation Methodology Because the Rule Excludes Case-Specific Contracted Rates from the QPA

The regulation governing how the QPA is calculated is codified at 45 C.F.R. § 149.140. TMA's Brief sets forth many reasons why this regulation must be vacated as contrary to the statute and arbitrary and capricious, and the Air Ambulance Plaintiffs join all of TMA's arguments, insofar as those arguments apply to them.[17] *See* ECF 25 at 17–30.

In addition to TMA's arguments, this regulation must also be set aside—as contrary to the statute and arbitrary and capricious—for an additional reason: It excludes, from the QPA

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[15] Any agreement to provide air ambulance services necessarily will include rates for both of the relevant billing codes. So the agreements whose rates are used to calculate the base-rate code's QPA should be the same agreements whose rates are used to calculate the mileage code's QPA.

[16] *See Initial Report on the Independent Dispute Resolution (IDR) Process*, Center for Medicare and Medicaid Services, p. 7, (Dec. 23, 2022) https://www.cms.gov/files/document/initial-report-idr-april-15-september-30-2022.pdf [available at: https://perma.cc/EQ9K-5NPN] (between April 15 and September 30, 2022, parties initiated over 90,000 disputes to the IDR process, over *five times* more than the amount CMS predicted would be submitted in an entire year).

[17] *See supra*, n. 9.

calculation, all of the many hundreds of thousands of "contracted rates" that have been agreed to, by insurers and providers, in case-specific agreements.

A. The July Rule Excludes Case-Specific Contracted Rates From the QPA

The great majority of air ambulance transports have historically been provided by out-of-network providers. *See* July Rule, 86 Fed. Reg. at 36,923 (noting that "in 2012, 75 percent of [air ambulance] transports were out-of-network and in 2017, 69 percent were out-of-network."). These out-of-network air transports often resulted in "case-specific" or "single-case" agreements between the air ambulance provider and the insurer. *See id.* at 36,882 (describing a "single case agreement" as an agreement "between a health care facility and a plan or issuer, used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network . . ."). Elsewhere in the July Rule, the Departments recognized that such agreements "constitute[] a contractual relationship." *See id.* at 36,882; 45 C.F.R. § 149.30 (defining the terms "participating emergency facilit[ies] and "participating health care facilit[ies]"). But the July Rule expressly excluded, from the QPA calculation only, any "single case agreement, letter of agreement, or other similar arrangement." 45 C.F.R. § 149.140(a)(1). According to the Departments, these agreements "do[] not constitute a contract" for QPA purposes *Id.*

B. Excluding Case-Specific Agreements Is Contrary to the Statute's Unambiguous Text

The QPA is defined by statute as the "median of the *contracted rates* recognized by the [insurer] . . . for the same or a similar item or service." 42 U.S.C. § 300gg-111(a)(3)(E) (emphasis added); *see also id.* § 300gg-112(c)(2) (noting that the QPA for air ambulance IDRs has the meaning set forth in Section 300gg-111(a)(3)). The statute does not define "contracted rates."

The July Rule does define "contracted rates." For purposes of the QPA calculation *only*, the July Rule excludes, from this definition, any "single case agreement, letter of agreement, or other similar arrangement . . . for a specific participant or beneficiary in unique circumstances." 45 C.F.R. § 149.140(a)(1). Such an agreement, according to the Departments, "does not constitute a contract" in the context of the QPA calculation. *Id.* This agency *ipse dixit* should be set aside because it is contrary to the NSA's plain text.

Case-specific rates are "contracted rates," under the plain and ordinary meaning of that unambiguous statutory term. *See Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, 587 F. Supp. 3d 528, 540 (E.D. Tex. 2022) ("In determining whether Congress has unambiguously spoken through a statute, the Court applies 'traditional tools of construction,' including 'text, structure, history, and purpose.'") (citing *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019)).

A "contract" is "[a]n agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law" and a "rate" is "[a]n amount paid or charged for a good or service." *Contract* and *Rate*, Black's Law Dictionary (11th ed. 2019). So, a "contracted rate" is an amount paid or charged for health care services under a "contract," i.e., under an agreement that is enforceable or otherwise recognizable at law. This meaning is plain and ordinary; it is immaterial that Congress did not include an explicit definition of this straightforward term.[18]

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[18] "The absence of a statutory definition does not render a word ambiguous." *Natural Resources Defense Council v. E.P.A.*, 489 F.3d 1364, 1373 (D.C. Cir. 2007). Instead, "[i]n the absence of an express definition, [courts] must give a term its ordinary meaning." *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012) (citing *FCC v. AT&T, Inc.*, 562 U.S. 397, 403 (2011)); *see also United States v. Lowe*, 118 F.3d 399, 402–04 (5th Cir. 1997) (using the plain meaning of undefined statutory terms to find such terms unambiguous).

A case-specific agreement meets the plain and ordinary definition of "contract." A case-specific agreement contains a promise by the insurer to pay, and a promise by the provider to accept, an agreed rate for the provider's services. These agreements would be enforceable at law if either party breached them. Thus, a case-specific agreement is a contract, and the "rate" it contains is a "contracted rate" for purposes of the QPA definition contained in 42 U.S.C. § 300gg-111(a)(3)(E). The plain text of the statute requires that case-specific agreements, and the rates they contain, be included in the QPA.

The Departments themselves acknowledged that Congress intended to include case-specific agreements in the QPA calculation. The July Rule begins by defining "contracted rate" broadly, as meaning "the total amount (including cost sharing) that an [insurer] has *contractually agreed to pay*" for health care services. 45 C.F.R. § 149.140(a)(1) (emphasis added). So far, so good. But then the July Rule abruptly parts ways from the plain and ordinary meaning of the statute, by declaring as follows:

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

Id. (emphasis added). In other words, the Departments' regulation first acknowledges that the term "contracted rate" includes any amount that the insurer has "contractually agreed to pay," but then immediately *excludes* huge numbers of these "contracted rates" by agency fiat, simply because those rates were agreed to in case-specific agreements rather than in-network contracts.

C. The Exclusion of Case-Specific Rates is Arbitrary and Capricious

Even if the Departments' regulation were a permissible interpretation of an ambiguous statute (it isn't), the exclusion of case-specific rates should also be struck down because it is arbitrary and capricious. *See Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1014 (5th Cir. 2019) (if

a statute is ambiguous, the Court proceeds to "asking whether the agency's construction is 'permissible.'") (quoting *Chevron*, 467 U.S. at 843). Where an agency rule has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," it is arbitrary and capricious and must be set aside. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The Departments' sole justification for excluding case-specific agreements, from the QPA calculation, is not persuasive. The Departments asserted that their decision "most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations."[19] July Rule, 86 Fed. Reg. at 36,889. But in the air ambulance industry, case-specific agreements are highly relevant evidence of "market rates," since so many providers are out-of-network with insurers. The Departments themselves acknowledged in the July Rule that only 25% and 31% of air ambulance transports in 2012 and 2017, respectively, were paid under traditional in-network contracts. *Id.* at 36,923. Because of their ubiquity, the rates agreed to in these case-specific agreements are objectively *more* indicative of the market rates for air ambulance services than are the minority of rates agreed to by in-network providers. So, if the goal of the QPA is to "reflect market rates," as the Departments contend, *id.* at 36,889, then there is no "rational connection" between (i) the Departments' finding (that out-of-network providers render the vast majority of emergency air ambulance transports) and (ii) the "choice made" by the Departments

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[19] Nowhere in the NSA does Congress say that the QPA must reflect "market rates" as contained only in "typical" in-network contracts between air ambulance providers and insurers.

to exclude the rates those providers agreed to, in case-specific agreements, from the QPA, *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

The regulation's arbitrariness is also evidenced by the Departments' differential treatment of case-specific agreements when promulgating the regulations defining "participating emergency facilit[ies]" and "participating health care facilit[ies]." *See* 86 Fed. Reg. at 36,882; 45 C.F.R. § 149.30. In that context, the Departments explicitly acknowledge the plain truth of the matter, which is that case-specific agreements "constitute[] a contractual relationship." 86 Fed. Reg. at 36,882. If a case-specific agreement "constitutes a contractual relationship," *id.*, for purposes of defining when a facility is in-network for NSA purposes, then such an agreement must also logically constitute a "contractual relationship" for purposes of creating the QPA, which is supposedly a proxy for the "market rate." Deeming the exact same relationship "contractual" for one purpose but not for another is irrational and arbitrary.

V. The Court Should Also Strike Down the July Rule's QPA Calculation Methodology Because the Rule Arbitrarily and Capriciously Allows Insurers to Include, in the QPA Calculation, Rates Agreed to By Providers Located In Widely Disparate Geographic Regions.

Part of the same QPA methodology regulation—45 C.F.R. § 149.140(a)(7)(ii)(B)—should also be struck down as arbitrary and capricious for an additional reason: It permits insurers to calculate QPAs based rates agreed to in widely disparate geographic regions.

The NSA provides that the QPA calculation, in any given dispute, should include only those "contracted rates" that are "provided in the geographic region" in which the service at issue was provided. 42 U.S.C. § 300gg-111(a)(3)(E)(i). If the insurer has "insufficient information" in the "geographic region" (i.e., fewer than three "contracted rates") then Congress created a fallback that requires the insurer to use a neutral third-party database of allowed amounts paid to providers for the services in that geographic region. *See id.* § 300gg-111(a)(3)(E)(iii). The scope of the

"geographic region" is thus significant because it determines which "rates" the insurer includes in the QPA calculation.

The NSA directs the Departments to "establish through rulemaking" the "geographic regions applied for purposes" of the QPA calculation. *Id.* § 300gg-111(a)(2)(B). The NSA requires the Departments to "tak[e] into account access to items and services in rural and underserved areas, including health professional shortage areas" when establishing the "geographic regions." *Id.*

The July Rule provides that air ambulance QPAs are calculated using "contracted rates" from one of two different "geographic regions" within a state, depending on the location where the patient is picked up: "one region consisting of all metropolitan statistical areas [MSAs] . . . in the State," i.e., all urban and suburban areas, and "one region consisting of all other portions of the State," i.e., all rural or "frontier" areas. 45 C.F.R. § 149.140(a)(7)(ii)(A). But if the insurer has fewer than three contracted rates in the applicable state-based geographic region, then the regulation provides a special rule: The insurer is directed not to use the fallback option (i.e., the allowed amounts recorded in a neutral third-party database) but instead to immediately broaden the "geographic region" to include all of the MSAs contained in the *Census Division*, or all of the rural areas contained in the *Census Division*. *Id.* § 149.140(a)(7)(ii)(B).

There are only nine Census Divisions nationwide and they encompass enormous areas. *See Census Regions and Divisions of the United States*, U.S. Census Bureau, https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf (last visited January 16, 2023) [available at: https://perma.cc/4QWX-7738]. For example, the "South Atlantic" Census Division stretches from Delaware down to the Florida Keys; the "Mountain" Census Division extends from Arizona up to Montana; the "Pacific" Division extends up the Pacific coastline and includes Alaska and Hawaii. *See id.* This regulation therefore means that a contracted rate for a

medical air transport in Fairbanks, Alaska, could dictate the QPA for a medical air transport in Los Angeles or Honolulu; and that a contracted rate in the Florida Keys could dictate the QPA in Virginia's Shenandoah Valley.

The Departments' asserted justification, for their over-broadening of the term "geographic region," is not rational. The Departments claim that by broadening this region to this extent, they will thereby minimize the possibility that the insurer will have "insufficient information" in its own records to calculate a QPA, and thus have to resort to the fallback, a neutral third-party claims database to determine the QPA.[20] *See* July Rule, 86 Fed. Reg. at 36,892–93; 42 U.S.C. § 300gg-111(a)(3)(E)(iii) (if there is "insufficient information," the QPA is based upon the rate for such service as determined by the insurer through the use of a third-party database). This is not a rational reason, since Congress itself endorsed the fallback option. The Departments do not even attempt to explain why that fallback, the neutral database, would not serve the supposed purpose of the QPA, which is to serve as a proxy of the "market rates" in the relevant region.

By requiring a QPA calculation tailored to a "geographic region," Congress cannot have meant to dictate payments in one market based on rates agreed to in geographically and economically unique markets that are thousands of miles, and even oceans, apart. This is clear by the very fact that Congress authorized the fallback option of the neutral database. *See* 42 U.S.C. § 300gg-111(a)(3)(E)(iii). In other words, Congress foresaw the problem (an insurer lacks sufficient "contracted rates" in the relevant region) and provided the solution to it: the fallback of the neutral third-party claims database. Accordingly, Congress cannot have meant to authorize the

---

[20] If this is a problem, it is a problem of the Departments' own creation by their exclusion from the pool of potential contracted rates for purposes of the QPA calculation the many thousands of case-specific agreements that the Departments themselves recognized are ubiquitous in the air ambulance industry. *See supra* at pp. 20–25.

Departments' different solution to this problem, which is to tell the insurer to instead use its contracted rates in an absurdly large geographic region.

The grotesquely large geographic regions will produce irrational outcomes for air ambulance providers who will have to contend with contracted rates from distant states dictating payment in vastly different markets. The Departments' unexplained failure to consider all of these "important aspect[s] of the problem," *State Farm*, 463 U.S. at 43, when setting exceedingly broad geographic regions, also requires that this regulation be set aside.

CONCLUSION

The challenged regulations should be VACATED.

Date: January 17, 2023

Respectfully submitted,

By: */s/ Steven M. Shepard*

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Counsel to Air Methods Corporation and Rocky Mountain Holdings, LLC

CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2023, I electronically filed the foregoing document with the clerk of the court for the U.S. District Court, Eastern District of Texas, using the electronic filing system of the court. The electronic case filing system sent a "Notice of Electronic Filing" to the attorneys of record who have consented in writing to accept this Notice as service of this document by electronic means.

By: *Is/ Steven M. Shepard*
Steven M. Shepard

EXHIBIT A

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

TEXAS MEDICAL ASSOCIATION, et al., *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civil Action No. 6:22-cv-00450-JDK Lead Consolidated Case

DECLARATION OF CHRISTOPHER BRADY

1. My name is Christopher Brady. I am over the age of eighteen. I am employed by Air Methods Corporation. My job title is General Counsel. I have personal knowledge of the matters contained herein.

2. Approximately 53% of the bills that Air Methods transmits to payors for services subject to the No Surprises Act do not receive an initial payment or notice of denial of payment within 30 calendar days of the bill being transmitted by Air Methods to the payor.

3. The longest period that a payor has failed to make an initial payment or notice of denial of payment is more than 325 calendar days after Air Methods transmitted the bill to the payor for services subject to the No Surprises Act. Air Methods' records indicate an average of 104 calendar days between the time it submits a bill to the date payors make initial payments or notices of denial of payment.

4. Payors commonly state that their claims systems were not ready to process initial payments pursuant to the requirements of the No Surprises Act. But the majority of the time, payors have attributed their late payments to their not being educated on the No Surprises Act.

5. When Air Methods bills a payor for an air ambulance transport, it submits a single claim which contains at least two HCPCS codes: a base (or "lift-off") code, and a per-mile (or "mileage") code.

6. When payors send their initial payment or notice of denial for an air ambulance transport, payors send a single Explanation of Benefits ("EOB").

7. Between approximately April 2022 and August 2022, IDR entities rendered a single decision on both codes in approximately 109 IDR processes involving Air Methods.

8. In late August and early September 2022, IDR entities began informing Air Methods that the entities would now require each air ambulance transport to be submitted as two separate IDRs, one for each HCPCS code involved in the transport.

9. Around this same time, IDR entities also began closing already-pending IDRs and demanding that air ambulance providers re-submit disputes as two separate IDRs.

10. After IDR entities began requiring two separate IDRs for each air ambulance transport, Air Methods Corporation has been forced to submit two separate sets of IDR initiation, offer, and briefing documents for each disputed air transport. As a result, Air Methods Corporation has had to submit twice as many IDRs and pay twice the amount of IDR fees.

11. On October 21, 2022, I sent a letter to the Honorable Chaquita Brooks-LaSure, Administrator for the Centers for Medicare & Medicaid Services ("CMS"). In this letter, I informed CMS that IDR entities had recently begun requiring two IDRs for a single air ambulance transport (one for each of the two HCPCS air ambulance billing codes).

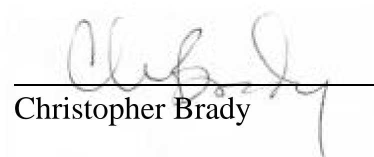
12. My October 21 letter emphasized that the new two-IDRs-per-transport policy was contrary to the statutory text of the No Surprises Act and its implementing regulations and created unnecessary administrative burdens. I wrote:

> Air Methods understands and appreciates the need to separate wholly district patient encounters that involve entirely different health care services into different IDR processes. However, requiring Air Methods to separate single transports into different IDR processes solely because two codes are billed for the same service causes unnecessary duplication. Furthermore, requiring air ambulance IDR processes to be conducted in this way disregards the text and intent of the NSA, Medicare billing guidelines, and industry practices calling for two service codes for one transport.
>
> As a result of this new requirement, IDR entities have required Air Methods to re-submit each previously submitted claims as two separate claims. This has created significant administrative and financial burdens on our business, as it essentially doubles the work and fees required for a single air ambulance transport for these prior claims as well as for each claim moving forward.

My letter requested that CMS issue new guidance clarifying that each air ambulance HCPCS code for one transport may be submitted in a single IDR process, and to allow Air Methods to re-file claims in the IDR process that have previously be deemed ineligible due to the existence of two HCPCS codes for one transport.

13. As of the date of this declaration, CMS has not responded to my October 21, 2022 letter.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 17, 2023.



Christopher Brady

EXHIBIT B

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

TEXAS MEDICAL ASSOCIATION, et al.,	)	
	)	
Plaintiffs,	)	
	)	Case No.: 6:22-cv-00450-JDK
v.	)	
	)	Lead Consolidated Case
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
	)	
Defendants.	)	

DECLARATION OF MARC MARIANI

1. My name is Marc Mariani. I am over the age of eighteen. I am employed by Health Services Integration. My job title is Managing Director and Chief Financial Officer. I have personal knowledge of the matters contained herein.

2. Health Services Integration provides revenue cycle management services to emergency healthcare providers, including providers of ground and air ambulance services. As part of these revenue cycle management services, Health Services Integration handles verification of insurance, compliance reviews, claim follow-up, fair billing and collection practices, and medical necessity reviews.

3. Health Services Integration handles certain components of billing for air ambulance transports performed by East Texas Air One. This includes generating and transmitting bills to insurers for East Texas Air One's emergency air ambulance transports. Since January 1, 2022 Health Services Integration's work for East Texas Air One has included billing for emergency air ambulance transports covered by the No Surprises Act. These bills are submitted in East Texas Air One's name; East Texas Air One, and not Health Services Integration, is the billing party and bears the risk that the insurer will not pay the bill.

4. For transports covered by the No Surprises Act, insurers have frequently delayed payment on East Texas Air One's air ambulance transports for months despite having received all documentation necessary to process the claims. In one instance, 253 days passed between an insurer's receiving the bill for a transport by East Texas Air One and the insurer's making an initial payment on the claim. And, as of the date of this declaration, one insurer has failed to make any initial payment or provide a notice of denial for two emergency air ambulance transports which were performed in March 2022 and which are covered by the No Surprises Act.

5. Insurers have delayed initial payment or notice of denial for more than 30 days following submission of East Texas Air One's bills in approximately 67% of East Texas Air One's transports since January 1, 2022.

6. Insurers' most frequently cited causes of delay are (A) duplicative requests for East Texas Air One's trip documents (which are attached to each claim when submitted), (B) requests for information regarding a coordination of benefits issue or third-party liability from the patient (i.e. the member of the insurance plan), and (C) requests for medical records from both sending and receiving facilities, i.e., from providers *other than* East Texas Air One.

7. In many cases, insurers have simply missed the 30-day deadline imposed by the No Surprises Act despite not needing any further documentation.

8. Insurers have included late-payment interest for fewer than 1% of their payments made outside the mandatory 30-day payment window.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 16, 2023.

Signature:

Marc Mariani

EXHIBIT C

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

TEXAS MEDICAL ASSOCIATION, et al., *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civil Action No. 6:22-cv-00450-JDK Lead Consolidated Case

DECLARATION OF STEVEN M. SHEPARD

1. My name is Steven M. Shepard. I am over the age of eighteen. I am employed by Susman Godfrey, LLP. My job title is Partner. I have personal knowledge of the matters contained herein.

2. On September 13, 2022, I sent a letter to Ellen Montz, Director, Consumer Information and Insurance Oversight ("CCIIO") at the Center for Medicare and Medicaid Services ("CMS"), on behalf of an air ambulance company.

3. In this letter, I informed CMS that IDR entities had recently begun requiring two IDRs for a single air ambulance transport (one for each of the two HCPCS billing codes), and had begun to reject, as "ineligible," IDRs that had been previously submitted with both billing codes. My letter stated that this behavior appeared to be motivated by the IDR entities' understanding of CMS's August 2022 publication of the *Technical Guidance for Certified IDR Entities*, Center for Medicare and Medicaid Services (Aug. 18 2022), perma.cc/R2G9-DW5L.

4. My September 13 letter pointed out that this new two-IDRS-per-transport policy was contrary to the statutory text (which requires one IDR for each "service," not two IDRs, and which defines a "transport" as a single "service"). My letter also argued that the new policy was contrary to common sense. I wrote:

> When [an air ambulance provider] submits a claim for its services, it submits one claim (containing both codes). Payors similarly send one initial payment or denial, and send one Explanation of Benefits (EOB) (again, containing both codes). Although the QPAs for each code are obviously different, the other relevant factors, in the IDR process, are identical: e.g., the patient acuity, the ambulance vehicle type, and the provider training are all the same because both codes refer to just one single transport, by one aircraft with one flight crew.
>
> If allowed to continue, this new practice will quickly double the amount of air ambulance IDRs. That will significantly increase costs for providers, payors, IDR entities, and CMS itself, and will likely also lead to further delays in the IDR process. This new practice might also result in conflicting IDR determinations, in which one IDR entity accepts the payor's offer for the flat-fee code, and another IDR entity accepts the provider's offer for the mileage code, even though both codes refer to the same transport, for the same patient, by the same vehicle and flight crew.

My letter requested that CMS instruct the IDR entities to revert to their prior practice of conducting a single IDR per transport, in which IDR the entities would adjudicate both HCPCS codes.

5. On September 15, 2022, I participated in a Zoom videoconference with the Deputy Director of CCIIO and other CCIIO and CMS employees. During that videoconference, I re-iterated the points made in my September 13, 2022 letter and summarized above. The Deputy Director indicated that he understood the point and that he and his staff would consider it.

6. On September 28, 2022, I spoke by phone with an executive of an IDR entity. The executive informed me that CMS representatives had held a call with all IDR entities "that morning." The executive also told me that, on this call, CMS stated that the August 2002 Technical Guidance required IDR entities to conduct two separate IDRs for each air transport

(one for each HCPCS code) and to refuse, as "ineligible," any IDR submissions that sought a determination of both HCPCS codes.

7. As of the date of this declaration, CMS has not responded to my September 13, 2022 letter or to the similar comments I made during September 15, 2022 Zoom meeting.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 17, 2023.

Signature:

Steven M. Shepard

EXHIBIT D

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

TEXAS MEDICAL ASSOCIATION, et al., *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civil Action No. 6:22-cv-00450-JDK Lead Consolidated Case

DECLARATION OF JOSHUA D. ARTERS

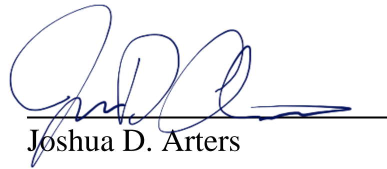
1. My name is Joshua D. Arters. I am over the age of eighteen. I am employed by Polsinelli PC. My job title is Associate. I have personal knowledge of the matters contained herein.

2. In late August and early September 2022, IDR entities began informing air ambulance providers that the entities would now require each air ambulance transport to be submitted as two separate IDRs, one for each HCPCS code involved in the transport.

3. Around this same time, IDR entities also began closing already-pending IDRs and demanding that air ambulance providers re-submit disputes as two separate IDRs.

4. After IDR entities began requiring two separate IDRs for each air ambulance transport, Air Methods Corporation has been forced to submit two separate sets of IDR initiation, offer, and briefing documents for each disputed air transport. As a result, Air Methods Corporation has had to submit twice as many IDRs and pay twice the amount of IDR fees.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 17, 2022.



Joshua D. Arters

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

TEXAS MEDICAL ASSOCIATION, et al.,	)	
	)	
Plaintiffs,	)	
	)	Case No.: 6:22-cv-00450-JDK
v.	)	
	)	Lead Consolidated Case
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
	)	
	)	
Defendants.	)	
	)	

[PROPOSED] ORDER GRANTING THE AIR AMBULANCE PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

For the reasons stated in the Memorandum accompanying Plaintiffs' LifeNet, Inc., East Texas Air One, LLC, Air Methods Corporation, and Rocky Mountain Holdings, LLC's ("Air Ambulance Plaintiffs") Motion for Summary Judgment, and in the Texas Medical Association ("TMA") Plaintiffs' Memorandum in support of TMA's Motion for Summary Judgment, together with all other briefing and oral argument thereon, the Air Ambulance Plaintiffs' Motion for Summary Judgment is GRANTED.

The Court has already vacated the portions of *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,889 (July 13, 2021) ("*IFR Part I*" or "the July Rule") and the Departments' *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* (Aug. 19, 2022) that were challenged in TMA's Motion for Summary Judgment.

In addition, the Court also VACATES the following provisions of the July Rule that are codified as follows:

(1) The last sentences of 45 C.F.R. § 149.130(b)(4)(i), 26 C.F.R. § 54.9817-1T(b)(4)(i), and 29 C.F.R. § 2590.717-1(b)(4)(i), each of which states: "For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services."; and

(2) The last sentences of 45 C.F.R. § 149.140(a)(1), 26 C.F.R. § 54.9816-6T(a)(1), and 29 C.F.R. § 2590.716-6(a)(1), each of which states: "Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, does not constitute a contract;" and

(3) 45 C.F.R. § 149.140(a)(7)(ii)(B), 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B), and 29 C.F.R. § 2590.716-6(a)(7)(ii)(B), each of which states: "If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 C.F.R. § 414.605);" and

(4) 5 C.F.R. § 890.114(a) to the extent it requires compliance with the foregoing provisions.

All of the foregoing vacated provisions, cited above, are DECLARED to have been promulgated by Defendants in violation of the Administrative Procedure Act (APA) because they

are "arbitrary, capricious, [and] an abuse of discretion" and are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. §§ 706(2)(A), (C). The Defendants are ENJOINED from enforcing the foregoing vacated provisions, cited above.

The Court further DECLARES that it is unlawful for arbitrators to consider QPAs that were affected by the Departments' unlawful rules, and that arbitrators therefore should not consider any QPA in any air ambulance IDR for which the insurer (1) included ghost rates; (2) excluded risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments; (3) included rates from a different plan sponsor; (4) excluded rates from case-specific or single-case agreements; or (5) expanded the geographic scope of "contracted rates" used to calculate the QPA(s) to the Census Division under 45 C.F.R. § 149.140(a)(7)(ii)(A), 26 C.F.R. § 54.9816-6T(a)(7)(ii)(B), or 29 C.F.R. § 2590.716-6(a)(7)(ii)(B).

The Court also VACATES the Defendants' informal guidance requiring that each of the two billing codes, for an air ambulance transport, must be adjudicated in two separate IDRs. The Court DECLARES that this guidance is in violation of the Administrative Procedure Act (APA) because it is "arbitrary, capricious, [and] an abuse of discretion" and is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. §§ 706(2)(A), (C). The Court ENJOINS the Defendants to instruct IDR entities that they are to adjudicate both air-ambulance billing codes together in one IDR proceeding, rather than splitting the billing codes into separate IDR proceedings.

SO ORDERED.