IN THE 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

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN OPPOSITION TO PLAINTIFFS' SUMMARY JUDGMENT MOTIONS

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For the reasons stated below, the Defendants respectfully request that the Court award summary judgment in their favor.

INTRODUCTION

The No Surprises Act ("NSA" or the "Act") protects millions of Americans from surprise medical bills they did not expect, at prices that many cannot afford. The Act spares patients from one million surprise medical bills *every month*.[1] It protects patients from the fear, stress, and frustration of paying for out-of-network medical care they did not choose—and, in many cases, never knew they were receiving in the first place. It sets patient cost sharing based on predictable metrics. It takes patients out of the middle of billing disputes between providers and group health plans and health insurance issuers, requiring, instead, that providers and payers resolve disputes directly, with the aid of an arbitrator if necessary. The Defendants here—the Departments of Health and Human Services, the Treasury, and Labor—have worked tirelessly over the past two years to build, from the ground up, the regulatory framework needed to implement the Act. This has been a tremendous, multifaceted undertaking. The Departments have, for example, issued regulations and guidance setting forth how to calculate patient cost-sharing, explaining how payers and providers can negotiate out-of-network payments and participate in the Act's Independent Dispute Resolution ("IDR") process, and implementing other provisions of the law. And these efforts have been paying off for patients every month.

With this lawsuit, however, Plaintiffs seek to undermine Congress's core goals, and the relief they request would not only grind many aspects of the legislative plan to a halt—some fifteen months after the Act went into effect—but also by drive up the costs of out-of-network medical care for patients and their families. Under the Act, a patient's cost-sharing responsibility for covered services—

[1] *See* Remarks of President Joe Biden – State of the Union Address as Prepared for Delivery (Feb. 7. 2023), https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/02/07/remarks-of-president-joe-biden-state-of-the-union-address-as-prepared-for-delivery/.

such as out-of-network emergency care, services provided by an out-of-network provider at an in-network facility, or an out-of-network air ambulance transport—depends on the "recognized amount," a statutory term of art. In the absence of a specified state law or All-Payer Model Agreement governing out-of-network medical costs, the recognized amount is the qualifying payment amount ("QPA"), which determines the patient's cost-sharing obligations.[2] The QPA serves as a rough proxy for what the in-network rate would have been for the medical service and is generally calculated using contracted rates for in-network services from 2019, adjusted for inflation.

Plaintiffs challenge regulations first issued in July 2021 that they claim unlawfully depress the QPA. They ask this Court to vacate those regulations in order to increase the QPA—thereby increasing costs borne by patients. But their complaint is misdirected. To start, they fail to show that vacating the challenged provisions would increase the QPA, or that it would it make a provider's offer more likely to be selected by an arbitrator. The challenged provisions, in any event, are entirely consistent with the Act and reflect the Departments' reasonable interpretation of the Act in connection with their express authority to promulgate regulations. Plaintiffs' quarrel is thus with the Act itself, not with the Departments' proper implementation of Congress's directives. Plaintiffs also challenge regulations relating to the timing of out-of-network payments and the resolution of air ambulance disputes during the IDR process. But the Departments' interpretations are entitled to deference, and this Court should reject Plaintiffs' claims.

If this Court nevertheless agrees with Plaintiffs on any of the myriad claims in this case, it should remand without vacatur. In this case, even more so than in previous litigation relating to the Act, vacatur would be highly disruptive and cause immediate negative consequences for patients, payers, and providers. Vacatur in this case would interfere with the ability to calculate patient cost-

[2] With respect to out-of-network air ambulance services, a patient's cost sharing for covered services is based on the lesser of billed charges or the QPA.

sharing amounts, would disrupt payers' offers of payment to facilities and providers, and would hamstring arbitrators' ability to consider the QPA in the arbitration process.

STATEMENT OF THE ISSUES

1. Did the Departments reasonably exercise the rulemaking authority that Congress granted them in the No Surprises Act by establishing the qualifying payment amount methodology and disclosure requirements consistent with the terms and purposes of the Act, to the extent that Plaintiffs have shown standing to challenge aspects of that methodology?

2. Did the Departments reasonably exercise the rulemaking authority that Congress granted them in the No Surprises Act by imposing reasonable payment deadlines consistent with well-understood, industry-standard terms?

3. Did the Departments reasonably exercise the rulemaking authority that Congress granted them in the No Surprises Act by limiting batching in IDR proceedings to services involving the same billing service code for air ambulance services?

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. Before the No Surprises Act, Providers' Surprise Billing Practices Imposed Devastating Financial Consequences on Patients and Drove Up the Overall Cost of Health Care.

Most group health plans and health insurance issuers offering group or individual health insurance coverage ("payers") "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) (AR 166). When an individual receives care from a provider or facility outside of their plan's or issuer's network, however, the plan or issuer 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 balance of the bill. *Id.* This practice, where the provider bills the patient for the difference between the charges the provider billed and the amount paid by the patient's health plan, is known as balance billing.

"A balance bill may come as a surprise for the individual." *Id.* Surprise billing occurs, for example, when a patient receives care from a provider whom the patient could not have chosen in advance, or whom the patient did not have reason to believe would be outside the network of the

patient's insurance plan. *Id.* These bills have arisen most frequently in three circumstances. First, in emergency situations, a patient may be unable to choose which emergency department he or she goes to (or is taken to); even if the patient goes to an emergency department that is in-network, he or she may still receive care from out-of-network providers working at that facility. *Id.* Second, a patient may schedule a medical procedure in advance at an in-network facility, but may not be aware that providers of ancillary services, such as radiologists, anesthesiologists, or pathologists, are out-of-network. *Id.* "Unlike most medical services, for which patients have an opportunity to seek in-network providers, patients generally are not able to choose these emergency and ancillary providers." Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, 26 AM. J. MANAGED CARE 401, 401 (2020) (AR 1383). Third, surprise billing has been even more pronounced when a patient receives services from an out-of-network air ambulance provider. *See* Erin C. Fuse Brown et al., *The Unfinished Business of Air Ambulance Bills*, HEALTH AFFAIRS FOREFRONT (Mar. 26, 2021) (AR 2843). These providers have imposed staggering surprise bills, averaging tens of thousands of dollars. *Id.* (AR 2845).

In such circumstances, the patient's inability to choose an in-network provider has created a pronounced market distortion: these providers have little incentive to join health plan or insurance networks, negotiate fair prices in advance for their services, or moderate their charges for out-of-network care. This market distortion has led to a widespread phenomenon of surprise billing, which had been rapidly growing before Congress acted. Indeed, it was "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 4574). From 2010 to 2016, "the incidence of out-of-network billing increased from 32.3% to 42.8% of emergency department visits, and the mean potential liability to patients increased from $220 to $628. For inpatient admissions, the incidence of out-of-network billing increased from 26.3% to 42.0%, and the mean potential liability to patients

increased from $804 to $2040." *Id.* And air ambulance services are even more likely to involve out-of-network care, with approximately 77% of air ambulance transports performed by out-of-network providers. *See* 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). 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." Brown et al., *The Unfinished Business of Air Ambulance Bills*, (AR 2845). Air Methods Corporation, in particular, took advantage of this market distortion by increasing its prices for medical transports by 283% 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).

That trend led to unexpected, and devastating, medical bills for patients. For example, patients have faced a $7,924 surprise bill after emergency jaw surgery; a $20,243 surprise bill for emergency care for a bike crash; and a $27,660 surprise bill after being hit by a public bus. Sarah Kliff, *Surprise Medical Bills, the High Cost of Emergency Department Care, and the Effects on Patients*, 2019 JAMA INTERN. MED. 1457, 1457 (Nov. 2019) (AR 4013). "[A]mong the most shocking [examples of balance billing abuses] was a spinal surgery patient who received a bill of $101,000 despite having confirmed that her surgeon was in-network." H.R. REP. NO. 116-615, pt. 1, at 52 (2020) (AR 329); *see also* Erin L. Duffy et al., *Prevalence and Characteristics of Surprise Out-Of-Network Bills from Professionals in Ambulatory Surgery Centers*, 39 HEALTH AFFAIRS 783, 785 (2020) (AR 1391) (finding 81% increase in average amounts of surprise bills at ambulatory surgical centers from 2014 to 2017). "Given that nearly half of individuals in the United States 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." Zack Cooper et al., *Surprise! Out-of-Network Billing for Emergency Care in the United States*, 128 J. POL. ECON. 3626, at 3627 (Sept. 2020) (AR 1066, 1067).

Beyond the 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. Congress found that this surprise billing epidemic had created a "market failure." H.R. REP. NO. 116-615, at 53 (AR 330). "The presence of this market failure in certain provider specialties is strongly supported by evidence reflecting the highly inflated payment rates for these services." *Id.* That 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," and, as a result, "[t]hese higher payments get passed along to all consumers (including those who do not even access care) in the form of higher insurance premiums." *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). These costs have direct effects on all consumers: higher out-of-pocket expenses and exorbitant surprise bills for out-of-network care, as well as rising overall health care costs through higher premiums. H.R. REP. NO. 116-615, at 53 (AR 330). This has resulted in "commercial health insurance premiums as much as 5% higher than they otherwise would be in the absence of this market failure," Duffy et al., 26 AM. J. MANAGED CARE at 403 (AR 1385), placing a financial burden "on employer plan sponsors as well as individuals," *Examining Surprise Billing: Protecting Patients from Financial Pain: Hearing Before the H. Comm. on Educ. and Labor, Subcomm. on Health, Employment, Labor and Pensions*, 116th Cong. 39 (2019) (statement of Ilyse Schuman, Senior Vice-President, American Benefits Council) (AR 471).

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

Congress enacted the NSA to address these surprise billing practices and to rein in the cost of health care. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182, 2758-2890 (2020). The Act protects insured patients from unexpected liabilities arising from the most common forms of surprise billing. If an insured patient receives emergency care or air ambulance services, or if

he or she receives scheduled care at certain types of in-network facilities, health care providers and facilities are generally prohibited (absent, in certain circumstances, the patient's consent) from balance billing the patient for any part of his or her care that is furnished by an out-of-network provider or facility. *See* 42 U.S.C. §§ 300gg-131, 300gg-132, 300gg-135.[3] Likewise, the patient's cost-sharing responsibilities for out-of-network services may not exceed his or her financial responsibilities "that would apply if such services were provided by a participating provider or a participating emergency facility." *Id.* §§ 300gg-111(a)(1)(C)(ii), (b)(1)(A), 300gg-112(a)(1).[4] If, for example, the patient's health insurance policy would require him or her to pay coinsurance of 20% of the cost of an in-network service, the patient's responsibility for any out-of-network service would be limited to the same 20% co-insurance. *Id.* § 300gg-111(a)(1)(C)(ii), (iii), (b)(1)(A), (B).

Crucially, to effectuate the statute's goal of "No Surprises," 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.[5] Otherwise, the "recognized amount" is the "qualifying payment amount (as

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

[4] The provisions of the No Surprises Act that apply specifically to air ambulance services are codified in 42 U.S.C. § 300gg-112.

[5] For example, Texas has enacted a state law governing patients' cost-sharing responsibilities for out-of-network services and the arbitration process for disputes between providers and insurers over

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 setting the methodology for determining the QPA). With respect to air ambulance services, the patient's cost-sharing responsibilities are calculated based on the rates that would apply for these services if they were furnished by such a participating provider, which the Departments interpret to be the lesser of the billed amount or the QPA. *See* 42 U.S.C. § 300gg-112(a)(1); 86 Fed. Reg. at 36,884. Thus, in states without an All-Payer Model Agreement or specified state law, the QPA often determines the patient's financial obligations at the outset. The QPA provides clarity and predictability to protect patients from surprise medical bills. But, if the QPA increases, patient costs increase as well.

The QPA is a statutory term of art. It is generally defined, for a given item or service and for a given plan or issuer, as "the median of the contracted rates recognized" by the group health plan or issuer, 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 issuer in a given insurance market, "consistent with the methodology established by the Secretary under paragraph (2)(B)." 42 U.S.C. §§ 300gg-111(a)(3)(E)(i)(I), 300gg-112(c)(2). The QPA is based on the issuer or group health plan's calculation of the median contracted rates for its plans as of January 31, 2019; this amount is subject to an inflation adjustment under a methodology to be established by the Departments. *Id.* § 300gg-111(a)(3)(E)(i)(I). The statutory text treats the QPA 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

payments for such services. Tex. Ins. Code Ann. § 751.001 *et seq.* That law does not apply to group health plans that are subject to ERISA. *See Requirements Related to Surprise Billing; Part II,* 86 Fed. Reg. 55,980, 56,091 (Oct. 7, 2021).

insured patient's cost-sharing responsibilities.

The Act also establishes a procedure to resolve disputes between health care providers or facilities and plans or issuers over the amount of payment for such a service, in which the QPA is used as a reference point. The Act specifies that a plan or insurer must issue an initial payment, or notice of a denial of payment, to a provider or facility within 30 calendar days after the provider or facility submits a bill to the plan or insurer for an out-of-network service. *Id.* §§ 300gg-111(a)(1)(C)(iv), (b)(1)(C), 300gg-112(a)(3)(A). If the provider or facility is not satisfied with this determination, either party may initiate a 30-day period of open negotiation with the plan or insurer over the claim. *Id.* §§ 300gg-111(c)(1)(A), 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-111(c)(1)(B), 300gg-112(b)(1)(B). The Act establishes a system of "baseball-style" arbitration under which both the provider or facility and the group health plan or issuer will each submit a proposed payment amount 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 certain relevant information including the QPA. *Id.* §§ 300gg-111(c)(5)(A)(i), 300gg-112(b)(5)(A)(i). The arbitrator's decision is binding on the parties and is not subject to judicial review except under certain circumstances described in the Federal Arbitration Act. *Id.* §§ 300gg-111(c)(5)(E), 300gg-112(b)(5)(D).

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 (AR 335); *see also id.* at 48 (AR 325) (structuring the IDR process "to reduce costs for patients and prevent inflationary effects on health care costs"). "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). Over ten years, the Act is expected to reduce the deficit by $16.8 billion. *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.

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

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

The Departments released their first set of interim final rules on July 1, 2021 ("July 2021 IFR"). 86 Fed. Reg. 36,872. Those rules implemented the Act's provisions that prohibit providers from balance billing their patients for out-of-network medical services in certain situations; limit patients' cost-sharing responsibilities for these services; require providers to make disclosures to patients about federal and state protections against balance billing; codify certain additional patient protections; set forth complaint processes for violations of the Act's balance-billing and out-of-network cost-sharing protections; and, most relevant here, set the methodology for determining the QPA. *See id.* at 36,876. This methodology begins with a calculation of "the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation." *Id.* at 36,888.

To calculate the median of a plan's or issuer's contracted rates, the rule looks to the contracted payment rate for a particular service under each of the plans or policies that the payer has negotiated

in advance with providers of that service for each applicable insurance market. 45 C.F.R. § 149.140(a)(1).[6] The Departments recognized that, in some cases, plans or issuers may not have a contract in place with a particular provider for a given service, and that the plan or issuer may enter into a "single case agreement" to govern payment for that service. 86 Fed. Reg. at 36,889. The Departments excluded payment rates under these single case agreements from the calculation of the median, because "[t]he term 'contracted rate' refers only to the rate negotiated with providers and facilities that are contracted to participate in any of the networks of the plan or issuer under generally applicable terms of the plan or coverage and excludes rates negotiated with other providers and facilities." *Id.* The Departments found that "this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." *Id.*

The statute requires the QPA for a particular service to be calculated as the median of a plan's or issuer's contracted rates for that service "that is provided by a provider in the same or similar specialty." 42 U.S.C. § 300gg-111(a)(3)(E)(i). The July 2021 IFR defines "provider in the same or similar specialty" as the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice. 86 Fed. Reg. at 36,891. If a plan or issuer has contracted rates for a service code that vary based on provider specialty, the median contracted rate is calculated separately for each provider specialty. *Id.* For the purpose of this calculation, the Departments concluded that all providers of air ambulance services "are considered to be a single provider specialty." *Id.* To reduce the burden on sponsors of self-insured group health plans, the July 2021 IFR permits such sponsors to allow their third-party administrators to determine the QPA for the sponsor by calculating the median contracted rate using the contracted rates recognized by all self-insured group health plans administered by the third-party administrator (not only those of the

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

particular plan sponsor). *Id.* at 36,890.

The Act also directs that the QPA for a given service be calculated on the basis of the median of contracted rates for the service "provided in the geographic region in which the item or service is furnished," 42 U.S.C. § 300gg-111(a)(3)(E)(i), and instructs the Departments to issue regulations defining these geographic regions, *id.* § 300gg-111(a)(2)(B)(iii). For air ambulance services, the Departments defined a "geographic region" as "one region consisting of all [metropolitan statistical areas] MSAs in the state, and one region consisting of all other portions of the state." 86 Fed. Reg. at 36,893; *see* 45 C.F.R. § 149.140(a)(7)(ii)(A). Alternatively, if the group health plan or issuer lacks sufficient information to calculate the median of contracted rates for the service using that definition, then it must "apply broader regions based on Census divisions—that is, one region consisting of all MSAs in each Census division and one region consisting of all other portions of the Census division." 86 Fed. Reg. at 36,893; *see* 45 C.F.R. § 149.140(a)(7)(ii)(B).

The Departments explained that they did not apply a narrower definition of geographic regions for air ambulance services because smaller regions would be more likely to "result in more instances of insufficient information" to calculate a median of contract rates, "[g]iven the nature of air ambulance services, the infrequency with which they are provided relative to the other types of items and services subject to the No Surprises Act, and the lower prevalence of participating providers of air ambulance services." 86 Fed. Reg. at 36,893. The Departments recognized that, in instances where a plan or issuer has insufficient information to calculate a QPA based on median contracted rates, the Act permits the QPA to be calculated on the basis of rates of allowed amounts of payment found in a third-party database. 86 Fed. Reg. at 36,888; 42 U.S.C. § 300gg-111(a)(3)(E)(iii). But they explained that this fallback should "be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region." 86 Fed. Reg. at 36,888. In addition, they explained, "[u]sing larger geographic regions, for which plans and issuers are

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

B. The September 2021 and August 2022 Rules Established the Independent Dispute Resolution Process.

The Departments released a second set of interim final rules in September 2021 ("September 2021 IFR"). 86 Fed. Reg. 55,980. These rules implemented Congress's directive that the Departments "establish by regulation one independent dispute resolution process," 42 U.S.C. § 300gg-111(c)(2)(A), for the resolution of disputes between providers and facilities and group health plans and issuers over the amount of payment for certain out-of-network services. Many of the same Plaintiffs in this lawsuit challenged these interim final rules, arguing that they impermissibly adopted a presumption in favor of the QPA. This Court agreed, and it vacated portions of the September 2021 IFR. *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* ("*TMA I*"), 587 F. Supp. 3d 528, 540 (E.D. Tex. 2022), *appeal dismissed*, No. 22-40264, 2022 WL 151743454 (5th Cir. Oct. 24, 2022); *see also LifeNet, Inc. v. U. S. Dep't of Health & Hum. Servs.* ("*LifeNet I*"), No. 6:22-CV-162-JDK, 2022 WL 2959715 (E.D. Tex. July 26, 2022).[7] After this Court vacated the portions of September 2021 IFR, the Departments promulgated final rules that instruct "[t]he certified IDR entity [to] select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service." 45 C.F.R. § 149.510(c)(4)(ii)(A); *see Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618, 52,626 (Aug. 26, 2022).[8] Under these final rules, the QPA does not dictate the outcome of the arbitration process.

[7] 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."

[8] Although this Court vacated certain provisions of the August 2022 final rules, the Court's opinion and order did not disturb the portion of the final rules directing arbitrators to select the offer that best represents the value of the item or service. *See Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.* ("*TMA II*"), 6:22-cv-373, 2023 WL 1781801 (E.D. Tex. Feb. 6, 2023).

C. The Departments Provided Subsequent Guidance.

The Departments have received many questions about the Act's requirements and have issued guidance to help people understand the law and promote compliance. After the July 2021 IFR was issued, for example, stakeholders brought to the Departments' attention certain contractual agreements in which providers accept low contracted rates for service codes that they are not likely to bill or that are not utilized by their specific provider specialty. The stakeholders raised concerns that the inclusion of these rates in the QPA may artificially lower the QPA.

In response to this concern, the Departments clarified in an August 2022 "Frequently Asked Questions" document that "if a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate (and consequently the QPA) must be calculated separately for each provider specialty." FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55 ("Aug. FAQs") at 16 (Aug. 19, 2022) (AR 10860). "Plans and issuers are required to calculate separate median contracted rates by provider specialty both in instances where their contracting process purposefully sets different rates for different specialties and in instances where the contracting process otherwise results in different rates for different specialties." *Id.* "For example, if a plan's or issuer's contracted rates for a given anesthesia service are clustered at one rate for anesthesiologists and at another rate for all other provider specialties because those providers do not provide and bill for anesthesia services, the plan or issuer must calculate one median contracted rate for the anesthesia service code for anesthesiologists, and one separate median contracted rate for the same anesthesia service code for all other provider specialties." *Id.* at 17 (AR 10861). In other words, if a plan's or issuer's contracted rates vary based on provider specialty, then the plan or issuer must calculate the QPA separately for each provider specialty when determining the QPA.

Because plans and issuers may have reasonably and in good faith not understood the July 2021

IFR to require the calculation of separate median contracted rates when the plan's or issuer's contracting process unintentionally results in contracted rates that vary based on provider specialty, the Departments allowed plans and issuers 90 days to come into conformity with the clarified QPA calculation process. That 90-day period ended on November 17, 2022.

IV. This Case

On November 30 and December 1, 2022, Plaintiffs brought these now-consolidated lawsuits challenging certain regulations implementing the Act's provisions. Specifically, the Plaintiffs Texas Medical Association, Tyler Regional Medical Center, and Dr. Adam Corley ("TMA Plaintiffs"), challenge the July 2021 IFR as inconsistent with the Departments' statutory authority and arbitrary and capricious. They fault the IFR in several general respects. First, they allege that it impermissibly allows payers to include rates that were contracted for, but not "provided," under that contract. Second, they allege that it impermissibly allows payers to include out-of-specialty rates in calculating the QPA. Third, they allege that it impermissibly excludes bonus and incentive payments from the rates used to calculate the QPA. Fourth, they allege that it impermissibly allows a self-funded plan to use its third-party administrator to calculate the QPA based on the contracted rates recognized by the self-funded plans administered by the third-party administrator. And fifth, they allege that the disclosure requirements relating to the QPA are inadequate for providers or facilities to determine whether a payer calculated the QPA correctly.

Plaintiffs LifeNet, Inc., Air Methods Corporation, Rocky Mountain Holdings LLC, and East Texas Air One, LLC ("Air Ambulance" or "AA" Plaintiffs) raise claims that overlap with those of the TMA Plaintiffs as well as several additional challenges to the July 2021 IFR. They raise additional complaints with the QPA calculation—specifically, they argue that the QPA calculation improperly includes only the rates recognized under a plan contract and excludes one-off single case agreements to resolve isolated disputes, and contend that census divisions may not serve as the geographic area

when a plan or issuer has insufficient data to calculate the QPA. As for the additional challenges, the Air Ambulance Plaintiffs first take issue with the July 2021 IFR's requirement that payers issue an initial payment or notice of denial of payment no later than 30 days after receiving a "clean claim" from a provider or facility. They also take issue with the Departments' interpretation of the September 2021 IFR allowing only items or services billed under the same service code to be resolved in a single IDR proceeding.

STANDARD OF REVIEW

When evaluating a challenge to an agency's interpretation of a statute, a court should first ask "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). If it has, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. Where Congress has not spoken directly to the issue at hand, the court should defer to the agency's interpretation so long as it is "based on a permissible construction of the statute." *Id.* at 843. That is true "even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005).

When reviewing agency action under the Administrative Procedure Act ("APA"), a court may set aside agency action when 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.* 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. THE AIR AMBULANCE PLAINTIFFS' CLAIMS SHOULD BE DISMISSED UNDER THE RULE AGAINST CLAIM SPLITTING.

This Court should not consider the Air Ambulance Plaintiffs' claims because they are barred by the rule against claim splitting. Only a year before this case was filed, the Association of Air Medical Services ("AAMS") filed a similar case, raising several identical claims, in federal court in Washington, D.C. *Ass'n of Air Med. Servs. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-3031 (D.D.C. Nov. 16, 2021). The claim-splitting bar prohibits these twin suits, and this Court should therefore dismiss the Air Ambulance Plaintiffs' subsequent claims in this case.

The rule against claim splitting "prohibits a plaintiff from prosecuting its case piecemeal and requires that all claims arising out of a single wrong be presented in one action." *Ameritox, Ltd. v. Aegis Scis. Corp.*, CIV. A. 3:08-CV-1168-D, 2009 WL 305874, at *4 (N.D. Tex. Feb. 9, 2009) (quoting *Sensormatic Sec. Corp. v. Sensormatic Elecs. Corp.*, 273 F. App'x 256, 265 (4th Cir. 2008); *see also Chinn v. Giant Food, Inc.*, 100 F. Supp. 2d 331, 333 (D. Md. 2000) ("The cases are legion that a party may not institute new actions duplicating existing litigation."). "In a claim splitting case, the second suit will be barred if the claim involves the same parties and arises out of the same transaction or series of transactions as the first claim." *Ameritox*, 2009 WL 305874, at *4. Parties have "no right to maintain two separate actions involving the same subject matter at the same time in the same court and against the same defendant[s]." *Oliney v. Gardner*, 771 F.2d 856, 859 (5th Cir. 1985). This rule makes sense: it "is to protect the defendant from being harassed by repetitive actions based on the same claim." *In re Super Van Inc.*, 92 F.3d 366. 371 (5th Cir. 1996).

That is the case here. AAMS is a trade association representing 93% of the U.S. air ambulance industry. Nearly all of the Air Ambulance Plaintiffs here are members or close affiliates of members of the trade association plaintiff in the D.C. case. Air Methods is itself a member of AAMS, LifeNet, Inc. is Air Methods' business partner, and Rocky Mountain Holdings is a wholly owned subsidiary of

Air Methods. Indeed, Air Methods has submitted declarations in support of summary judgment in both the D.C. case and this case. *Ass'n of Air Med. Servs.*, No. 1:21-cv-3031 (D.D.C.), ECF No. 1-7 (Decl. of David Portugal, Chief Financial Officer of Air Methods); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 6:22-cv-450 (E.D. Tex.), ECF No. 26-1 (Decl. of Christopher Brady, General Counsel of Air Methods). This case raises the same core claims as *AAMS* and presents no claim that could not have been brought there. And the parties in both cases seek the same relief: vacatur of the portions of the July 2021 IFR setting the QPA calculation methodology. This Court should find the Air Ambulance Plaintiffs' claims barred by the doctrine of claim splitting. *JTH Tax, LLC v. Butschek*, CIV. A. 6:20-CV-26, 2020 WL 5083523, at *4-6 (S.D. Tex. Aug. 3, 2020) (dismissing complaint under Rule 12(b)(6) for claim splitting).

The *AAMS* lawsuit, though fully briefed since February 2022 and argued in March 2022, has not yet been decided. But in contrast to the doctrine of res judicata, the rule against claim splitting "do[es] not require a prior judgment." 18 Charles Alan Wright, et al., Federal Practice and Procedure § 4406 (3d ed. April 2022 update); *see, e.g., Sensormatic*, 273 F. App'x at 265 (affirming dismissal based on claim-splitting even where there was no final judgment in earlier action); *Oxbow Energy, Inc. v. Koch Indus., Inc.*, 686 F. Supp. at 278, 282 (D. Kan. 1988) (holding that even absent a final judgment, a party cannot split claims); *Hartsel Springs Ranch of Colo., Inc. v. Bluegreen Corp.*, 296 F.3d 982, 987 n. 1 (10th Cir. 2002) (noting that motion to dismiss based on claim-splitting often cannot wait until final judgment in first-filed action). Because this lawsuit involves plaintiffs who would be bound by a final judgment in the *AAMS* case and involves the same defendants and the exact same claims that are currently pending in D.C., the doctrine of claim splitting bars the Air Ambulance Plaintiffs' claims here.

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

As explained above, the NSA defines the "qualifying payment amount" in relevant part as "the median of the contracted rates recognized by the plan or issuer . . . for the same or a similar item or

service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished" as of January 31, 2019, subject to an inflation adjustment. 42 U.S.C. § 300gg-111(a)(3)(E)(i); *see also id.* § 300gg-112(c)(2). The Act further instructs the Departments to issue regulations that establish the "methodology . . . to determine the qualifying payment amount," including the definition of the geographic regions used to make that determination. *Id.* § 300gg-111(a)(2)(B)(i), (iii). The Departments reasonably exercised their statutory authority to set this methodology, and reasonably explained their decision. The APA requires nothing more. *See Prometheus Radio Project*, 141 S. Ct. at 1158.

A. The Departments Established a Reasonable Methodology for Calculating the QPA Based on the Median of the Contracted Rates Recognized on January 31, 2019.

Plaintiffs insist that the QPA should not be based on the contracted rates recognized under the agreements negotiated between providers or facilities and payers, but instead should be based only on the rates for the items or services that "were 'provided'" within some unspecified time period. TMA Br. 18, ECF No. 25. But Plaintiffs' preferred methodology is inconsistent with the statutory text, illogical, and indeterminate.

The Act defines the term "qualifying payment amount" as

> the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market . . . as the plan or coverage) as the total maximum payment . . . under such plans or coverage, respectively, on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary.

42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). By defining the term with reference to the "median of the contracted rates recognized . . . on January 31, 2019," Congress directed the QPA to be calculated based on the median contracted rates recognized between providers and facilities and health plans and

issuers under the terms of the plan or coverage as they existed on that date. "Plans" and "coverage" are terms of art under the PHSA and ERISA, *id.* § 300gg-91(a)(1), (b)(1), and "[w]hen a statute includes an explicit definition, we must follow that definition," *Digit. Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 776-77 (2018) (quoting *Burgess v. United States*, 553 U.S. 124, 130 (2008)). The Act directs that the QPA be based on the median of *the rates themselves*, with each *rate* being a single data point in the calculation of the median. 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I) (specifying "median of the contracted rates recognized"); *see* 86 Fed. Reg. at 36,889 (explaining that a median is "calculated by arranging in order from least to greatest the contracted rates of all plans . . . or all coverage"). As the Departments recognized, "the rate negotiated under a contract constitutes a . . . contracted rate regardless of the number of claims paid at that contracted rate." *Id.* Plaintiffs cannot rewrite the contracts negotiated between providers and plans just as they cannot rewrite the statute itself.

In the insurance market, contracted rates are generally negotiated prospectively, with a provider and a plan typically agreeing sometime in the prior year as to the prices that will be paid under the plan or coverage for various items and services furnished in the forthcoming year. In other words, the "contracted rates recognized" are negotiated ex ante—they are forward-looking rates that the parties agree to in advance. At the time the contracts are negotiated, neither the providers nor the payers can know for certain how many times a particular service will be provided, or a particular contracted rate paid, but they agree that, any time that item or service is provided under the contract, the contracted rate will be paid. A provider and payer may agree to a rate for a service that the provider does not anticipate ever providing but ends up providing several times over the course of the contract. In that situation, the provider would be paid based on the rate recognized in the contract. Likewise, a provider may negotiate a competitive rate for a service the provider hopes to provide frequently but ends up providing rarely. In that situation, too, the provider would be paid based on the rate recognized in the contract. For precisely these reasons, the statute doesn't impose any minimum

number of times an item or service must be provided under a contract for the rates agreed to in that contract to be considered "the contracted rates." 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). The rates recognized under the plan or coverage are the rates that will apply to a particular item or service—regardless of how many times that item or service is provided. By basing the QPA calculation on the median of the contracted rates recognized under the plan or coverage, Congress designed a simple mechanism for calculating the QPA that can be based entirely on information contained within the four corners of the contracts themselves. *See id.* (contracted rates "determined with respect to all such plans of such sponsor or all such coverage offered by such issuer"). Congress focused on the information readily discernable from the plan and coverage documents and for obvious reasons. Plaintiffs' argument that the QPA should instead be based only on rates that were actually provided a sufficient number of times during some unspecified time period would require a burdensome, retrospective examination of paid claims and medical records.

Plaintiffs' interpretation would also require rewriting the statute's plain text. Plaintiffs, for example, argue that the QPA should be based only on services that "ha[ve] been provided" or "were 'provided'" during some unspecified time period. TMA Br. 18, 19. But the Act itself does not use any language suggesting that the items or services must have previously been provided during any particular time period, or even that those rates must have actually been paid. Rather, the Act bases the QPA on the median of the "contracted rates recognized"—not "paid." Congress could have required that the QPA be based on services that "have been provided" or based on rates that "have been paid," but instead chose to focus on the rates that the parties have agreed in advance will apply to an "item or service that *is* provided" under the terms of the contract. "[U]nless the context indicates otherwise . . . words used in the present tense include the future as well as the present," 1 U.S.C. § 1, but "the present tense generally does not include the past," *Carr v. United States*, 560 U.S. 438, 448 (2010). The Departments' interpretation of the statutory text was therefore entirely reasonable.

Their interpretation is also wholly consistent with Congress's intent. After all, Congress intended the QPA to reflect the rates that the parties have negotiated in advance—rates that will apply to any items or services provided under the contract during the term of the contract. *See* H.R. REP. NO. 116-615, at 58 (AR 335) (describing recognized amount "based on a market-based benchmark of the median contracted rate for similar services" without imposing requirements on how often those services are provided). Plaintiffs' reading directly contradicts that intent.

Plaintiffs' argument becomes even more illogical upon closer inspection. Plaintiffs argue that the QPA should be based only on services actually provided, but the statute defines the QPA with reference to a specific date: January 31, 2019. *See* 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I) (specifying "the median of contracted rates recognized . . . on January 31, 2019"). The fact that Congress chose a single date for calculating the QPA demonstrates that it intended to take a snapshot of the contracts as they existed on that date to calculate the QPA for future use (adjusted for inflation). Plaintiffs' interpretation of the statute as requiring the QPA to be based on an accounting of the items or services previously provided would impermissibly read the "on January 31, 2019" directive entirely out of the statute. *See Nielsen v. Preap*, 139 S. Ct. 954, 969 (2019) ("[T]he interpretive canon against surplusage" is "the idea that 'every word and every provision is to be given effect.") (quoting Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 174 (2012)). And surely, Plaintiffs do not mean to suggest that the "on January 31, 2019" directive should be implemented by calculating the QPA only with reference to items or services that were provided on that date itself. *See United States v. Turkette*, 452 U.S. 576, 580 (1981) ("absurd results are to be avoided"). Plaintiffs' interpretation is thus inconsistent with the fact that Congress tethered the QPA definition to a specific date.

Furthermore, Plaintiffs seem to suggest not only that the QPA must be based on rates for services that were provided during some unspecified time period, but also that the services must not have been provided "rarely." TMA Br. 27. But Plaintiffs do not explain what time period they think

these services should have been provided in or how often—must they have been provided at least once a month? Six months? A year? Or should the number of times vary with how common or rare the service is, such that a heart transplant need have been provided only once in the last year, but an x-ray should have been provided a dozen times? Plaintiffs' failure to offer answers to any of those questions reveals the weakness of their proffered interpretation and underscores why the Department's understanding of the QPA as the median of the rates recognized under terms of the plans or coverage as they existed on January 31, 2019 is a reasonable and correct reading of the statute.

That plain-text understanding is reflected in the July 2021 IFR. The IFR explains that the contracted rates that form the basis of the QPA calculation mean "the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay . . . for covered items and services." 45 C.F.R. 149.140(a)(1). The preamble to the IFR explains that each negotiated rate is a unique data point because it represents the amount that a payer has agreed to pay each time that particular item or service is provided. 86 Fed. Reg. at 36,889. For example, if a plan or issuer has a contract with multiple providers, with separate negotiated rates for each provider, each unique contracted rate constitutes a single data point for purposes of determining the median contracted rate. *Id.* Like Congress, the Departments focused on the rates that payers have contractually agreed to pay, not the number of times an item or service was provided.

Even if the statute were more ambiguous, Congress directed the QPA calculation to be "consistent with the methodology established by the Secretary," thus explicitly delegating rulemaking authority to the Secretary to establish the methodology for calculating the QPA. The Secretary's interpretation of the statute, and the regulations exercising that congressionally delegated authority, are thus entitled to deference. *See Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 277 (2016) ("granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute" when statute is open to multiple reasonable interpretations).

As discussed more fully below, basing the QPA calculation on the contracted rates recognized on January 31, 2019, would not necessarily have the effect of driving the QPA below the median of in-network rates for services actually provided and paid for during some undefined period in the past. This is because, when calculating the QPA, payers must use contracted rates for providers in the same or similar specialty—*i.e.*, the providers who are most likely to actually provide the item or service at issue—any time the rates vary by provider specialty. Thus, the examples that Plaintiffs use, of a dermatologist who accepts below-market rates for anesthesia services because the dermatologist does not provide those services, would not properly be included in the QPA calculation for anesthesia services provided by anesthesiologists. TMA Br. 14. Instead, if the rate for anesthesia services is materially higher in contracts with anesthesiologists (who provide anesthesia services) than it is in contracts with dermatologists (who do not) then the QPA for anesthesia services provided by anesthesiologists should be based on the contracts with anesthesiologists and should not include the rates from the dermatologists' contracts. By basing the QPA on the median of the recognized in-network rates under the contracts of the plan or coverage, Congress designed, and the Departments effectuated, a system based on agreed-upon rates resulting from arms-length negotiations. Such a reasonable interpretation is entitled to deference and is not arbitrary or capricious.

B. The Departments Established a Reasonable Methodology for Calculating the QPA that Requires a Specialty-Specific Calculation Whenever Rates Vary by Specialty.

Plaintiffs' claims about "ghost rates" or "out-of-specialty rates" driving down the value of the QPA are similarly misguided. The July 2021 IFR explained that "if a plan or issuer has contracted rates for a service code that vary based on provider specialty, the median contracted rate is calculated separately for each provider specialty." 86 Fed. Reg. at 36,891. The Departments recognized, however, "that not all plans or issuers vary contracted rates by provider specialty, in which case requiring plans and issuers to calculate separate median contracted rates for each provider specialty would increase

the burden associated with calculating the QPA without adding specificity to the QPA." *Id.* This interpretation is consistent with how the Act defines the QPA. The statute bases the QPA on rates from providers "in the same or similar specialty." 42 U.S.C. § 300gg-111(a)(3)(E)(i). But when rates do not vary by specialty, the rates included in the calculation are necessarily the same as the *rates* that providers in the same or similar specialty charge. Accordingly, the IFR requires that any time there is a material difference in contracted rates by specialty, the QPA must be calculated in a specialty-specific manner. In other words, when there is no material difference in the contracted rates by specialty, the IFR reasonably permits payers to calculate the QPA without regard to provider specialty because doing so is less administratively burdensome and would have no material impact on the QPA.

Contrary to Plaintiffs' unsupported suggestion, this reasonable, pragmatic interpretation of the Act in fact avoids the possibility that including artificially low out-of-specialty rates will drive down the QPA.[9] When calculating the QPA separately for each provider specialty would be pointless (because the contracted rates do not vary by specialty) the Departments declined to impose an entirely unnecessary burden on plans and issuers. Interpreting a statute in a way that reduces unnecessary burdens—especially when it causes no harm to Plaintiffs—is a reasonable way to interpret a statute. *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 529 & n.34 (2d Cir. 2017) (deferring to agency's interpretation of a statute that sought to avoid the "potential for such disruptive results" and finding this desire to avoid burdensome disruption "could support the EPA's interpretation of the Clean Water Act"); *see also Nat'l Auto. Dealers Ass'n v. FTC*, 864 F. Supp. 2d 65, 80 (D.D.C. 2012) (concluding that it was "reasonable and desirable" for the agency to interpret the statute in a way that avoided burdensome "practical effects" of alternative interpretation). This

[9] In fact, by tying the QPA to in-network rates under 2019 contracts, Congress preserved the status quo that had resulted in significantly higher in-network rates for the provider specialties that could use the ability to go out-of-network as negotiating leverage. By tying the QPA to payment rates that were in effect before the enactment of the Act, Congress carried forward certain financial benefits that were associated with provider specialties whose billing practices had prompted the Act in the first place.

approach also recognizes that different plans and issuers define "same or similar specialty" differently in their business practices. 86 Fed. Reg. at 36,891.

After the July 2021 IFR was issued, stakeholders brought to the Departments' attention certain contractual arrangements in which a plan or issuer offers most providers the same fee schedule and leaves it up to the provider to negotiate higher rates for the services they are most likely to bill. As a result of this practice, a provider's contract may include some rates for services that they declined to negotiate and that may not reflect the prevailing market value for those services. In the August FAQs, the Departments clarified that whenever the contracted rate varies by specialty—whether the variation is the result of a plan or issuer purposefully setting different rates based on specialty or whether the contracting practice described above otherwise results in different rates based on specialty—the QPA must be calculated separately for each provider specialty. Aug. FAQs at 16 (AR 10860). And the Departments clarified that any time "there is a material difference in the median contracted rates for a service code between providers of different specialties" then the "QPAs must be separately calculated" for each specialty. *Id.* at 17 (AR 10861). The Departments explained that whether a material difference exists "depends on all of the relevant facts and circumstances" and that plans and issuers are expected to exercise good faith reasonable judgment in calculating the QPA in accordance with this guidance. Plans and issuers that fail to do so risk fines, penalties, and other legal consequences. *See id.* at 16 (AR 10860) ("Providers, facilities, and providers of air ambulance services with concerns about a plan's or issuer's compliance with the requirements of [the regulations] may contact the No Surprises Help Desk . . . submit a complaint . . . or contact the applicable state authority.").

The examples that Plaintiffs complain of are clearly not permitted under the Departments' interpretation. For example, Plaintiffs argue that "including out-of-specialty rates tends to drive down QPAs," TMA Br. 10, but the July 2021 IFR and the August FAQs explain that if an out-of-specialty rate materially differs from an in-specialty rate, such that it actually would "drive down" the QPA,

then that QPA must be calculated using only specialty-specific rates. Thus, Plaintiffs' hypothetical primary care physician whose contract includes low rates for radiology services because that provider "did not meaningfully attempt to negotiate those rates with the insurer" would not be included in calculating the QPA for radiology services provided by a radiologist if including those rates would "skew[] the QPA away from market rates." TMA Br. 10. (They would, however, be included in calculating the QPA for radiology services provided by a primary care provider, because then the QPA would be based on rates from providers in the same or similar specialty.). And because the Departments clarified that the median rates must be calculated separately by provider specialty any time there is a material difference in rates for different specialties, any out-of-specialty rates that are materially lower than the rates for a particular specialty would be excluded from the QPA calculation for that particular specialty. In other words, Plaintiffs' reading of the August FAQs to suggest that only $0 rates, but not "not-quite-$0" rates, would be excluded from the QPA calculations is flatly inaccurate. TMA Br. 19. A "not-quite-$0" rate would presumably be materially different from whatever the in-specialty rate is, and therefore an out-of-specialty "not-quite-$0" rate should be excluded from the QPA calculations. "To the extent contracted rates for a service code vary based on only certain provider specialty types, the plan or issuer must calculate a separate median contracted rate for each provider specialty for which the rates differ." Aug. FAQs at 17. The IFR therefore does not do what Plaintiffs claim it does, nor is it arbitrary or capricious. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (holding that courts may defer to an agency's "reasonable" reading of a regulation).

Payers may include out-of-specialty rates in the QPA calculation only when doing so would have no material impact on the QPA and therefore would not injure Plaintiffs in the first place. Thus, even if this Court were to set aside the challenged regulation, it would not impact the QPA calculations, and would not, as Plaintiffs assume without evidence, result in the QPA going up, and accordingly, would not redress their claimed injuries. *See Kitty Hawk Aircargo, Inc v. Chao*, 418 F.3d 453,

458 (5th Cir. 2005) (explaining that to establish standing, Plaintiffs must show a "concrete and particularized" injury that would be "redressed by a favorable decision') (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992))).

C. The Departments Reasonably Excluded Bonus and Incentive Payments from QPA Calculations.

The July 2021 IFR, in setting out the methodology for calculating the median contracted rates used to calculate the QPA, "[e]xclude[s] risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments." 45 C.F.R. § 149.140(b)(2)(iv). Under the Act, a patient's cost-sharing obligations for out-of-network emergency services, air ambulance services, and nonemergency services furnished by out-of-network providers at in-network facilities are determined by reference to the "recognized amount." 42 U.S.C. § 300gg-111(a)(1)(C)(iii). When there is no applicable specified state law or All-Payer Model Agreement in place, the "recognized amount" is defined as the lesser of the billed charges or the QPA. *Id.* § 300gg-111(a)(3)(H). The Departments excluded incentive-based or retrospective payments from the calculation of the QPA because "excluding these payments and payment adjustments from the median contracted rates used to determine cost sharing . . . is consistent with how cost sharing is typically calculated for in-network items and services." 86 Fed. Reg. at 36,894. The July IFR thus incorporated pre-existing industry norms that have long been used to calculate patient cost-sharing amounts. *See City of Dallas v. FCC*, 118 F.3d 393, 395 (5th Cir. 1997) (looking to industry practice and holding that agency regulation interpreting statute to align with industry standards was reasonable). For such in-network cost-sharing, the "amount is customarily determined at or near the time an item or service is furnished, and is not subject to adjustment based on changes in the amount ultimately paid to the provider or facility as a result of any incentives or reconciliation process." 86 Fed. Reg. at 36,894. This means that, where the Act does not apply, cost sharing is typically calculated based on the allowed amount or provider charges at or around the time the item or service is furnished, and is not later adjusted for additional

payments that might be made by the payer to the provider. *Id.* at 36,893-94.

Plaintiffs argue that Section 300gg-111(a)(3)(E)(i)(I)'s language defining the QPA as "the median of the contracted rates recognized by the plan or issuer . . . as the total maximum payment under such plans or coverage" means that the QPA should be based on the total potential payment under a contract, including bonuses and incentive-based payments. TMA Br. 20-21. But Plaintiffs misread the plain text of the statute and argue for an illogical result. Plaintiffs pluck the word "maximum" out of the statute and briefly argue that its presence should justify including the additional payments in the QPA calculation. Yet Plaintiffs essentially read the word "potential" into the phrase "total maximum payment" in their quest to capture bonuses within the scope of the contracted rate calculation. But courts may not "add words to the law to produce what is thought to be a desirable result. That is Congress's province." *E.E.O.C. v. Abercrombie & Fitch Stores, Inc.*, 575 U.S. 768, 774 (2015). Bonus and incentive payments are rarely tied to specific contracted rates for particular items and services; they are more often paid as an annual lump-sum, Plaintiffs have failed to show that it would even be possible to calculate the impact of bonus and incentive payments on a particular median rate. These payments are themselves not taken into account when calculating cost-sharing amount for an item or service. Rather, they are "retrospective" payments or constitute subsequent "adjustments" to payments. 45 C.F.R. § 149.140(b)(2)(iv).

When Congress defined the QPA using the term "total maximum payments" it did so with reference to "the cost-sharing amount imposed for such item or service." 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). Cost-sharing amounts are customarily determined at or near the time an item or service is furnished and are not subject to changes based on the amount ultimately paid. 86 Fed. Reg. at 36, 894. Here, patient cost-sharing depends directly on the QPA, and, consistent with how patient cost sharing is typically calculated, the QPA is not subject to adjustment based on the amount ultimately paid to the provider as a result of any incentives or reconciliation process. *Id.* Of course,

the amount ultimately paid to a provider or facility, whether reached through open negotiation or after the arbitration process, may vary significantly from the QPA. The Departments therefore reasonably determined that the QPA is calculated the same way cost-sharing is ordinarily calculated, excluding bonus payments. Plaintiffs' temporal leap to include *potential* payments or potential subsequent adjustments in the QPA calculation makes little sense in this context.[10]

Nor would it make practical sense to include bonus and incentive payments in these sorts of patient cost-sharing calculations for out-of-network services. After all, bonus and incentive payments are certainly not guaranteed, nor are they typically tied to a particular item or service. Bonus and incentive payments depend on specific conditions, such as utilization adjustments, that would not apply in the context of out-of-network care. *See id.* It was thus reasonable for the Departments to exclude these sorts of prospective and retrospective incentive payments from the QPA calculation.

D. The Departments Reasonably Permitted Third-Party Administrators to Calculate the QPA for Self-Insured Plans and Plaintiffs have Provided no Evidence that this Practice Drives Down the QPA.

The statute states that the QPA must be "determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market." 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I). The QPA is calculated based on plans offered "within the same insurance market," which the statute defines "in the case of a self-insured group health plan, other self-insured group health plans." 42 U.S.C. 300gg-111(a)(3)(E)(iv)(IV). The statute, then, inherently contemplates that the QPA for self-insured plans may be calculated with reference to other self-insured group health plans. The July 2021 IFR permits self-insured health plans to "allow their third-party administrators to determine the QPA for the sponsor by calculating the median contracted rate

[10] The regulation likewise requires the QPA calculations to "exclude . . . penalty" based payment adjustments. Plaintiffs do not argue that the QPA should be discounted to reflect penalties, but there is no indication that Congress would have intended the QPA methodology to function as a one-way ratchet, only including adjustments that would drive up costs. 45 C.F.R. § 149.140(b)(2)(iv).

using the contracted rates recognized by all self-insured group health plans administered by the third-party administrator (not only those of the particular plan sponsor)." 86 Fed. Reg. at 36,890; *see* 45 C.F.R. § 149.140(a)(8)(iv). Thus, the IFR permits the third-party administrator to calculate the QPA for the self-funded plan, using the rates recognized under all plans administered by the third-party administrator. 86 Fed. Reg. at 36,890. Additionally, because the rates for all plans administered by the third-party administrator will likely be identical, since the administrator typically has one network that all of its self-funded plans rely on, Plaintiffs have failed to show that this practice affects the QPA.

Plaintiffs claim that "aggregating contracted rates across plan sponsors violates the Act." TMA Br. 21. They argue that while, in the statute, the QPA is based on the median contracted rates of the "plan sponsor," the July 2021 IFR allows self-funded plans to outsource the QPA calculation to the third-party administrator that administers the plan, based on that administrator's contracted rates, and that somehow this results in a lower QPA. *Id.* Plaintiffs' baseless suggestion is that self-funded plan sponsors will decide whether to calculate the QPA using the contracted rates recognized by all self-insured group health plans administered by the third-party administrator, instead of using only those rates of the particular plan sponsor, based solely on whichever calculation will yield the lowest possible QPA. *See id.* at 11 ("[T]he Departments allowed self-insured group health plans to pick whichever method leads to lower QPAs on balance. These plans can be expected to opt into their third-party administrator's group calculation if it generally serves to lower their applicable QPAs."). But Plaintiffs' argument—and its implications—are misplaced in several ways.

To start, Plaintiffs have no standing to advance such an argument—they have not been injured, and they offer only wild speculation as to how they might be. As stated above, a Plaintiff, to establish an injury in fact must show that they suffered "an invasion of a legally protected interest" that is both "concrete and particularized and "actual or imminent, not conjectural or hypothetical." *Kitty Hawk Aircargo, Inc*, 418 F.3d at 458 (quoting *Lujan*, 504 U.S. at 560)). Plaintiffs have fallen far

short of that standard here. TMA's theory, barely explained in its briefing, is that self-funded plan sponsors, motivated solely by obtaining the lowest possible QPA, would necessarily choose to use the aggregated rates of a third-party administrator, instead of the rates of a plan sponsor, based on the assumption that the calculation would yield the lowest QPA. TMA Br. 11, 21. But this is sheer speculation. As even Plaintiffs' own declarations reveal—in conspicuously identical phrasing across declarants—persons with no apparent knowledge of how self-funded plans operate merely speculate that they must be acting solely with this penny-pinching motive. *See, e.g.*, ECF No. 25-1 Ex. A ¶ 20 ("[I]t is in their financial interest for QPAs to be as low as possible. Accordingly, I *would expect* a reasonable self-funded group health plan to take advantage of this option if doing so would on balance decrease the health plan's QPA's." (emphasis added)); ECF No. 25-2 Ex. B ¶ 21 (same); ECF No. 25-4 Ex. D ¶ 19 (same). There is no evidence beyond those conclusory statements, provided by individuals with no personal knowledge of how self-funded plans operate, to suggest that is the case. Plaintiffs certainly offer no evidence or, in fact, any basis at all, to theorize that self-funded plans are choosing how to calculate the QPA based on achieving the lowest possible QPA (a burdensome procedure that, itself, would require calculating two sets of QPAs and then evaluating which one is lower), or that this provision has any consistent effect on the QPA calculations. Their brief and declarations offer nothing more than wholly speculative and unsupported assertions to that effect. *See, e.g.*, TMA Br. 11, 21. TMA has therefore not shown that this actually affects the QPA calculation, or that QPAs would be higher if calculated based only on a plan sponsor's contracted rates. Indeed, because a third-party administrator typically makes the same network rates available to all of the self-insured plans that it administers, the QPAs would likely be identical for each of the self-insured plans regardless whether the QPAs are determined separately for each self-insured plan or in the aggregate at the administrator level. This Court should reject Plaintiffs' attempt to manufacture an injury here.

In any event, the Departments provided a reasonable explanation for permitting self-funded

plans to allow the third-party administrator to perform the QPA calculations. *See* 86 Fed. Reg. at 36890. This is the case for several reasons. *First*, the administrative costs would be substantial. Self-funded plans bear significant administrative burdens associated with administering a health plan on their own. *See* 86 Fed. Reg. at 36,873, 36,890 36,927. Accordingly, and "[t]o reduce the burden imposed on sponsors of self-insured group health plans, these interim final rules permit sponsors of self-insured group health plans to allow their third-party administrators to determine the QPA for the sponsor." 86 Fed. Reg. 36,890; *see also* Aug. FAQs at 18 (AR 10862) (explaining the function behind the rule as "to reduce [the] burden on self-insured group health plans"). *Second*, it would be impractical. Some employers with self-funded plans offer their employees several options of benefits packages and some may even offer plans from multiple third-party administrators. Aug. FAQs at 18 (AR 10862). Instead of allowing each administrator acting on behalf of the plan to calculate a median contracted rate separately for those benefits package options that it administers, in Plaintiffs' view, self-funded plans should be required to calculate a QPA based on the median of the aggregated rates across all the benefits package options administered by multiple different third-party administrators. On its face, this would be very difficult and burdensome. The rule therefore does not require self-funded plans to "aggregate[] [contracted rates] across multiple mutually-exclusive benefit package options administered by different [third party administrators] to calculate a median contracted rate." Aug. FAQs at 18. (AR 10862).

Third, the alternative would problematically increase reliance on third-party databases. *See* 86 Fed. Reg. at 36,890. Requiring self-funded plans to calculate the QPA based only on the plans they sponsor would reduce the number of real market rates included in QPA calculations, which may often result in insufficient information to calculate the median of the contracted rates for such plans. That in turn would increase reliance on third-party databases. That reliance is problematic: Congress intended third-party databases to be a secondary method of determining the QPA—indeed, Congress

permitted the use of such databases only in the limited circumstance when there is insufficient information. *See* 42 U.S.C. § 300gg-111(a)(3)(E)(iii) (permitting use of such databases only "[i]n the case of a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage that does not have sufficient information to calculate the median of the contracted rates described in clause (i)(I)"). Congress intended to maximize the situations in which the QPA is based on real-life market negotiations, and this approach furthers Congressional intent by minimizing reliance on third-party databases. 86 Fed. Reg. at 36,890.

E. The Departments Reasonably Excluded One-Off Single Case Agreements from the Calculation of the Median of Contracted Rates.

As noted above, the July 2021 IFR directs group health plans and health insurance issuers, for the purposes of calculating this median of a plan's or issuer's contracted rates, to look to the contracted payment rate for a particular service under each of the contracts that the plan or issuer has negotiated in advance with providers of that service. 45 C.F.R. § 149.140(a)(1). Because the calculation includes only contracts that have been negotiated under the terms of the plan or coverage in advance, "single case agreements" that may be negotiated between a provider and a health plan or issuer, either at the time that a service is performed or after the fact, are excluded. *See* 86 Fed. Reg. at 36,889. As the Departments explained, they understood the statutory term "contracted rate" to refer "only to the rate negotiated with providers and facilities that are contracted to participate in any of the networks of the plan or issuer under generally applicable terms of the plan or coverage and excludes rates negotiated with other providers and facilities." *Id.* The Departments found that "this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations." *Id.*

In challenging the exclusion of single case agreements from the calculation of the median, Plaintiffs principally argue that Section 300gg-111(a)(3)'s use of the term "contracted rate" unambiguously refers to the rate of payment for a health service under any contractual arrangement

that a provider may enter into with a payer. ECF No. 26, AA Br. 21-22. But Plaintiffs ignore the defined meaning of that term as contained in the statute. The QPA is "the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market . . . as the plan or coverage) as the total maximum payment . . .under such plans or coverage, respectively, on January 31, 2019," adjusted for inflation. 42 U.S.C. § 300gg-111(a)(3)(E)(i). The statute specifies that the contracted rates are those under the "plan or coverage" and "plans" and "coverage" are terms of art under the PHSA and ERISA. A "group health plan" is an employee welfare benefit plan that provides medical care for employees and their dependents. *Id.* § 300gg-91(a)(1). And "health insurance coverage" means benefits consisting of medical care under a policy offered by a health insurance issuer. *Id.* § 300gg-91(b)(1). The plain text of the statute, then, does not direct the Departments to include all contracts in the calculation of the median; it instead instructs them to include the payment rates that are contracted for *under* the generally applicable terms of a health plan or health insurance policy. Moreover, the statute refers to plans or coverage that are offered in a particular insurance market, *id.* § 300gg-111(a)(3)(E)(i), and "insurance market" is itself a term of art, *see id.* § 300gg-111(a)(3)(E)(iv). Single case agreements are not included in plans or coverage offered to individuals in a particular market, nor do they set recognized rates under such plans or coverage. The Departments thus properly determined that any payment arrangements made under single case agreements do not figure into the calculation of the median. *Cf. Ass'n for Cmty. Affiliated Plans v. U.S. Dep't of Treasury*, 966 F.3d 782, 785 (D.C. Cir. 2020) (discussing definition of individual health insurance coverage). Moreover, it makes little sense to think that Congress would have intended the Departments to include single case agreements that were in place on a single day, January 31, 2019, in the calculation of the median. *See* 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I) (defining the QPA by reference to contracted rates "on January 31, 2019").

Plaintiffs also contend that the Departments acted arbitrarily in excluding single case agreements from the calculation of the median of contracted rates for air ambulance services, given that air ambulance providers rarely enter into agreements in advance to establish in-network rates for their services. AA Br. 23-24. But that precisely describes the problem that Congress sought to resolve in enacting the No Surprises Act. Congress recognized that a substantial majority of air ambulance services are furnished by out-of-network providers, and that these providers' ability to remain out-of-network has created a "market failure" that has permitted these providers to charge far more than the price that they would be able to command in a fair and functioning market. H.R. REP. NO. 116-615, at 52-53 (AR 330). Congress accordingly sought to limit patients' cost-sharing responsibilities for air ambulance services to an amount based on the rate that would apply if the service were provided in-network. *See* 42 U.S.C. § 300gg-112(a)(1). If anything, the in-network payment amounts for air ambulance services are themselves highly inflated, since they reflect the ability that these providers have prior to the enactment of the Act to refuse to join provider networks and to rely solely on balance billing. Congress was well aware that prices for certain health care providers and services have skyrocketed in recent years, reflecting a market failure and calling for a course correction to protect consumers from rising costs. *See* H.R. Rep. No. 116-615 at 53 (AR 330) (noting that "surprise billing represents a market failure" that has "enable[d] some providers to charge amounts for their services that exceed the marginal cost of producing those services and resulting in compensation far above what is needed to sustain their practice."). And Congress understood that "[t]he presence of this market failure in certain provider specialties is strongly supported by evidence reflecting the highly inflated payment rates for these services[]" with air ambulance providers being some of the biggest offenders of these highly inflated payment rates. *Id.*; *see also* Brown et al., *The Unfinished Business of Air Ambulance Bills* (AR 2845). The Act thus reduces some of the upward pressure on air ambulance payment rates, and the Departments reasonably chose a methodology that honored Congress's intent

on this score. *See, e.g.*, *Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1049 (D.C. Cir. 1997) (deferring to rule that is "reasonable and consistent with the statutory purpose and legislative history"). If the Departments included single case agreements in the calculation of the median contracted rates, Congress's intent to remedy the market failure would be thwarted.

Plaintiffs also assert that the Departments acted inconsistently by excluding single case agreements from the calculation of the median contracted rate, but including the same agreements as contracts for purposes of determining whether a health care facility is "participating" for the purposes of the Act's balance-billing rules. AA Br. 25. The Act does not ban balance billing in all contexts; for example, under certain circumstances, the Act protects a patient from balance billing from out-of-network providers only if he or she receives care from such a provider during a scheduled visit to a facility that is otherwise a "participating" facility under the patient's plan or policy. 42 U.S.C. § 300gg-132. The definition of whether a particular facility is "participating" thus can be important for determining whether a particular service is subject to the Act's protections or not. Because an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual's care to be delivered on an in-network basis, the Departments reasonably determined that the balance billing protections should apply. 86 Fed. Reg. at 36,889 n.48. For this purpose, the Act defines a "participating health care facility" as a facility that has a either a "direct *or indirect* contractual relationship with the plan or issuer, respectively, with respect to the furnishing of such an item or service at the facility." *Id.* § 300gg-111(b)(2)(A)(i) (emphasis added). Whether a provider or facility is a participating provider or facility at any point in time is different from whether the payer had a contract with that provider or facility that set rates that were recognized by the payer on January 31, 2019 for purposes of calculating the QPA, and it serves a different purpose in the statutory scheme. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally

and purposely in the disparate inclusion or exclusion." *Bates v. United States*, 522 U.S. 23, 29-30 (1997) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). The Departments reasonably determined that a single case agreement could constitute a contractual relationship that would cause a facility to be a "participating facility," thereby triggering the Act's balance-billing protections, even though that agreement is excluded from the calculation of the median of contracted rates.

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

The Act also directs that the QPA for a given service be calculated on the basis of the median of contacted rates for the service "provided in the geographic region in which the item or service is furnished," 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I), and instructs the Departments to issue regulations defining these geographic regions, *id.* § 300gg-111(a)(2)(B)(iii). The Departments exercised this authority by defining a "geographic region," for air ambulance services, as "one region consisting of all MSAs in the state, and one region consisting of all other portions of the state." 86 Fed. Reg. at 36,893; *see* 45 C.F.R. § 149.140(a)(7)(ii)(A). If this definition leaves the group health plan or health insurance issuer with insufficient information to calculate a median of contracted rates, then a broader definition is applied of "regions based on Census divisions—that is, one region consisting of all MSAs in each Census division and one region consisting of all other portions of the Census division." 86 Fed. Reg. at 36,893; *see* 45 C.F.R. § 149.140(a)(7)(ii)(B). The statute expressly delegates to the Departments the authority to define geographic region, and the Departments did just that. *See City of Arlington v. FCC,* 569 U.S. 290, 296 (2013). ("Statutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency.").

The Air Ambulance Plaintiffs contend that the Departments abused their discretion in adopting this definition, because, in their view, Congress would not have intended for the Departments to use regions of this size. AA Br. 27. Contrary to this claim, Congress deferred to the Departments' selection of geographic regions, *see* 42 U.S.C. § 300gg-111(a)(2)(B)(iii), and the

Departments reasonably explained their decision to exercise their statutory discretion in this way. They determined that geographic regions should not be defined overly narrowly for air ambulance services, given that such an approach would be more likely to "result in more instances of insufficient information" to calculate a median of contracted rates, "[g]iven the nature of air ambulance services, the infrequency with which they are provided relative to the other types of items and services subject to the No Surprises Act, and the lower prevalence of participating providers of air ambulance services." 86 Fed. Reg. at 36,893. The Departments recognized that the Act permits the use of a third-party database of allowed amounts in cases where there is otherwise insufficient information to calculate a QPA.42 U.S.C. § 300gg-111(a)(3)(E)(iii). They sought, however, to minimize the use of this stop gap, as they thought the statute was best read to contemplate that this mechanism "will be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region." 86 Fed. Reg. at 36,888. In addition, "[u]sing larger geographic regions, for which plans and issuers are likely to have more information, is expected to reduce the likelihood that the median of contracted rates would be skewed by contracts under which the parties have agreed to particularly high or low payment amounts." *Id.* at 36,892.

The Departments thus reasonably explained their decision to define geographic regions in this way. *See Prometheus Radio Project*, 141 S. Ct. at 1158. A broader definition of geographic regions was needed to ensure that there was sufficient information to calculate a median of contracted rates. Plaintiffs also note that the Departments could have chosen to increase reliance on the "fall-back option" of third-party databases, AA Br. 27, but, again, the Departments reasonably explained their decision not to adopt this alternative. They sought to establish a methodology under which the QPA is calculated on the basis of actual information from market negotiations between air ambulance providers and health plans or health insurance issuers, and to ensure that the QPA would not be skewed by outliers with unusually high or low payment amounts.86 Fed. Reg. at 36,888, 36,892. The

Act did not foreclose the Departments from exercising their discretion in this way.

III. THE DEPARTMENTS ADOPTED A REASONABLE APPROACH FOR SETTING A DEADLINE FOR MAKING AN INITIAL PAYMENT OR NOTICE OF DENIAL OF PAYMENT

The Air Ambulance Plaintiffs claim that they have experienced problems in receiving an initial payment or notice of denial of payment within the deadlines imposed by the Act. AA Br. 11-16. They take issue with the regulation providing that "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. § 130(b)(4)(i), arguing that it allows payers to delay making an initial payment or providing a notice of denial of payment indefinitely. However, Plaintiffs attribute to the Departments an interpretation of the relevant regulation that does not accurately reflect the Departments' views of what the current regulations require. Indeed, Plaintiffs do not acknowledge the Departments' explanations, in both the preamble to the July 2021 IFR and in the August FAQs, that interpret the relevant regulation to require a payer to issue an initial payment or notice of denial of payment within 30 days of receiving a bill containing the relevant information from the provider or facility. The Departments' interpretation of the statute and regulation is not in excess of the Departments' statutory authority nor is it arbitrary or capricious. Indeed, there may not even be a difference from Plaintiffs' interpretation.

The Act states that the plan or issuer "shall send to the provider an initial payment or notice of denial of payment" "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).[11] This deadline is repeated in the regulation, which requires that the plan or issuer send an initial payment or a notice of denial of payment "[n]ot later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance

[11] The Departments recognize that an initial payment or notice of denial of payment is different from an adverse benefit determination, which may be appealed through the plan's or issuer's claims and appeals process. *See* 86 Fed. Reg. at 36, 901.

services." 45 C.F.R. § 149.130(b)(4)(i). The regulation goes on to explain that "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). According to Plaintiffs, some payers have interpreted this regulation to permit delaying payment until the payer receives information *from third parties* that the payer believes is necessary for the claim determination. AA Br. 11. However, such an interpretation is inconsistent with the Departments' views, as explained in the preamble announcing this rule and in the August FAQs. There, the Departments explained that the "information necessary to decide a claim for payment" refers to the industry-standard "clean claim," which governs the information that providers and facilities must include in a bill under many existing state laws. 86 Fed. Reg. at 36,900. A "clean claim" "generally means a claim that has no defect, impropriety or special circumstance, including incomplete documentation that delays timely payment." Federal IDR Process Guidance for Disputing Parties (Apr. 2022), at 33 (AR 10978). Therefore, under the current regulations, a payer could not withhold initial payment or notice of denial of payment based on a lack of information outside of the provider's control, when the information provided by the provider is sufficient to decide a claim for payment under the terms of the plan or coverage.

Health insurance issuers are already required under most state laws to make payment to providers and facilities, like Plaintiffs in this case, within a certain number of days of receiving a "clean claim." 86 Fed. Reg. at 36,900. This regulation, therefore, reasonably references industry standards that providers and facilities are already familiar with under many existing state laws. "The provisions are technical: They call to mind Justice Frankfurter's injunction that when a statute is 'addressed to specialists, [it] must be read by judges with the minds of the specialists.'" *Becerra v. Empire Health Found.*, 142 S. Ct. 2354, 2362 (2022) (citations omitted). And the Departments were within their authority to interpret the statutory term "bill for such services" to align with the industry standard definition of a "clean claim." When attempting to ascertain "what meaning Congress intended to invoke when using

a phrase . . . industry practice . . . [is a] prime source[] for the court to determine congressional intent." *City of Dallas*, 118 F.3d at 395. Moreover, courts have acknowledged that, when a statute uses a technical term, it is reasonable to assume that "Congress intended it to have the meaning ascribed to it by the industry under regulation." *Id.* (defining term "seaman" in accordance with industry practices).[12] Interpreting the statutory language "bill for such services" otherwise might require payers to issue an initial payment or notice of denial of payment when faced with incomplete bills that lack necessary information—such as the patient's information, the provider's information, or what services were provided. Rather than adopt a reading that would lead to such absurd results, the Departments borrowed from familiar industry standard practices. The Departments thus adopted a reasonable interpretation of the Act that incorporated a well-established industry practice for when a "bill for such services" would trigger payment deadlines, an interpretation that aligns with the industry-wide definition of a "clean claim" that providers and facilities are already familiar with under many state laws. 86 Fed. Reg. at 36,900.

The Departments therefore agree with Plaintiffs that the regulation does not permit payers to withhold payment on a "clean claim" based on the need to obtain additional information from third parties over which the provider or facility has no control when the information provided by the provider is sufficient to decide a claim for payment under the terms of the plan or coverage. The Departments elaborated on this interpretation in the August FAQs, which explained that the 30-day deadline is "30 calendar days after the plan or issuer received a bill related to such an item or service from a nonparticipating provider, facility, or provider of air ambulance services that includes the information necessary to decide a claim for payment (*i.e.*, a 'clean claim')." Aug. FAQs at 20 (AR

[12] Texas law, for example, defines a "clean claim" as a claim by a physician or health care provider "submitted using the Centers for Medicare and Medicaid Services Form 1500" or the "Professional 837 (ASC X12N 837) format" or by an institutional provider "submitted using the Centers for Medicare and Medicaid Services Form UB-92" or the "Institutional 837 (ASC X12N 837) format. Tex. Ins. Code Ann. § 1301.131.

10864). Thus, as is evident from the Departments' explanation of the timeline, the 30-day deadline begins running when the payer receives "a bill . . . from a nonparticipating provider, facility, or provider of air ambulance services" that would meet the well-known definition of a "clean claim." *Id.* The bill—*i.e.,* the "clean claim"—is what triggers the 30-day deadline under the No Surprises Act just as it triggers payment deadlines under many state laws.[13]

The Departments understand that Plaintiffs allege that some payers may not be following the applicable deadlines. Those payers risk penalties and other enforcement action. As the August FAQs advise, "[p]roviders, facilities, and providers of air ambulance services with concerns about a plan's or issuer's compliance with the requirements to timely make an initial payment or provide notice of denial of payment may contact the No Surprises Help Desk . . . or submit a complaint. . . . The Departments will generally enforce the applicable provisions of the No Surprises Act, in conjunction with states where applicable." Aug. FAQs at 20 (AR 10864).

IV. THE DEPARTMENTS ADOPTED A REASONABLE INTERPRETATION OF THE REGULATIONS TO RESOLVE SEPARATELY BILLED SERVICE CODES IN SEPARATE IDR PROCEEDINGS.

The Departments reasonably concluded that the relevant regulations require that payment disputes concerning air ambulance transports, which are billed under two separate service codes (a "lift" rate and a per-mile rate), must be resolved in two separate IDR proceedings. Plaintiffs' complaints that this interpretation—which applies consistently to all specialties, including others that may have unique billing practices—conflicts with the statute and is arbitrary and capricious are

[13] Many state laws impose payment deadlines for making initial payments on clean claims, and those state laws may carry various penalties for dilatory payment (often known as "prompt pay laws"). *See, e.g.*, *S. Texas Health Sys. v. Care Improvement Plus of Texas Ins. Co.*, 159 F. Supp. 3d 763, 767 (S.D. Tex. 2016) (explaining that one of Texas's "prompt pay laws," "Texas Insurance Code at § 843.342[,] sets out escalating penalties for HMOs that fail to pay valid claims on or before the date they are due"). Although ERISA and FEHBA preempt most state laws as applied to group health plans and FEBHA plans, respectively, not all items or services subject to the Act are provided under the terms of plans or coverage subject to ERISA or FEBHA, and state laws that regulate group health insurance issuers are not preempted.

mistaken. But the Departments opted to take a consistent interpretation of the statutory and regulatory text and their interpretation, though not Plaintiffs' preferred interpretation, is reasonable.

The Act directs the Secretary to "specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination," otherwise referred to as "batching." 42 U.S.C. § 300gg-111(c)(3)(A). The statute sets forth some minimum requirements that must be met before any items or services may be considered jointly as part of a single IDR process. *Id.* § 300gg-111(c)(3)(A)(i)-(iv) (permitting batching "only if" items and services "are furnished by the same provider or facility," payment "is required to be made to the same group health plan or health insurance issuer," the items and services "are related to the treatment of a similar condition," and the "items and services were furnished during a 30 day period"). But the statute directs the Secretary to specify criteria in addition to these minimum requirements. *Id.* § 300gg-111(c)(3)(A). If the Secretary's authority were limited to parroting the criteria enumerated in the statute, there would have been no need for Congress to direct him to "specify criteria" for batching, as Congress should not be presumed to make empty gestures. *See Fund for Animals, Inc., v. Kempthorne*, 472 F.3d 872, 878 (D.C. Cir. 2006) (Kavanaugh, J.); *Ysleta Del Sur Pueblo v. Texas*, 142 S. Ct. 1929, 1939 (2022) ("[W]e must normally seek to construe Congress's work 'so that effect is given to all provisions, so that no part will be inoperative or superfluous, void or insignificant.'") (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)). It was therefore up to the Departments to fill the gap expressly left by Congress. *Nat'l Cable & Telecomms. Ass'n*, 545 U.S. at 986. The Act also requires the treatment of batching of services that apply to non-air ambulance services to apply "in the same manner and to the same extent" to air ambulance services. 42 U.S.C § 300gg-112(b)(3).

The Secretary specified the criteria under which multiple items or services may be "batched" into a single IDR dispute in the September 2021 IFR. The IFR provides that "[b]atched items and services may be submitted and considered jointly as part of one payment determination by a certified

IDR entity only if . . . [t]he qualified IDR items and services are the same or similar items and services." 45 C.F.R. § 149.510(c)(3)(i),(C). The regulation goes on to define "same or similar items and services" to be those that are "billed under the same service code." *Id.* "Same or similar items or services" is a term of art used throughout the regulations, and the regulations define that term to have a consistent meaning everywhere it is used, *see* 86 Fed. Reg. at 36,890 ("under the interim final rules, the term 'same or similar item or service means a health care item or service billed under the same service code"), consistent with the caution to "avoid interpretations that would 'attribute different meanings to the same phrase.'" *Cochise Consultancy, Inc.*, *v. United States*, 139 S. Ct. 1507, 1512 (2019). Thus, the Departments reasonably applied a consistent definition to mean that a single "service" is billed under the same service code.

The regulations therefore require the batching of items or services for resolution in a single IDR proceeding to be limited to services billed under the same service code. 45 C.F.R. § 149.510(c). Air ambulance transports result in two separate service codes. Each service code also carries with it a unique QPA, which the arbitrator must consider during the IDR process. 42 U.S.C. § 300gg-112(b)(5)(C)(i)(I). Therefore, under the text of the regulation, the multiple service codes that result from each air ambulance transport require separate IDR proceedings for each service code. The Departments applied a consistent approach to air ambulance services as they applied to other specialty services—many of which carry their own unique billing and coding practices. The Departments' consistent interpretation of a single phrase is hardly arbitrary or capricious. To the contrary, it is reasonable and entitled to deference.

Plaintiffs argue that each air ambulance transport should be considered a single "service" under the Act, notwithstanding the fact that each "service" results in multiple billing codes. AA Br. 17. However, this would require defining "services" one way for air ambulance transports and a different way in all other instances under the Act. Such anomalous and inconsistent definitions of the

same phrase are to be avoided. *See Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020). An air ambulance transport is also referred to as "air ambulance services" throughout the text of the Act and the regulations. *See* 42 U.S.C. § 300gg-112(a) ("a participant . . . who receives air ambulance services"), (b)(1)(B) ("In the case of open negotiations. . . with respect to air ambulance services, that do not result in a determination of an amount of payment for such services"); *see also* 45 C.F.R. § 149.140(c)(1)(v) (discussing "air ambulance services" consisting of mileage service codes). Therefore, the Departments interpreted the batching regulation in a consistent manner, which has the result of requiring each air ambulance service code to be resolved in a separate IDR process.

V. THE DEPARTMENTS ADOPTED REASONABLE QPA DISCLOSURE REQUIREMENTS.

The Departments adopted reasonable disclosure requirements for payers concerning the QPA calculation. Congress gave broad discretion to the Departments in instructing them to issue rules regarding the information plans and issuers "shall share with the nonparticipating provider or nonparticipating facility" when determining the QPA. 42 U.S.C. § 300gg-111(a)(2)(B)(ii). The statute says nothing more beyond that broad directive, and the Departments set up reasonable disclosure rules that balance the importance of transparency with reducing burden on plans and issuers by minimizing potentially voluminous disclosure requirements. 86 Fed. Reg. at 36,898 ("The Departments seek to ensure transparent and meaningful disclosure about the calculation of the QPA while minimizing administrative burdens on plans and issuers.").

While Plaintiffs contend that the disclosure rules are "unreasonable" and "unreasonably explained" for various reasons, TMA Br. 27, they argue that the rules should *not* be set aside on that basis, *id.* at 30. Instead, Plaintiffs ask that the current rules remain in place—a sure sign that they are not currently causing any harm—and urge the Court to "remand for further rulemaking" concerning additional disclosure requirements. *Id.* But while the APA permits courts to "compel agency action unlawfully withheld," 5 U.S.C. § 706(1), such relief is in the nature of mandamus, which requires a

plaintiff to show, among other things, an unambiguous right to the requested relief—a standard that Plaintiffs make no attempt to meet. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (a plaintiff may challenge agency inaction only where a statute makes "a specific, unequivocal command" ordering a "precise, definite act . . . about which [an official] had no discretion whatever"). Plaintiffs' claim here is thus much like seeking review of a denial of a petition for rulemaking—a petition they never filed. *See* 5 U.S.C. § 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."). If they had, any denial would be separately reviewable under the APA, but under a standard of deference "so high as to be 'akin to non-reviewability.'" *New York v. U.S. Nuclear Regulatory Comm'n*, 589 F.3d 551, 554 (2d Cir. 2009) (quoting *Capital Network Sys. Inc. v. FCC*, 3 F.3d 1526, 1530 (D.C. Cir. 1993)). In such cases, the APA "standard is applied 'at the high end of the range of deference and an agency refusal is overturned only in the rarest and most compelling of circumstances.'" *Id.* (citation omitted). This claim should be rejected for these reasons alone.

Regardless, the disclosure requirements are entirely reasonable. They mandate that a plan or issuer provide "the QPA for each item or service involved"; "a statement certifying that . . . [t]he QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and [that] each QPA shared with the provider or facility was determined in compliance with the methodology outlined in these interim final rules"; upon request "information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the specific items and services at issue and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount"; if a related service code was used to determine the QPA for a new service code, then "information to identify which related service code was used; and if an eligible database was used to determine the QPA, then "information to identify which database was used to determine the QPA"; upon request,

"a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA," *id.* at 36,898-99, and, if the QPA was based on a downcoded service code or modifier, a statement the code was downcoded, and explanation of why it was downcoded, and the amount the QPA would have been had the code not been downcoded. 45 C.F.R. § 149.140(d)(1)(ii). These disclosure requirements were promulgated with the goal of helping parties agree on out-of-network payment rates. For example, the discussion of the disclosure requirement regarding bonus and other incentive payments specifies that "[h]aving information about whether the median contracted rate excludes these types of payment adjustments[,]" was included because it "will better inform the open negotiation and IDR process." *Id.* at 36,899.

Plaintiffs' argument that these rules are not "reasonably explained" is a nonstarter. While Plaintiffs may disagree with the result, there can be little doubt that the Departments' reasoning is plainly set forth, and a court must uphold even a decision of "less than ideal clarity so long as the agency's path may reasonably be discerned," *Sierra Club*, 900 F.3d at 913 (citation omitted)—a bar that is easily met here. And Plaintiffs' contention that the rules are substantively unreasonable because, at bottom, the required disclosures are not "meaningful" is equally mistaken. TMA Br. 27-30. TMA Br. 27-30. As an initial matter, it is common ground that "meaningful disclosures are necessary." TMA Br. 27-28. As the Departments explained, the regulations are intended "to ensure transparent and meaningful disclosure about the calculation of the QPA." 86 Fed. Reg. at 36,898. This is further bolstered by the existence of an audit process, which offers additional checks on the disclosure process and calculation of the QPA. 42 U.S.C. § 300gg-111(a)(2)(B)(iv); *see also id.* § 300gg-111(a)(2)(A)(i)(II). The Departments may also audit an insurer on the basis of a complaint. *Id.* § 300gg-111(a)(2)(A)(ii)(II). Although Plaintiffs complain that HHS has performed "only *nine* audits of QPAs per year," TMA Br. 28, they offer no explanation why they believe this number is inadequate. In any event, payers found

to be operating in violation of the regulations are subject to fines and penalties. 42 U.S.C. § 300gg-22; 45 C.F.R. § 150.301 (authorizing civil money penalties).

Plaintiffs err in contending that the Departments were obligated to mandate a disclosure of "(1) each rate that was included in the QPA; (2) the specialty of the provider who agreed to that rate; (3) the number of times that rate was *actually paid* by the insurer; or (4) the amount of any incentive payments excluded from the rates." TMA Br. 28. The statute itself requires nothing of the sort and mandating this level of disclosure could be extremely burdensome on plans and issuers. To the contrary, when it came to disclosures, the statute delegated "considerable authority to fill in, through interpretation, matters of detail related to its administration." *Barnhart v. Walton*, 535 U.S. 212, 225 (2002). And regardless the QPA calculation is itself transparent—governed by exhaustive and detailed regulations and subject to audit. The regulations explain in detail how to calculate a median, leaving little mystery to the QPA calculations process. *See* 86 Fed. Reg. at 36,889.

In short, under a broad statutory directive, the Departments struck a reasonable balance between "ensur[ing] transparent and meaningful disclosure about the calculation of the QPA" on the one hand "while minimizing administrative burdens on plans and issuers." 86 Fed. Reg. at 36,898. That balance reflects a reasonable policy choice by the Departments and is not arbitrary or capricious.

VI. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED.

In the event the Court agrees with Plaintiffs, any relief should be no broader than necessary to remedy the demonstrated harms of any specific 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). Plaintiffs' invocation of the APA does not justify a departure from these principles. Nothing in the APA's directive to "set aside" unlawful "agency action" mandates that "agency action" shall be set aside globally, rather than as applied to the plaintiffs. 5 U.S.C. § 706(2). Moreover, any relief should be limited to the particular provisions, if any, that are found to be invalid.

See K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 294 (1988) (severing invalid provisions of a regulation).

At most, the Court should remand the matter to the Departments without vacatur of the challenged provisions. The QPA plays a critical role in many aspects of the new processes effected by the Act and without clear guidance on how to calculate the QPA, every one of those processes could come to a screeching halt. Vacatur would be highly disruptive, as it would require an immediate pause of all calculation of patient cost-sharing, offers of payment, and IDR proceedings under the Act while payers are forced to somehow recalculate the QPA without adequate guidance from the Departments. QPAs have already been calculated and been in use for over a year, and third-party administrators have been administering plans consistent with the Department's rules since they took effect. *See Am. Hosp. Ass'n v. Becerra*, No. CV 18-2084, 2023 WL 14337, at *5 (D.D.C. Jan. 10, 2023) (remanding HHS rule without vacatur because vacatur would be "highly disruptive" due to the "staggering value and number of transactions at issue" affected by the rule). 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.

Dated: March 3, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 3rd day of March, 2023, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ Anna Deffebach
ANNA DEFFEBACH

IN THE 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.

No. 6:22-cv-00450-JDK

Lead Consolidated Case

ORDER

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

IT IS SO ORDERED.