UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF KENTUCKY SOUTHERN DIVISION AT LONDON

PHI HEALTH, LLC, and EMPACT MIDWEST, LLC,

Case No.

Plaintiffs, ORIGIN

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,

U.S. OFFICE OF PERSONNEL MANAGEMENT,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,

U.S. DEPARTMENT OF LABOR,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,

U.S. EMPLOYEE BENEFITS SECURITY ADMINISTRATION,

ALI KHAWAR, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,

U.S. DEPARTMENT OF THE TREASURY,

JANET YELLEN, in her official capacity as Secretary of the Treasury,

INTERNAL REVENUE SERVICE, and

CHARLES RETTIG, in his official capacity as Commissioner of Internal Revenue, ORIGINAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF Defendants.

ORIGINAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

This is an action by Plaintiffs PHI Health, LLC ("PHI") and EMpact Midwest, LLC ("EMpact") challenging, under the Administrative Procedure Act and the U.S. Constitution, various regulations that implement the "No Surprises Act" of 2020, Pub. L. 116-260, div. BB, tit. I (Dec. 27, 2020), which regulations were promulgated by Defendants: the U.S. Department of Health and Human Services, the U.S. Department of Labor, the U.S. Department of the Treasury, the U.S. Office of Personnel Management (the "Departments"), and the current leaders of those Departments in their official capacities (the "Department Officials"). Plaintiffs allege as follows:

INTRODUCTION

1. Plaintiffs provide emergency medical services to patients in this District. PHI is an air ambulance company with bases in London, KY and Somerset, KY. EMpact is a physicians' practice group that provides professional emergency medicine services in four hospitals located in the District.

2. Plaintiffs, as conscientious members of the healthcare community, support the No Surprises Act's general purpose of preventing patients from being saddled with medical bills for emergency services, when the patient has insurance that purports to pay for those services. Plaintiffs agree that this purpose is a worthy one, and as a threshold matter, are not challenging the provisions of the Act that prohibit balance billing.

3. Plaintiffs challenge the regulations issued by the Departments, that contrary to the language and purpose of the Act, permit insurers to pay providers less than reasonable

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reimbursement rates for their services, and create a nearly insurmountable presumption that the insurer's payment is adequate.

4. Plaintiffs support the system—promised by the No Surprises Act, but not delivered by the implementing regulations challenged here—in which providers have a fair process to adjudicate their claims for reasonable compensation against the commercial health plans and health insurers directly, rather than putting the patient "in the middle" of the dispute.

5. The No Surprises Act, as drafted and intended by Congress, was a bipartisan compromise: In exchange for pre-empting providers' long-standing right to seek reasonable compensation from the *patient*, the Act substituted a new "Independent Dispute Resolution" (IDR) process, in which providers could enforce their right to reasonable payment directly against the patient's commercial health plan or health insurer. If the provider and insurer could not agree on a reimbursement amount, each could submit an "offer" to an IDR entity, which would select one of the two offers after unbiased and equal consideration of certain evidence presented by both parties.

6. The regulations promulgated by Defendants, however, provided insurers with superior power in the IDR process by including a presumption in favor of the insurers' median contract rate for the services subject to the dispute; i.e. the rate set for the services during a time when balance billing was permitted and that assumed certain volume for providers that does not exist in non-contract relationships. Contract rates are also overwhelmingly determined by insurers and forced onto network providers that have far inferior leverage to negotiate fair rates. Further, the regulations excluded consideration of single case agreements, which are negotiated by insurers and out-of-network providers in circumstances where patients cannot receive services from in-

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network providers, and are likely the best evidence of truly negotiated, agreeable, and reasonable out-of-network rates.

7. The regulations are the foreseeable result of the Defendants' failure to provide stakeholders, including healthcare providers, with an opportunity for comment before the regulations took effect, as the Administrative Procedure Act requires. The regulations unfairly tilt the IDR Process heavily in favor of the commercial payors contrary to Congress's statutory directives; are arbitrary and capricious; are in excess of statutory authority; and violate providers' rights under the Fifth Amendment of the U.S. Constitution.

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PARTIES

8. PHI is a limited liability company that provides air ambulance services. PHI operates two airbases in the London Division of this District, which are located in Somerset, KY, and London, KY. From these bases, PHI conducted 1,214 flights in 2021 alone. Many of PHI's flights from these bases are or will be subject to the regulations challenged in this action. In total, PHI operates 80 air ambulance bases across 15 States, from which it provides services to patients located in 27 States. PHI transports more than 22,000 patients each year in its 109 planes and helicopters.

9. EMpact is a limited liability company that provides professional emergency medical services atfour hospitals located in this District . EMpact is indirectly owned by thirteen emergency physicians. EMpact bills patients and their health plans and insurers for professional emergency services. Many of EMpact's services, provided in this District, are or will be subject to the regulations challenged in this action.

10. Defendant U.S. Department of Health and Human Services is an executive department of the United States headquartered in Washington, D.C.

11. Defendant Xavier Becerra is the Secretary of Health and Human Services. He is sued only in his official capacity.

12. Defendant U.S. Department of the Treasury is an executive department of the United States headquartered in Washington, D.C.

13. Defendant Janet Yellen is the Secretary of the Treasury. She is sued only in her official capacity.

14. Defendant Internal Revenue Service is a bureau of the Department of the Treasury and is headquartered in Washington, D.C.

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15. Defendant Charles Rettig is the Commissioner of Internal Revenue. He is sued only in his official capacity.

16. Defendant U.S. Department of Labor is an executive department of the United States headquartered in Washington, D.C.

17. Defendant Martin J. Walsh is the Secretary of Labor. He is sued only in his official capacity.

18. Defendant U.S. Office of Personnel Management (OPM) is an executive agency of the United States headquartered in Washington, D.C.

19. Defendant Kiran Ahuja is the Director of OPM. He is sued only in his official capacity.

JURISDICTION AND VENUE

20. The Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331 and 28 U.S.C. § 1346(a).

21. Plaintiffs' causes of action are provided by the Administrative Procedure Act, 5 U.S.C. §§ 702-706, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Constitution of the United States.

22. Venue is proper in this judicial district under 28 U.S.C. § 1391(e). This is an action against the United States and various of its Departments and Department Officials in their official capacities. Both Plaintiffs provide emergency medical services in this District for which Plaintiffs' rights to reimbursement, from health benefit plans and health insurance issuers, has been and will be affected by the regulations challenged in this action. Thus, a substantial part of the events giving rise to Plaintiffs' claims occurred and are occurring in this District. Moreover, PHI operates two airbases in this District, and EMpact resides in this District.

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BACKGROUND

I. Background on PHI and Air Ambulances

23. Air ambulances play a vital role in responding to medical emergencies. Without air ambulances, many critically ill and injured patients would not have timely access to necessary medical care. More than 85 million Americans—over a quarter of the U.S. population—live farther than a one-hour drive from a Level 1 or Level 2 trauma center.¹

24. Traumas, strokes, heart attacks, burns, and high-risk neonatal or pediatric cases account for 90% of helicopter air ambulance transports nationally. Without air ambulances, many of these patients would be denied timely access to the care they need.

25. The need for air ambulance services has grown more acute in rural areas during the last twenty years. Since 2005, more than 180 rural hospitals have closed, including 19 closures in $2020.^2$

A. PHI Answers the Call Without Regard to the Patient's Ability to Pay

26. Almost all of PHI's flights are conducted in immediate response to emergency calls that PHI receives from doctors, hospitals, first responders (*e.g.*, police, firefighters, paramedics), and from emergency dispatchers.

27. Approximately 80% of PHI's patients would have suffered irreparable harm without PHI's air ambulance services and approximately 3% would have died.

28. Pursuant to applicable law, internal policy, and the operational requirements of providing emergency care, PHI *never* refuses or delays service to inquire about payor source or

¹ Am. Med. Ass'n, Air Ambulance Regulations and Payments 2 (2018), perma.cc/2WR8-D747.

² *Rural Hospital Closures*, Cecil G. Sheps Ctr. for Health Servs. Rsch., (last visited Nov. 15, 2021), perma.cc/LE9K-U3QX.

ability to pay. PHI assesses, treats, and transports patients based solely on clinical determination again, *without* considering their ability to pay or what health insurance they have.

29. PHI has a duty to respond to medical emergencies without giving any consideration to the patient's ability to pay or health insurance coverage. PHI's duty to respond arises not only

from PHI's and its employees deep commitment to patient health, but also from state statutes and

regulations³ and from the accrediting bodies that govern PHI.⁴

³ In Kentucky, see 202 Ky. Admin. Regs. 7:510 § 5(2)(b) (An air ambulance provider shall have policies requiring "[d]ispatch of requests for emergency service within two (2) minutes of the call taker's determination of the correct address or location of the emergency incident site and completion of a weather check"); 202 Ky. Admin. Regs. 7:555(15) ("An agency shall not refuse a request for emergency pre-hospital response if a unit is available in its geographic service area."). In other states, see, for example, Ala. Admin. Code r. 420-2-1-.20(1) ("In no event shall an emergency medical provider service responding to the scene of an emergency fail to treat a patient because of the patient's inability to pay or perceived inability to pay for services."); Ala. Admin. Code r. 420-2-1-.29(1) ("A licensed [Emergency Medical Services Personnel] shall perform his or her job duties and responsibilities in a manner that reflects the highest ethical and professional standards of conduct."), id. (2)(v) ("Disregarding a duty to act" is "Misconduct"); Fla. Stat. § 395.4045(1) (mandating that EMS providers, including air ambulance services, "shall transport trauma alert victims"); Fla. Stat. § 401.45(1) (barring denial of necessary emergency treatment or transport); Fla. Stat. § 401.411(1)(a) (authorizing denial, suspension or revocation of license for denial of such treatment or transport); Fla. Stat. § 381.026(4)(d)(2) ("A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide such treatment."); N.M. Code R. § 18.3.14.8 ("It shall be unlawful for an ambulance service, or any of its personnel or agents, to refuse to provide service to a person in need of emergency medical treatment or transportation, or to require advance payment prior to rendering such service."); N.M. Admin. Code 7.27.5.16 (requiring air ambulance services to meet the most recent standards published by the CAMTS, which in turn bars requiring "a guaranteed payment prior to transport," infra n.4); Okl. Stat. tit. 63 § 1-2504.1(A) ("All licensed ambulance services shall respond appropriately, consistent with the level of licensure, when called for emergency service regardless of the patient's ability to pay."); 25 Tex. Admin. Code § 157.36(b) (authorizing suspension, revocation or non-renewal of "EMS certification or paramedic license" for "failing to respond to a call while on duty and/or leaving duty assignment without proper authority" or "abandoning a patient"); 25 Tex. Admin. Code § 157.11(n)(5)(requiring EMS provider to ensure "that all personnel are currently certified or licensed by the department"); 12 Va. Admin. Code 5-31-350 ("In the case of an emergency illness or injury, an EMS agency may not refuse to provide required services including . . . emergency transport and interfacility transport based on the inability of the patient to provide means of payment for services rendered by the agency."); 12 Va. Admin. Code 5-31-380 ("An EMS agency shall provide service within its primary service area as defined by the local EMS response plan.")

⁴ See Comm'n on Accreditation of Medical Transport Sys. (CAMTS), Eleventh Edition Accreditation Standards of the Commission on Accreditation of Medical Transport Systems 02.02.01(3)(a) (2018), https://perma.cc/D54Q-ZSQ5 ("Emergency transports do not require a guaranteed payment prior to transport."). Although CAMTS is a voluntary organization, its standards are made mandatory by various state regulations. *See, e.g.*, N.M. Admin. Code 7.27.5.16. Other jurisdictions—such as the City of Mesa, AZ—make CAMTS accreditation a pre-condition of submitting to detailed inspection requirements by that jurisdiction.

30. PHI is certified by the Federal Aviation Administration as an air carrier authorized to conduct on-demand operations, pursuant to 14 C.F.R. Part 135 (a "Part 135 certificate"). PHI also holds ambulance licenses issued by each State in which it maintains a base. The Part 135 certificate authorizes PHI to provide air transportation, while the state ambulance licenses enable PHI to provide medical ambulance operations and to bill for its medical services.

B. PHI's Commitment to Quality and Safety

31. PHI has invested substantial efforts and capital to build a cadre of capable pilots, mechanics, flight nurses, and flight paramedics. These are highly skilled positions that require significant training and certifications.⁵ PHI's personnel have a substantial number of years of industry experience, including average tenures at PHI of more than 5 years for flight nurses and flight paramedics, approximately eight years for pilots and mechanics, and approximately thirteen years for flight respiratory therapists.

32. PHI currently plays a leading role in improving aviation safety in the air ambulance industry. The Federal Aviation Administration has on several occasions adopted industry-wide safety protocols first pioneered by PHI years earlier. For example, PHI developed and introduced the Enhanced Operational Control Matrix, which the FAA later adopted as a best practice. PHI was the first company to receive the prestigious Vision Zero Aviation Safety Award, and is the only company to win the award twice; it was the first company of its size to equip all of its aircraft with night vision goggles; it increased Inadvertent Instrument Meteorological Conditions (IIMC) training through Line Oriented Flight Training (LOFT); it has installed new emergency locator

⁵ Air ambulance personnel are skilled staff. Clinicians require state licenses to practice, and many possess advanced licenses (e.g., pediatric, trauma, neonatal). They are also required to take more than 120 hours of onboarding training for advanced clinical practice once hired. Similarly, pilots must be certified to fly the particular aircraft types in PHI's fleet, and they undergo similar onboarding training of more than 120 hours when hired by PHI. All positions require stringent annual recurrent training to maintain certifications.

transmitters with upgraded military frequency on all of its aircraft; and it has adopted a "Fourth to Go — One to Say No"⁶ protocol to engage each professional to ensure safety standards on every flight.

33. PHI's exemplary safety record is the result of its significant capital investment. For example, PHI invested more than \$4.8 million to install two-axis autopilot systems⁷ in its aircrafts.

C. PHI's Business Depends Critically Upon Receiving Payments from Commercial Insurers

34. Most air ambulance services are provided by independent companies like PHI. These companies typically provide just the one service: transport. These companies cannot operate that service at below cost if they are to remain in business.

35. PHI's business depends upon receiving payments from non-government, commercial health plans and health insurers that cover PHI's emergency patients.

36. PHI annually reviews and, if appropriate, re-sets its standard rates for its emergency services.⁸ PHI charges its standard rates to all emergency patients; however, as described below, the amount PHI ultimately collects may depend on several factors, including whether PHI is an innetwork provider.

37. An "in-network" provider has a contract with the health plan or insurer to provide services for set rates of payment. Such contracts bar the provider from seeking any additional payment from the insured patient other than the amount of "cost-sharing" (including any copay or

⁶ This procedure allows any of three flight personnel or the aircraft mechanic to prevent a flight due to safety concerns.

⁷ Two-axis autopilot controls an aircraft along both its pitch and roll axes.

⁸ There are four rates used by PHI and other air ambulance companies: (1) a "base fee" for launching a fixed-wing aircraft (this is a set dollar amount that does not vary based on the length of the flight); (2) a "mileage fee" for fixed-wing aircraft transport (a set dollar amount per mile, which is multiplied by the number of miles that the patient is transported); (3) a "base fee" for launching a helicopter; and (4) a "mileage fee" for helicopter transport.

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deductible) that the patient is required to pay under the terms of the patient's own health plan or insurance policy.

38. An "out-of-network" provider has no such pre-service contract in place with the health plan or insurer.

39. PHI has tried for years to negotiate in-network contracts—also known as participating provider agreements—with all of the nation's large insurers. Those efforts have mostly failed. Most insurers have refused to agree to acceptable rates for PHI's services, even though many of these same insurers have typically agreed to pay acceptable rates on a case-specific basis, *after* PHI has transported one of their insureds.

40. One reason why insurers often refuse to agree to in-network contracts, providing reasonable compensation to independent air ambulance providers like PHI, is that insurers lack power to steer patients toward particular air ambulance providers in exchange for discounted rates, like they can for scheduled medical services. Nor are most emergency patients able to select and preplan which air ambulance transport they will use. Instead, air ambulance services are typically dispatched by persons other than the patient—such as doctors, first responders, and emergency dispatchers. As a result, a primary incentive for in-network contracting—the ability to negotiate volume discounts based on an insurer's power to steer a significant volume of patients to a preferred provider—is absent from the air ambulance market.

41. Another reason why insurers often refuse to agree to in-network agreements with independent air ambulance providers, like PHI, is that insurers demand that independent air ambulance providers accept in-network rates similar to the rates agreed to by hospitals and hospital groups. These larger entities can—and frequently do—offer their air ambulance services *below the cost of providing those services* and make up the loss through provision of additional services once

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the patient arrives at the hospital. The additional treatment generates revenue more than sufficient to make up for the loss on the transport. Further, in hospital provider agreements, air ambulance transport rates are typically just one line item in a much larger agreement, are not heavily negotiated, and represent only a small volume of services provided by these entities (and a small percentage of anticipated revenues).

42. On information and belief, some larger entities (such as hospital groups) include low rates for air ambulance services in their omnibus in-network agreements, even though these entities *do not even operate air ambulances*. These rates are therefore entirely fictional. They are agreed to by a provider that has neither the intent nor the ability to provide that service.

D. PHI Negotiates Individual, Case-Specific Contracts With Insurers For Whom PHI Is an "Out-of-Network" Provider

43. Whenever PHI transports an emergency patient for whom PHI is an "out-ofnetwork" provider, PHI promptly bills the plan or insurer. That bill demands payment at PHI's standard rates.

44. On most occasions, PHI then negotiates with the insurer to reach an agreement over the amount that the plan or insurer will actually pay.

45. These negotiations often result in case-specific contracts between PHI and the plan or insurer: PHI agrees to accept some amount (typically, a discount off PHI's billed standard charges) and the plan or insurer agrees to pay that amount. The case-specific contract will also specify the amount of the patient contribution (*i.e.*, copay, coinsurance and deductible) that PHI is allowed to collect. Thus, many of the after-the-fact negotiations between PHI and the plan or insurer result in a written contract that sets the agreed-upon rate that PHI is to be paid. However, despite the fact that these "single-case agreements" are the best evidence of arms-length bargaining between insurers and providers, the Departments' prohibited consideration of the rates negotiated in "single-case agreements" by IDR entities determining reasonable reimbursement for out-ofnetwork services.

II. Before the No Surprises Act, PHI's Negotiations With "Out-of-Network" Insurers Depended on PHI's State-Law Rights to Reasonable Compensation

46. Until the No Surprises Act, PHI had the right to seek reasonable compensation from the patient directly. Even though PHI rarely invoked this right, PHI's power to do so was a powerful source of leverage in its negotiations with insurers.

47. A medical provider's right to reasonable compensation, from the recipient of emergency medical services, has been recognized for centuries by the common law of all States. *See, e.g.*, Restatement (Third) of Restitution and Unjust Enrichment § 20 (2011) ("The claim for emergency medical services rendered in the absence of contract is one of restitution's paradigms."). Although some states had abolished this right for other medical providers by enacting statutes that forbid "balance billing" of the patient, those state laws are preempted with respect to air ambulance providers by the Airline Deregulation Act (ADA).⁹

48. The *amount* of compensation has long been recognized as the reasonable "market value" of the services provided. Restatement (Third) of Restitution § 50(2)(b); *see also, e.g., ConFold Pac., Inc. v. Polaris Indus., Inc.*, 433 F.3d 952, 958 (7th Cir. 2006) (Posner, J.) ("market value"); *Cotnam v. Wisdom*, 104 S.W. 164, 166 (Ark. 1907) (a provider rendering emergency medical services, "who brings to such a service due skill and care, earns the reasonable and customary price therefor" (quoting *Ladd v. Witte*, 92 N.W. 365, 367 (Wis. 1902)).

⁹ E.g., Guardian Flight LLC v. Godfread, 991 F.3d 916, 920-21 (8th Cir. 2021); Bailey v. Rocky Mountain Holdings, LLC, 889 F.3d 1259, 1272 (8th Cir. 2018) (holding restrictions on balance billing by air ambulances were preempted by the ADA and recognizing that "Florida law gives such providers a legal entitlement to a reasonable fee"); Ferrell v. Air EVAC EMS, Inc., 900 F.3d 602, 609 (8th Cir. 2018) (an air ambulance provider "can assert" a claim for restitution against the patient "to recover for the services it provided," and the court will "necessarily look to governing principles of state law" to resolve the claim).

49. The No Surprises Act, unlike the ADA, does preempt PHI's right to bring an action for compensation against the patient, for any amount in excess of the patient's "cost sharing" or co-pay amount. 42 U.S.C. § 300gg-135 (air ambulance provider "shall not bill, and shall not hold liable, such participant, beneficiary, or enrollee for a payment amount for such service furnished by such provider that is more than the cost-sharing amount for such service").

50. In addition to seeking reasonable compensation *from the patient*, PHI also had the ability, in some circumstances, to obtain reasonable compensation *from the patient's insurer*, based on state-law causes of action such as quantum meruit, unjust enrichment, specific state statutes,¹⁰ and implied-in-fact contract.¹¹ These state-law causes of action, against the insurer, were not preempted by the ADA. *See Ferrell*, 900 F.3d at 609.¹²

51. The No Surprises Act, unlike the ADA, does preempt—as a practical matter— PHI's state-law causes of action against out-of-network insurers. The Act does this by granting the insurer the right to invoke the new Independent Dispute Resolution ("IDR") Process.

¹⁰ E.g., Bell v. Blue Cross of Calif., 131 Cal. App. 4th 211, 221 (2005) (emergency room physician brought statutory and quantum meruit claim, under California law, against insurer); *Merkle v. Health Options, Inc.*, 940 So. 2d 1190, 1199 (Fla. Dist. Ct. App. 2006) (emergency medical provider brought "unjust enrichment/quantum meruit" claim under Florida law against insurers); *MHA, LLC v. Amerigroup Corp.*, 539 F. Supp. 3d 349, 361 (D.N.J. 2021) (hospital brought unjust enrichment and quantum meruit claims against insurer under New Jersey Law); *see also Midwest Special Surgery, P.C. v. Anthem Ins. Companies*, No. 4:09CV646 TIA, 2010 WL 716105, at *5 (E.D. Mo. Feb. 24, 2010) (medical practice brought unjust enrichment and quantum meruit claims against insurer under Special Surgery Missouri law).

¹¹ See, e.g., Wagner v. Summit Air Ambulance, LLC, No. CV-17-57-BU-BMM, 2018 WL 1902842, at *2 (D. Mont. Apr. 20, 2018) (air ambulance provider stated claim for breach of implied-in-fact contract, under Montana law); *Med. Mut. of Ohio, v. Air Evac EMS, Inc.*, 341 F. Supp. 3d 771, 782 (N.D. Ohio 2018) (same result under Ohio law).

¹² See also Wagner, 2018 WL 1902842 (implied-in-fact contract claim not preempted by ADA); *Med. Mut. of Ohio*, 341 F. Supp. 3d at 782 (same).

III. EMpact Provides Emergency Medical Treatment Without Regard to Patients' Ability to Pay

52. EMpact and its physicians are required by federal and state law, by the ethical principles of the medical profession, and by EMpact's contracts with hospitals, to provide evaluation and, where appropriate, emergency medical services, to all patients in those hospitals' emergency rooms—regardless of the patient's health plan or health insurance coverage, and regardless of the patient's ability to pay.

53. EMpact is an out-of-network provider for many health benefit plans and health insurers.

54. Prior to the enactment of the No Surprises Act, EMpact had rights and a cause of action, under Kentucky's state law, to recover from its patients the reasonable value of EMpact's emergency medical services, under the doctrine of *quantum meruit. See generally Hughes & Coleman, PLLC v. Chambers*, 526 S.W.3d 70, 74 (Ky. 2017) (doctrine "entitl[es] a person who has rendered services to recover payment for the reasonable value of those services. Its focus, then, is on the value of the benefit conferred to the other person").

55. Like PHI, EMpact preferred not to put the patient "in the middle" of EMpact's disputes with the health plan or insurer regarding the dollar amount that EMpact was owed for its out-of-network services to patients. However, EMpact's state-law right to seek reasonable compensation from the patient, in an action for *quantum meruit*, was an important foundation for EMpact's negotiations with commercial health plans and insurers.

IV. The IDR Process, Created by the No Surprises Act, Was Intended to Be a Meaningful Substitute for Providers' Pre-Existing State-Law Rights to Reasonable Compensation

56. The No Surprises Act was enacted on December 27, 2020, as part of the Consolidated Appropriations Act, 2021. Pub. L. 116-260, 134 Stat. 1182, div. BB, tit. I (2020). Its

relevant requirements went into effect on January 1, 2022. For convenience and simplicity, this Complaint cites the No Surprises Act as codified in the PHS Act, which appears at 42 U.S.C. §§ 300gg-111 *et seq*.¹³ The provisions of the Act at issue here are: 42 U.S.C. § 300gg-111, which governs IDRs for emergency medical services other than air ambulances; 42 U.S.C. § 300gg-112, which governs IDRs for air ambulances; and 42 U.S.C. §§ 300gg-131 and -135, which forbid providers from billing the patient in excess of the patient's "cost sharing" amount.

57. The No Surprises Act substitutes, in place of providers' state-law causes of action described above, a new form of adjudication: the IDR Process. The name of the law itself—"No Surprises"—is a reference to the elimination of providers' cause of action against the patients. The name "Independent Dispute Resolution" indicates that Congress intended to provide a method by which providers could obtain reasonable compensation from health plans and insurers directly.

58. The No Surprises Act permits providers and insurers to engage in an IDR Process similar to "binding final offer arbitration," also referred to as "baseball-style" arbitration. Each party—the provider and the insurer—submits an "offer" of the payment amount. The IDR entity then picks one of the two offers.

59. The Act provides that the IDR entity's determination is "binding upon the parties involved," absent fraud or misrepresentation, and "shall not be subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of Title 9 [i.e., the Federal Arbitration Act]." 42 U.S.C. § 300gg-111(c)(5)(E); *see id.* § 300gg-112(b)(5)(E).

¹³ The NSA made parallel amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. These other provisions, enacted into ERISA and the IRC, are the same in all material respects as the codification in the PHS Act, which is cited in this Complaint.

60. In determining which offer to select, the No Surprises Act requires that the IDR entity "shall . . . tak[e] into account" a list of "considerations" specified in the statute. 42 U.S.C. § 300gg-111(c)(5)(C)(ii); *id.* § 300gg-112(b)(5)(A). There are some differences between the "considerations" listed for air ambulance IDRs and for all other IDRs. The statutory "considerations" are:

"Considerations in determination" for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5).	"Considerations in determination" for <i>air</i> <i>ambulance</i> IDRs. 42 U.S.C. § 300gg- 112(b)(5)(C).
"[T]he qualifying payment amounts [QPAs] for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region as such qualified IDR item or service."	Substantially the same.
"Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years."	Substantially the same.
Any information the IDR entity requests from the parties.	Same.
Any additional information submitted by a party relating to an offer.	Same.
"The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual."	Substantially the same.
"The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service"	"The training, experience, and quality of the medical personnel that furnished such services." "The quality and outcomes measurements of the provider that furnished such services."
"The market share held by the nonparticipating provider or facility or that of the plan or issuer	The "[a]mbulance vehicle type, including the clinical capability level of such vehicle."

"Considerations in determination" for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5).	"Considerations in determination" for <i>air</i> <i>ambulance</i> IDRs. 42 U.S.C. § 300gg- 112(b)(5)(C).
in the geographic region in which the item or service was provided."	
"The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service."	-1 - 1 1 1

61. The "qualifying payment amount" (QPA) is the median of the rates that the specific plan or insurer agreed to pay for similar items or services, in 2019,¹⁴ in the geographic area in which the items or services at issue in the IDR were provided. 42 U.S.C. § 300gg-111(a)(3); 42 U.S.C. § 300gg-112(b)(5)(C)(i)(I). The statutory definition of the QPA is the same for air ambulance IDRs and all other IDRs. *Id.* The statutory language requiring the IDR to "consider" the QPA is the same for air ambulance IDRs and all other IDRs and all other IDRs and all other IDRs. 42 U.S.C. § 300gg-112(b)(5)(C)(i); *id.* § 300gg-112(b)(5)(C)(i).

V. The Departments' Implementing Regulations Were Issued Without Public Notice or an Opportunity to Comment

62. Congress instructed the Departments to issue implementing regulations providing further guidance on two discrete areas of the No Surprises Act:

a. By July 1, 2021, the Departments were instructed to "establish through rulemaking" the "methodology" for "determin[ing]" the QPA; the "information" that the health plan or insurer must "share with the ... provider" regarding the QPA; and the "geographic region" whose rates should be considered when calculating the QPA. 42 U.S.C. § 300gg-111(a)(2)(B).

¹⁴ If the insurer did not have sufficient agreements, in 2019, to calculate a median rate (i.e., the insurer had fewer than three such rates) then the insurer is permitted to instead consult a public "database." 42 U.S.C. § 300gg-111(a)(3)(E)(iii)(I). If that insurer had three or more rates in 2020, then the insurer will be permitted, in 2023, to use the median of those rates it paid in 2020. *See id.* (a)(3)(E)(v)(II).

b. By December 27, 2021 (i.e., within one year of enactment), the Departments were to "establish by regulation one ... IDR process under which" the IDR entity "determines . . . in accordance with the succeeding provisions of this subsection, the amount of payment" owed to the provider. 42 U.S.C. § 300gg-112(b)(2)(A).

63. On July 13, 2021, the Departments published an Interim Final Rule ("IFR") entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021) ("IFR Part I"). IFR Part I includes rules for determining the QPA, among other matters. IFR Part I took effect on September 13, 2021, and is applicable to plan and policy years beginning on or after January 1, 2022. 86 Fed. Reg. at 36,872.

64. On October 7, 2021, the Departments published a second Interim Final Rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) ("IFR Part II"). IFR Part II contains rules for conducting the IDR Process. IFR Part II took effect immediately—i.e., on October 7, 2021—and is, in general, applicable to plan, policy, or contract years beginning January 1, 2022.

65. On information and belief, the voluminous, detailed regulations contained in IFR Part I and IFR Part II were developed and issued through a coordinated inter-agency process driven to conclusion by the Executive Office of the President.

66. IFR Part I and IFR Part II represent the end of the Departments' collective decisionmaking process.

67. Although the Departments placed language in the IFRs, indicating that they invited comments on certain aspects of the published regulations, the Departments are not under any binding legal obligation to review and consider such comments, much less to revise the rules based on any comments received.

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68. The Administrative Procedure Act (APA) required the Departments to provide public notice of the proposed regulations and an opportunity for comment, unless the Departments "for good cause" found that notice and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). The Departments would then have been required to provide a meaningful response to substantive comments received. *See, e.g., Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) ("An agency must consider and respond to significant comments received during the period for public comment.").

69. This bedrock procedural protection of the APA is designed to ensure that members of the public have notice of proposed regulations that might affect their interests and an opportunity to present their views to the agency. Public comments—and the agencies' response to them—inform and improve an agency's decision-making and promote public confidence in the administrative process.

70. The No Surprises Act does not contain any express permission for the Departments to depart from the APA's notice-and-comment requirement.

71. The Departments could have complied with the APA and provided the public with notice and an opportunity to comment on the IFRs.

72. The Departments knew the importance of receiving comments from the interested stakeholders before issuing the regulations that are challenged here. During now-HHS Secretary Xavier Becerra's confirmation hearing, he acknowledged "we have to get this arbitration [i.e., the IDR Process] right."¹⁵ During an April 2021 congressional hearing on HHS's budget request, when asked whether HHS would give stakeholders advance notice and an opportunity to comment on

¹⁵ Confirmation hearing of Xavier Becerra before the Senate Health Committee (Feb. 23, 2021), https://perma.cc/JG6U-82VT (at minute 1:41:06).

regulations implementing the No Surprises Act, Secretary Becerra testified that, "coming from a background as the [California] attorney general where it was always important to take input whenever we would do rule making or take any action, in court or otherwise, I can guarantee you at HHS, before we take an action, we'll take the comments necessary, hear from all the stakeholders to make sure what we're doing is based on the facts, the science, and the law. I can guarantee you, sir, you will find we will have gone through a robust process to get there."¹⁶

73. Contrary to Secretary Becerra's promises, the Departments did not give notice, or an opportunity for public comment, on either IFR Part I or IFR Part II.

74. As to IFR Part I—published on July 13, 2021, and concerning the QPA determination methodology—the Departments claimed that it "would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place." *IFR Part I*, 86 Fed. Reg. at 36,917. The Departments asserted that allowing for notice-and-comment "would not have provided sufficient time for the Departments to develop and publish these rules by the statutory deadline." *Id.* The Departments also asserted that complying with notice-and-comment requirements would not have provided regulated entities sufficient time to implement the requirements. *Id.* They claimed that any delay in issuing final regulations would therefore "risk subjecting the public to prohibited balance bills and excess cost sharing." *Id.* at 36,918.

75. The Departments' excuses for issuing IFR Part I without notice-and-comment do not suffice to show "good cause." The Departments could have expedited their internal processes and provided for an abbreviated notice-and-comment period.

¹⁶ Health and Human Services Department Fiscal Year 2022 Budget Request before the House Appropriations Sub-Committee (Apr. 15, 2021), https://perma.cc/N5DF-FXM3 (at minute 49:06).

76. The Departments' failure to provide notice-and-comment was even more egregious as to IFR Part II—published on October 7, 2021, and concerning the IDR Process. In IFR Part II, the Departments explicitly acknowledged that the APA required notice and comment, and conceded that the full year between the NSA's enactment on December 27, 2020, and its effective date of January 1, 2022, "may have allowed for the regulations" to comply with the notice-and-comment requirement. *Id*.

77. Nonetheless, the Departments asserted that it was "impracticable and contrary to the public interest to engage in full notice and comment rulemaking" because "this timeframe would not provide sufficient time for the regulated entities to implement the requirements" that the Departments had ordained by fiat and without public input. *Id.* at 56,044.

78. The Departments did not state, in IFR Part II, that it would have been impossible to provide notice and comment on the IFR Part II regulations during the *full year* between the enactment of the No Surprises Act (on December 27, 2020) and its effective date (January 1, 2022).

79. The Department's excuses for not allowing notice and comment on the IFR Part II regulations do not suffice to show "good cause."

80. The Departments exercised their discretion to delay many *other* implementing regulations in order to provide for notice-and-comment on those regulations. These delays, and the reasons for them, are set forth in a guidance document published on August 20, 2021: *FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49* (Aug. 20, 2021).¹⁷ The Departments concluded that regulated entities could proceed, in the absence of regulation, by using a "good faith, reasonable interpretation of the statute." *Id.* at 8 (healthcare

¹⁷ Available at https://perma.cc/B7L7-QEKM.

provider directory requirements); *id.* at 8–9 (balance billing disclosure requirements for payors); id. at 9 (continuity of care requirements).

81. The rules contained in IFR Part I and IFR Part II are codified in the Code of Federal Regulations (C.F.R.). For convenience, this Complaint refers to these rules as codified at Title 45, Subtitle A (Department of Health and Human Services), Subchapter B (Requirements Relating to Health Care Access), Part 149 (Surprise Billing and Transparency Requirements).¹⁸

82. There are four regulations challenged in this Complaint. From IFR Part II: 45 C.F.R. § 149.510 (which generally regulates how the IDR Process is conducted); 45 C.F.R. § 149.520 (which contains slight modifications to the IDR Process for air ambulance services). From IFR Part I: 45 C.F.R. § 149.140 (which governs how the QPA is determined); and 45 C.F.R. § 149.130 (which regulates the amount of "cost sharing" for which an air ambulance provider may bill the patient).

VI. The Implementing Regulations Give Presumptive Weight to the QPA, In Deviation from Congress's Clearly Expressed Intent that All Factors Be Considered

A. The QPA Presumption

83. The most egregious flaw in the Departments' rulemaking is the command that the IDR entity presume that the QPA is the correct rate. This QPA Presumption was promulgated in IFR Part II on October 7, 2021, and is codified in six provisions of the regulations, as shown in the bolded text in the chart below:

¹⁸ The Departments also codified these regulations in the C.F.R. under the titles applicable to ERISA and the Internal Revenue Service. *See* 26 C.F.R. § 54.9816-1T *et seq.*; 29 C.F.R. § 2590.716-1 *et seq.* These other codifications are the same, in all material respects, as the codifications in 45 C.F.R. Part 149, which are cited in this Complaint.

Regulatory Text (bold language contains the QPA Presumption)	Citation
"(viii) Material difference means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate."	45 C.F.R. § 149.510(a)(2)(viii)
 ii) Payment determination and notification. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must: (A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. 	45 C.F.R. § 149.510(c)(4)(ii)(A)
 (iii) Considerations in determination. In determining which offer to select, the certified IDR entity must consider: (C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate. 	45 C.F.R. § 149.510(c)(4)(iii)(C)
(iv) Examples. The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples: [four examples illustrating the QPA Presumption]."	45 C.F.R. § 149.510(c)(4)(iv)

Regulatory Text (bold language contains the QPA Presumption)	Citation
(B) If the certified IDR entity does not choose the offer closest to	45 C.F.R. §
the qualifying payment amount, the certified IDR entity's	149.510(c)(4)(vi)(B)
written decision must include an explanation of the credible	
information that the certified IDR entity determined	
demonstrated that the qualifying payment amount was	
materially different from the appropriate out-of-network rate,	
based on the considerations allowed under paragraph	
(c)(4)(iii)(B) through (D) of this section, with respect to the	
qualified IDR item or service.	
(b) Determination of out-of-network rates to be paid by	45 C.F.R. §
health plans and health insurance issuers; independent	149.520(b)(2)
dispute resolution process—	
(2) Additional information. Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.	

84. As mentioned above, the QPA is generally the *median* of the rates that the specific

insurer agreed to pay for similar items or services in 2019. See supra \P 61.

85. The Departments explained in IFR Part II that the QPA Presumption requires the IDR entity to "begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate." IFR II, 86 Fed. Reg. at 55,999. The QPA is to be the "presumptive factor." Id. at 55,996-97. The IDR entity must select the "offer" closest to the QPA unless the IDR entity "determines that *credible information* submitted by either party . . . *clearly demonstrates* that the out-of-network [OPA] is materially different from the appropriate rate." 45 C.F.R § 149.510(c)(4)(ii)(A) (emphasis added).

86. Two of the terms just italicized receive their own separate definitions in order to further hammer home that IDR entities should choose whichever offer is closest to the QPA.

a. "Credible information" is defined—for purposes of a process that lacks any discovery or evidentiary hearings—as "information that upon critical analysis is worthy of belief and is trustworthy." *Id.* (a)(v).

b. "Material difference" is defined as a "*substantial likelihood* that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information *significant* in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate." *Id.* (a)(viii) (emphasis added).

87. The "training ... of a certified IDR entity," referred to in the foregoing definition,

includes the Departments' guidance manual, Federal Independent Dispute Resolution (IDR)

Process—Guidance for Certified IDR Entities (the "IDR Guidance Manual").¹⁹

88. The December 2021 version of the IDR Guidance Manual further confirmed (with bold and underlining in the original) the Departments' desire that IDR Entities choose the offer closest to the QPA:

7.2.2 Certified IDR Entity: When and How to Apply the QPA In determining which payment offer to select, the certified IDR entity <u>must begin</u> with the presumption that the QPA is the appropriate OON rate for the qualified IDR item or service under consideration.

The certified IDR entity **must select the offer closest to the QPA**, <u>unless</u> credible information submitted by either party in relation to the offer (see Section 5.1) clearly demonstrates that the QPA is **materially different** from the appropriate OON rate for the qualified IDR item or service, based on the additional circumstances described below.

Id. at 19.

¹⁹ Available at https://perma.cc/Q7AX-BTE6.

89. When promulgating IFR Part II, the Departments gave examples of how their QPA

presumption will work in practice. 86 Fed. Reg., at 56,104. "Example 3" demonstrates how the QPA presumption effectively overrides all the other factors that Congress required the IDR entity to consider. That example reads in full:

(C) Example 3-(1) Facts. A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The plan submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(2) Conclusion. The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the plan's offer.

45 C.F.R § 149.510(c)(4)(iv)(C) (emphasis added).

90. In this example, the provider has done everything that could reasonably be expected of it in a proceeding without any discovery, without any evidentiary hearings, without any meaningful disclosure of the nature of the rates used by the insurer to determine "the QPA," and with just one written submission allowed. Based on its own records, the provider in this example has given the IDR entity "credible information" relating to many of the factors Congress listed—

the "acuity" (*i.e.*, seriousness) of the patient's medical condition, the "complexity" of the medical services, and the need for advanced "training" to provide those services. But none of this is enough to overcome the presumption. The provider is somehow supposed to "clearly demonstrate" that "the QPA"—a single number calculated by the insurer based on secret data never shared with the provider or the IDR entity—did not already account for those factors. (The Departments' failure to require additional disclosures by the plan or insurer, regarding how they calculated the QPA, is the subject of a separate challenge by Plaintiffs, described below. *Infra*, ¶¶ 108-119.)

91. How can the Departments possibly expect a provider, in this limited IDR process, to come forward with "credible information" "clearly demonstrating" that "the QPA"—a number calculated in secret, based on information known only to the insurer—has "failed to encompass" some factor? The answer, of course, is that the Departments do *not* expect the provider to do this. The Departments expect the provider to lose. That is the whole point of their arbitrary, capricious, contrary-to-statute QPA Presumption. And by dispensing with notice and comment rulemaking, the Departments avoided having to respond to comments pointing out that their approach deviates from the statute and will have adverse unintended consequences.

92. The QPA Presumption is further enforced by the Departments' requirement for a heightened explanation from the IDR entity whenever the IDR entity deviates from the QPA presumption. If the IDR entity selects the offer *closest to* the QPA, then the IDR entity is not required to explain why that offer was the appropriate out-of-network rate—or to explain why the IDR entity did not defer to other factors. *See* 45 C.F.R. § 149.510(c)(4)(vi). But if the IDR entity selects the offer that is *further from* the QPA, then the IDR entity must include, in its written decision, "an explanation of the credible information that the certified IDR entity determined

demonstrated that the [QPA] was materially different from the appropriate out-of-network rate, based on the considerations allowed [under the regulation]." *Id*.

93. The IDR entity is compensated with a flat fee of just \$200 to \$500 for each singleservice determination.²⁰ That fee does not change based on how much work the IDR entity does in the particular proceeding, or in providing the required heightened explanation.

94. By requiring a heightened explanation whenever the IDR entity deviates from the QPA presumption, the Departments have discouraged the IDR entity from selecting the "offer" farther from the QPA. This further enforces the QPA Presumption.

B. The QPA Presumption Deviates from the Statute

95. The QPA Presumption clearly deviates from the statute. The statute provides that the QPA is just one of the many varied "considerations" that the IDR entity "shall consider" when determining which offer to select. *See supra* ¶ 83 (chart listing all of the "considerations" listed in the Act). Only *one* of those considerations is the QPA. *Id*. The plain text of the statute does *not* give the QPA any greater weight than the other factors that the IDR entity "shall take into account."

96. The Departments' QPA Presumption upends the balance that Congress struck during the legislative process that produced the No Surprises Act. As the Chairman and the Ranking Member of the House Ways and Means Committee have recently explained in a letter to the Secretaries, the QPA Presumption "strays from the No Surprises Act in favor of an approach

²⁰ CMS, Technical Guidance No. 2021-01, at 4 (Sep. 30, 2021) ("For the calendar year beginning January 1, 2022, certified IDR entities must charge a fixed certified IDR entity fee for single determinations within the range of \$200-\$500, unless otherwise approved by the Departments pursuant to section IV of this guidance."), https://perma.cc/UFN5-VKBC; *see also* Ctrs. for Medicare & Medicaid Servs., *List of Certified Independent Dispute Resolution Entities* (Jan. 25, 2022), https://perma.cc/W5XS-9CQG.

that Congress did not enact in the final law," since "Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process."²¹

97. One hundred and fifty other Members of Congress have since reiterated this point. The QPA Presumption, they wrote, "do[es] not reflect the way the law was written, do[es] not reflect a policy that could have passed Congress, and do[es] not create a balanced process to settle payment disputes."²² These Members of Congress explained that the QPA Presumption is "contrary to the statute" and could "narrow provider networks and jeopardize access to patient care" and "exacerbate existing health disparities and patient access issues in rural and urban underserved communities." *Id*.

98. The Departments lacked any statutory authority to impose the QPA Presumption. Congress instructed the Departments to "establish by regulation one independent dispute resolution process under which . . . a certified IDR entity . . . determines . . . *in accordance with the succeeding provisions of this subsection* . . . the amount of payment." *Id*. (b)(2)(A) (emphasis added). Those "succeeding provisions of this subsection" included the other *eight* considerations that the Congress required that the IDR entity "shall take into account." Congress did *not* authorize the Departments to instruct the IDR entities to give presumptive weight to the QPA.

99. In their rulemaking, the Departments did not identify any gap or ambiguity in the No Surprises Act's description of how an IDR entity should select an appropriate out-of-network rate.

²¹ Letter from Chairman (Committee on Ways and Means) R. Neal & Ranking Member K. Brady to Secretary X. Becerra et al. (Oct. 4, 2021), https://perma.cc/GE9Q-4CK2 (emphasis omitted).

²² Letter from Congressman T. Suozzi et al. to Secretary X. Becerra et al. (Nov. 5, 2021), https://perma.cc/A2FU-QHGE.

100. Instead, the Departments claimed that the QPA Presumption is, in their opinion, the "best interpretation" of the Act. *IFR Part II*, 86 Fed. Reg. at 55,996. The Departments pointed to a number of non-existent canons of construction and arbitrary justifications to support that opinion: i) the QPA is listed first, in the list of factors that Congress directed the IDR entity to consider; ii) the other eight factors "are described in a separate paragraph" and are subject to "a prohibition on considering certain factors"; iii) the statute "sets out detailed rules for calculating the QPA" but "relatively limited guidance on how to consider or define" other factors; and cost-sharing amounts are based on the in-network rate, "which will generally be the QPA" (in light of the definitions in IFR Part I). *IFR Part II*, 86 Fed. Reg. at 55,996. These novel legal theories, of how a statute should be interpreted, are not grounded in any specialized agency expertise.

101. The Departments also cited various "policy considerations," such as "increas[ing] the predictability of IDR outcomes," encouraging parties to reach a consensual agreement "to avoid the administrative costs," and "reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act." *IFR Part II*, 86 Fed. Reg. at 56,061. But the Departments' policy preferences cannot trump the plain text of the No Surprises Act.

C. Plaintiffs' Challenge to the QPA Presumption Is Not Moot

102. On February 23, 2022, the U.S. District Court for the Eastern District of Texas issued an Order vacating five of the six regulatory provisions that implement the QPA Presumption. *Texas Medical Association, et al. v. U.S. Dep't Health & Hum. Serv'cs, et al.*, 21-cv-00425, Dkt. 113, 2022 WL 542879 (Feb. 23, 2022) (the "*TMA* Decision"). The *TMA* Decision gave two independent reasons: first, the QPA Presumption "rewrites clear statutory terms" of the No Surprises Act, *id.*, and second, the QPA Presumption was promulgated without the notice-and-comment procedure that the APA requires, id. at *14.

103. The *TMA* Decision does not moot Plaintiffs' claims. Although the *TMA* Decision struck down the five provisions contained in Section 149.510 that implement the QPA Presumption, the *TMA* Decision did *not* expressly vacate the sixth provision, found in Section 149.520: "This [additional] information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate." 45 C.F.R. § 149.520(b)(2).

104. On April 12, 2022—more than a month *after* the *TMA* Decision—Defendants updated the IDR Guidance Manual.²³ The updated manual continues to instruct IDR entities to apply the QPA Presumption to air ambulance IDRs:

6.4.1. When and How to Apply the QPA for Disputes Involving Air Ambulance Qualified IDR Services

For **air ambulance qualified IDR services**, in determining which payment offer to select, the certified IDR entity should consider **credible information** submitted by either party in relation to the offer to the extent that the information **clearly demonstrates** that the QPA is **materially different** from the appropriate OON rate for the qualified air ambulance service, based on the additional circumstances described in Section 6.4.2.

In cases where credible information clearly demonstrates that the QPA is materially different from the appropriate OON rate, or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the air ambulance qualified IDR items or services, which could be either offer submitted.

105. Moreover, on April 22, 2022, the Departments noticed an appeal of the TMA

Decision to the Fifth Circuit Court of Appeals.

- 106. The Departments have not formally agreed to or acquiesced in the TMA Decision.
- 107. The Departments have not formally stated that they will amend the challenged

regulations to conform with the TMA Decision.

²³ Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities, at 22 (Apr. 12, 2022), *available at* https://perma.cc/H87C-VJMJ.

VII. The Implementing Regulations Fail to Require the Payor to Make Necessary Disclosures Regarding How It Determined the QPA

108. The implementing regulations provide that the QPA is to be determined solely by the plan or insurer based on its own secret data. The plan or insurer discloses to the provider and the IDR entity only a final dollar amount, which the insurer represents to be the "median" of its own "contracted rates" in 2019. IFR Part II states: "[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly.... Rather, the certified IDR entity is responsible for considering only the information presented by the parties." 86 Fed. Reg., at 55,996.

109. Determining the QPA is not a ministerial task that can be performed without the exercise of independent judgment to resolve questions on which reasonable people might disagree.

110. In order to determine the QPA in any given dispute, the insurer must answer (at least) the following questions for each contracted rate that insured includes (or excludes) from the

QPA:

- (1) What *was* the contracted "rate"? Many insurers' contracts with in-network providers do not contain a simple menu of services, each with a set fee. Some contracts set a rate for a "bundle" of related services, without breaking out each one. Other contracts calculate payments on a "capitation," *i.e.*, a flat payment for all services the patient requires, typically paid over a fixed period of time.²⁴
- (2) Does the contract that sets this rate also provide for incentive payments (*e.g.*, increased or later payments based on total patient cost, patient outcome, or other variables)? If so, should those incentive payments be included or excluded in the "rate"? What was the dollar amount of the excluded payments? Which payments were included? If the provider performed multiple services, then what

²⁴ In IFR Part I, the Departments instructed the insurers to use a "derived amount" for the rates of services in such cases, *i.e.*, when the contract does not specify the rate for a given service. Calculating the "derived amount" is not straightforward, and the actual amount calculated may vary based on the *purpose* for which the insurer is performing the calculation. *See IFR Part I*, 86 Fed. Reg. at 36,893 (the "derived amount" is "the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c)").

portion of the incentive payments should be allocated to the air ambulance rate specifically?

(3) What is the "geographic area" in which this rate was applied in 2019?

(4) What is the "insurance market" for this rate?

(5) What is the "provider specialty" of the provider that agreed to this rate?

Each of the foregoing questions is likely to require the application of independent judgment by the insurer in order to determine what the rate actually is, and whether or not it should be included in the QPA determination.

111. The IDR Process does not provide for any discovery. There is no mechanism by which the IDR entity can learn whether the insurer even asked itself these questions when determining the QPA, let alone learn what the answers were and how the insurer arrived at them.

112. Even if the insurer determines the QPA correctly, more information would still be needed in order to assess whether the QPA in any particular case "reflects market rates under typical contract negotiations," which is the Departments' stated purpose of the QPA. *IFR Part I*, 86 Fed. Reg. at 36,889.

113. In order to find that the QPA "reflects market rates under typical contract negotiations," *IFR Part I*, 86 Fed. Reg. at 36,889, the IDR entity would need to know the answers to at least the following questions: (1) For each of the rates used in determining the QPA, how often was each rate *actually paid*? Were any of the rates, used in determining the QPA, never paid *at all*? (2) For each of the rates used in calculating the QPA, was the provider that accepted those rates an *independent* provider of air ambulance services, or was the provider instead a hospital that was offering below-cost air ambulance rates in a "loss leader" strategy? (3) For each rate included in the QPA, what was the specific geographic region in which that rate applied? (4) For each rate included in the QPA, was it a stand-alone rate, or was it instead a "derived amount" assigned by

the insurer for internal accounting or other purposes? If so, how was the "derived amount" calculated? (5) How many rates were used in calculating the QPA? (6) What was the *average* of the rates used in calculating the QPA? What was the *weighted average* of the rates used in calculating the QPA (taking into account how often each rate was actually paid)?

114. Congress knew that more information, about how the QPA was determined, would be necessary in order for the QPA to serve its purpose. Therefore, Congress instructed the Departments to "establish through rulemaking . . . the information" that the insurer "shall share with the nonparticipating provider . . . when making [a QPA] determination." 42 U.S.C. § 300gg-111(a)(2)(B)(ii).

115. The Departments also knew that additional information, about the QPA determination, would be necessary in order for the QPA to serve its intended purpose. The Departments stated, in IFR Part I, that "[t]he Departments recognize" that providers "need transparency regarding how the QPA was determined." *IFR Part I*, 86 Fed. Reg. at 36,898. In order to "decide whether to initiate the IDR process and what offer to submit," the provider "must know not only the value of the QPA, but also certain information on how it was calculated. The Departments seek to ensure transparent and meaningful disclosure about the calculation of the QPA...." *Id.*

116. Meaningful disclosures of this information, by the plan or insurer, are especially important because there is no other outside "check" on the accuracy or reliability of the QPA. HHS "expects to conduct no more than 9 audits annually" of QPAs. *IFR Part I*, 86 Fed. Reg., at 36,935. That is a very small percentage—significantly less than 1%—of the many thousands of health plans and insurers over whom HHS has supervisory authority, each of whom is likely to be calculating hundreds if not thousands of QPAs each year.

117. The Departments' regulation providing for disclosure of information relating to QPAs—45 C.F.R. § 149.140(d)(2)—is arbitrary and capricious, and an abuse of discretion, because it fails to provide a meaningful disclosure of the required information. The *only* information that the regulation requires the insurer to disclose, regarding its secret QPA determinations, is the following:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database . . . to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code . . . information to identify the related service code; and

(iv) If applicable, 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 (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

45 C.F.R. § 149.140(d)(2).

118. These "disclosures" are likely to be terse and uninformative. Consider, for example, an insurer whose QPA is based on three contracts with three hospital groups scattered across a Census division. Each hospital group has agreed to provide air ambulance services at variable rates that start below cost. All three contracts also provide for significant "incentive" payments if the patient is discharged within a set time period (which varies, based on diagnosis) and is not later readmitted for follow-on treatment. Such an insurer could satisfy the foregoing "disclosure" regulation by stating the following:

(i) The QPA includes at least one rate that was not on a fee-for-service basis and was determined using underlying fee schedule rates adjusted for total revenue paid.

- (ii) Not applicable.
- (iii) Not applicable.

(iv) The QPA includes at least one rate from a contract that provided for an incentive-based payment, which was excluded for purposes of the QPA calculation.

These disclosures would tell the provider, and the IDR entity, almost nothing of real importance regarding how the QPA was determined. They are insufficient to enable the provider or the IDR entity to even check whether the QPA was correctly determined in accordance with the statute and regulations, *see infra* ¶ 109, let alone to assess whether the QPA "reflects market rates under typical contract negotiations" with an independent air ambulance provider, *see infra* ¶ 113.

119. The Departments' regulation—45 C.F.R. § 149.140(d)(2)—also deviates from the text of the No Surprises Act. The No Surprises Act provides that the IDR entity "shall" consider "the qualifying payment amounts (as defined in subsection (a)(3)(E))." 42 U.S.C. § 300gg-112(c)(5)(C). That is a statutory command requiring the IDR entity to actually verify that the dollar amount submitted by the insurer, as "the QPA," was calculated correctly in accordance with the statutory directives. The statute does *not* permit the IDR entity to simply take the insurer's word for it that the insurer has done all these calculations correctly. Yet that is exactly what the Department's regulation contemplates, as the Departments made clear in IFR Part II: "[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly...." 86 Fed. Reg., at 55,996.

VIII. The Implementing Regulations Deviate From the Statute By Allowing the Group Health Plan to Elect to Use Its Administrator's Rates In Calculating the QPA

120. The No Surprises Act states the following regarding the method of calculating the QPA (with relevant language italicized):

(i) In general

The term "qualifying payment amount" means, subject to clauses (ii) and (iii), *with respect to a sponsor of a group health plan* and health insurance issuer offering group or individual health insurance coverage—

(I) for an item or service furnished during 2022, 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 (specified in subclause (I), (II), (III), or (IV) of clause (iv)) as the plan or coverage) as the total maximum payment (including the cost-sharing amount imposed for such item or service and the amount to be paid by the plan or issuer, respectively) under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary under paragraph (2)(B), increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over 2019, such percentage increase over 2020, and such percentage increase over 2021.

42 U.S.C. § 300gg-111(a)(3)(E)(i) (non-air ambulance IDRs); *see* 42 U.S.C. § 300gg-112(c)(2) (for air ambulances, "[t]he term 'qualifying payment amount' has the meaning given such term in section 300gg-111(a)(3) of this title").

121. The foregoing statutory language provides that the QPA is to be determined "with respect to all such plans of such sponsor." *Id.*

122. The "sponsor" of a group health plan is a defined term in the ERISA statute; in many cases, the sponsor is the employer of the plan beneficiaries.²⁵

²⁵ "The term "plan sponsor" means (i) the employer in the case of an employee benefit plan established or maintained by a single employer, (ii) the employee organization in the case of a plan established or maintained by an employee organization, (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or (iv) in the case of a pooled employer plan, the pooled plan provider." 29 U.S.C. § 1002(16)(B).

123. The "administrator" of a group health plan is, in many cases, a *different* entity from the plan's "sponsor." Many employers will, for example, contract with a third party administrator to administer the group health plans that they sponsor.²⁶

124. The statutory language, quoted above, does not call for the QPA to be determined based on the plans administered by the plan *administrator*. On the contrary, the statute refers to the plan *sponsor*. 42 U.S.C. 300gg-111(a)(3)(E)(i).

125. The regulation that governs the QPA calculation impermissibly deviates from the statute by permitting a plan sponsor to use, in the QPA calculation, all of the contracted rates of its *plan administrator*:

(b) Methodology for calculation of median contracted rate—

(1) In general. The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable)....

45 C.F.R. § 149.140(b)(1) (emphasis added). The referenced paragraph (a)(8)(iv) includes "a third-party administrator contracted by the plan."

126. To illustrate this deviation from the statute: Suppose that the patient's health coverage is provided by a self-insured health plan of the patient's employer, which plan is then administered by a Blue Cross Blue Shield entity. The *statute* requires the QPA to be calculated based on the median of the rates agreed to by that *sponsor's* plans, i.e., by the plans offered by that employer. 42 U.S.C. § 300gg-111(a)(3)(E)(i). The regulation, by contrast, allows the QPA to be calculated based on all of the rates agreed to by the plan's *administrator*. Moreover, there is no disclosure—to the provider or to the IDR entity—of whose rates were used in any QPA calculation.

²⁶ See 29 CFR § 2510.3-16.

IX. The Implementing Regulations Use An Arbitrary and Irrationally Broad Definition of the Relevant "Geographic Region" For Calculating QPAs

127. The No Surprises Act provides that the QPA, in any given dispute, should include only those "contracted rates" that are "provided in the geographic region" in which the disputed services were provided. 42 U.S.C. § 300gg-111(a)(3)(E)(i). The scope of the "geographic region" is therefore very important because it will affect which "rates" are included in the QPA determination, and which rates are excluded. If the QPA Presumption were upheld, then this issue—which "contracted rates" are in, and which are out—would be *the dispositive issue* in many cases.

128. The Secretary was directed to "establish through rulemaking" the "geographic regions applied for purposes" of this calculation. *Id.* § 300gg-111(a)(2)(B). In that rulemaking, the Secretary was directed to "tak[e] into account access to items and services in rural and underserved areas." *Id.*

129. IFR Part I arbitrarily ignores Congress's directive to consider service providers by "geographic region." Whenever the plan or insurer has an insufficient number of "contracted rates" within the state-based region in which the services were provided,²⁷ the regulations require the plan or insurer to greatly broaden the scope by including, in the QPA, all of its contracted rates in

²⁷ Air ambulance QPAs are calculated by dividing each state into two "geographic regions": "one region consisting of all metropolitan statistical areas . . . in the State," i.e., all urban and suburban areas, and "one region consisting of all other portions of the State," i.e., all rural areas. 45 C.F.R. § 149.140(a)(7)(ii)(A). But if the insurer has fewer than three contracted rates in this geographic region, then the insurer is directed to broaden the "geographic region" in the manner described above in the text. *Id.* (ii)(B). For all other items and services besides air ambulances, then the first region is either (a) the specific MSA in which the items or services were provided or (b) all other areas of the State, outside the MSAs. *Id.* (i)(A). If the insurer has fewer than three contracted rates in this geographic region" to be either (a) all MSAs in the State; or (b) all other areas of the State, outside the MSAs. *Id.* (i)(B). If the insurer still has fewer than three contracted rates in these broader regions, then the insurer is directed rates in these broader regions, then the insurer is directed rates in these broader region. (i)(B). If the insurer still has fewer than three contracted rates in these broader regions, then the insurer is directed to broaden the "geographic region" to be either (a) all MSAs in the State; or (b) all other areas of the State, outside the MSAs. *Id.* (i)(C).

(1) all metropolitan statistical areas (MSAs, *i.e.*, the urban and suburban areas) *in a Census division* or (2) all other areas (*i.e.*, the rural areas) in that Census division. 45 C.F.R. § 149.140(a)(7)(ii)(B) (air ambulance services); *id.* (7)(i)(C) (all other items and services).

130. A "Census division," of which there are only nine nationwide, is an enormous area.²⁸ For example, the "South Atlantic" Census Division stretches from Delaware down to the Florida Keys.²⁹ The "Mountain" Census Division extends from Arizona up to Montana.³⁰ This regulation thus means that a contracted rate from California could dictate the QPA for a medical air transport in Alaska or Hawaii; and that a contracted rate in the Florida Keys could dictate the QPA in Virginia's Shenandoah Valley.

131. By requiring a calculation tailored to a "geographic region," Congress cannot have meant to dictate payments in one market based on payments agreed to in geographically and economically unique markets that are thousands of miles, and even oceans, apart. The Departments' over-broadening of the term "geographic region" cannot be justified by concern about not having a sufficient number of "contracted rates." Instead, that is a problem of the Departments' own making by purposefully excluding substantial volumes of case-specific agreements from the QPA calculation. *See infra* ¶ 133.

132. This expansive definition of "geographic region" also violates the statutory directive that Departments account for "access to items and services in rural and underserved areas, including health professional shortage areas" when establishing the "geographic regions." 42 U.S.C. § 300gg-111(a)(2)(B).

²⁸ See Census Regions and Divisions of the United States, Census.gov (last visited Oct. 29, 2021), perma.cc/4QWX-7738.

 $^{^{29}}$ *Id*.

³⁰ *Id*.

X. The Implementing Regulations Arbitrarily Exclude Case-Specific Contracted Rates from the QPA Calculation

133. The Departments' regulation deviates from the statute by *excluding* the many thousands of case-specific contracted rates that out-of-network providers have negotiated with health plans and insurers—even though those rates *are* indicative of a "typical contract negotiation."

134. Case-specific agreements are extremely common in the air ambulance industry. The Departments acknowledged in IFR Part I that "in 2012, 75 percent of [air ambulance] transports were out-of-network and in 2017, 69 percent were out-of-network." 86 Fed. Reg. at 36,923. The vast majority of these transports resulted in a case-specific agreement between the provider and the insurer.

135. Case-specific agreements are also common in EMpact's experience in resolving billing disputes with plans and insurers relating to EMpact's out-of-network services.

136. Many of these case-specific agreements are memorialized in formal, written contracts between the provider and the insurer.

137. Including these case-specific agreements in the calculation of the QPA would help to achieve the QPA's supposed purpose, which according to the Departments is to "reflect[] market rates under typical contract negotiations." *IFR Part I*, 86 Fed. Reg. at 36,889.

138. The No Surprises Act defines the QPA as the "median of the contracted rates recognized by" the insurer. 42 U.S.C. § 300gg-111(a)(3)(E). Under the plain meaning of "contracted rate," a provider's *case-specific* contract with a plan or insurer, negotiated after providing its services to the patient, should be included.

139. The promulgated regulations deviate from the statutory text by explicitly excluding, from the QPA, any "single case agreement, letter of agreement, or other similar arrangement . . .

for a specific participant or beneficiary in unique circumstances." 45 C.F.R. § 149.140(a)(1). Such an agreement, according to the Departments, "does not constitute a contract." *Id*.

140. The Departments' conclusion that a case-specific agreement "does not constitute a contract," 45 C.F.R. § 149.140(a)(1), misunderstands what the term "contract" means. A "contract" is "[a]n agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law." Black's Law Dictionary (11th ed. 2019). That definition includes a case-specific agreement. Such an agreement contains a promise by the insurer to pay, and a promise by the provider to accept, an agreed rate for the provider's services. These agreements would be enforceable at law if either party breached them.

XI. The Implementing Regulations' Method for Determining Air Ambulance QPAs Is Arbitrary and Capricious, and Deviates from the Statute, Because It Includes Hospitals' Rates

141. The Departments' regulation regarding how air ambulance QPAs are to be calculated is also arbitrary and capricious, and deviates from the statute, for an additional reason: The regulation *includes*, in these QPAs, the insurers' "contracted rates" with *hospitals*, even though hospitals' negotiations with insurers are very different from independent air ambulance providers' negotiations.

142. The No Surprises Act provides that the QPA, in any given dispute, should include only those contracted rates that are "recognized" by the insurer as being "provided by a provider *in the same or similar specialty*" as the specific provider involved in the dispute at issue. 42 U.S.C. § 300gg-111(a)(3)(E)(i) (emphasis added).

143. Congress permitted the Departments, when issuing regulations on how the QPA should be calculated, to take into account the differences between provider specialties:

[The] methodology [for determining the QPA, established through the Department's rulemaking] may account for relevant payment adjustments that take into account quality or facility type (including higher acuity settings and the case-

mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities.

42 U.S.C. § 300gg-111(a)(2)(B).

144. The Departments exercised this authority by promulgating the following regulation: the key term "same or similar specialty" should be determined based on the insurer's "usual business practice." 45 C.F.R. § 149.140(a)(12). That is, the insurer should look to its own internal classifications of provider specialties and should include, in the QPA determination, only rates agreed to by providers having the same internal classification as the specific provider in the dispute at issue.

145. That general rule—the insurer should classify provider specialties based on the insurer's "usual business practice"—is in keeping with the text of the Act, which expressly provides that the QPA should include only rates with providers who are "recognized" by the insurer as having "the same or similar specialty." 42 U.S.C. § 300gg-111(a)(3)(E)(i).

146. The Departments explained that the general rule was intended to achieve a QPA that better approximates a market rate. *See IFR Part I*, 86 Fed. Reg. at 36,889 (stating that the QPA's purpose is to "reflect[] market rates under typical contract negotiations").

147. Thus, the Departments explained that if the provider in dispute is an "independent freestanding emergency department," then the QPA should only include rates with other "independent freestanding emergency departments," and should *not* include rates agreed to with larger hospitals that have emergency departments. That is because insurers "have not typically contracted with independent freestanding emergency departments." *IFR Part I*, 86 Fed. Reg., at 36,892-93; *see also* 45 C.F.R. § 149.140(a)(4)(ii).

148. That same consideration—lack of in-network contracting—also applies to independent providers of air ambulance services.

149. But "[w]ith respect to air ambulance services," the Departments decreed an exception to the general rule: "[A]ll providers of air ambulance services are considered to be a single provider specialty," regardless of the differences between these providers, and regardless of whether the insurer's usual business practice is to treat these providers as having different specialties. 45 C.F.R. § 149.140(a)(12).

150. This exception to the general rule means that insurers are directed to include *hospitals*' rates for air ambulance services, when determining the QPAs for use with *independent* providers of air ambulance services like PHI.

151. The Departments' decision to include hospitals, in the QPAs used for independent providers of air ambulance services, deviates from the Departments' own statement of the QPA's purpose, which is to "reflect[] market rates under typical contract negotiations." *IFR Part I*, 86 Fed. Reg. at 36,889.

152. An insurer's "typical contract negotiation" with a hospital or hospital group over the terms of an in-network contract is materially different from an insurer's "typical contract negotiation" with an independent provider of air ambulance services. A typical contract negotiation with a hospital or hospital group will involve setting rates for *thousands* of different services. A hospital often has a rational economic motive to offer its air ambulance services *below cost*, and hospitals frequently do so. *Supra* ¶ 41. Hospitals might even agree to a (low) rate for air ambulance services *despite having no air ambulances at all*, secure in the knowledge that they will never receive that rate. *Supra* ¶ 42. An insurer's negotiation with a hospital is therefore not "typical" of an insurer's "contract negotiation" with an independent air ambulance provider that offers just one service: air ambulance transport.

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153. The Departments *conceded* that "hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers." *IFR Part I*, 86 Fed. Reg., at 36,891.

154. The Departments' decision to include hospitals, in the QPAs used for independent providers of air ambulance services, also deviates from the statutory text. The statute requires that QPAs be determined using rates agreed to by those providers that the insurer "recognize[s]" to be "in the same or similar specialty" as the specific provider in the dispute for which the QPA is generated. 42 U.S.C. § 300gg-111(a)(3)(E)(i). In actual practice, insurers do "recognize" the many important distinctions between hospitals and independent air ambulance service providers. Many insurers classify these two kinds of providers (hospitals and independent air ambulance providers) as having different "practice specialties."

155. Defining all providers of air ambulance services as a "single provider specialty" by fiat, while using the insurer's "usual business practices" to classify every other "provider specialty," is an arbitrary and capricious decision. It deviates, without explanation, from Departments' decision to treat freestanding emergency departments as having a different "provider specialty" from hospitals with emergency rooms.

156. The effects of the Departments' regulatory choices—*including* hospital rates, and *excluding* single case agreements—can be illustrated using the following hypothetical example:

Insurer's Contracted Rates in 2019						
Provider		Contracted Rate	Number of Times the Insurer Paid that Rate to the Provider			
In-Network Provider (hospital)	A	\$5,000	0			
In-Network Provider (hospital)	B	\$7,000	2			

In-Network Provider C	\$10,000	3
	\$10,000	5
(hospital)		
In-Network Provider D	\$15,000	5
(independent provider)		
In-Network Provider E	\$19,000	5
(independent provider)		
In-Network Provider F	\$22,000	5
(independent provider)		
Single-case Agreement	\$24,000	1
(independent provider)		
Single-case Agreement	\$32,000	1
(independent provider)		
Single-case Agreement	\$33,000	1
(independent provider)		
Single-case Agreement	\$33,500	1
(independent provider)		
Single-case Agreement	\$36,000	1
(independent provider)		

In this example, the QPA is \$12,500 when calculated according to the implementing regulations because that is the median of the six *in-network* rates (i.e., the average of the two middle numbers, after the six in-network rates are placed in order). The \$5,000 in-network rate is included in this calculation, even though that provider was *never paid* that rate—which may be because that provider did not even maintain an air ambulance.

157. If the hospital rates were excluded, then the QPA would rise to \$19,000 (i.e., the middle number, after the three independent providers' in-network rates are placed in order).

158. If the single-case agreement rates were then included, the QPA would rise to \$28,000 (i.e., the average of the two middle numbers \$24,000 and \$32,000).

XII. The Implementing Regulations, for Air Ambulance Providers, Deviate from the No Surprises Act's Calculation of the Patient's "Cost Sharing" Amount

159. The No Surprises Act permits the provider to bill the patient for the amount of the patient's "cost sharing" (*e.g.*, co-pay or deductible). The Act also defines how this amount is calculated: "[T]he cost-sharing requirement with respect to [air ambulance services provided by

an out-of-network provider] shall be the same requirement that would apply if such services were provided by . . . a participating [*i.e.*, in-network] provider." 42 U.S.C. § 300gg-112(a)(1).

160. The Act does not delegate any rulemaking authority to the Departments to alter the calculation set forth in the statute and quoted above.

161. The Departments' implementing regulations, published in IFR Part I, deviate from the statutory calculation. The regulations define the amount of "cost-sharing" as follows: "The cost-sharing requirement must be calculated *as if* the total amount that would have been charged for the services by a participating [*i.e.*, in-network] provider were equal to the lesser of the [QPA] or the billed amount for the services." 45 C.F.R. § 149.130(b)(2).

162. The following example illustrates how this deviation will work in practice. Suppose the insurer issues the same policy in 2022 to Patient A and to Patient B. The policy states that the patient's "cost-sharing" amount for in-network air ambulance services shall be "20% of the allowed amount, up to a maximum cap of \$10,000." This is a relevant example—there are many such "80/20" plans in which the patient is responsible for paying 20% of the "allowed amount."

163. Suppose further that PHI (an out-of-network provider) provides emergency transport to both patients in 2022, and then sends its bills, calculated at PHI's standard rates, to the insurer. PHI's bill for the Patient A services is \$40,000, and its bill for the Patient B services is \$60,000. Under the plain text of the statute, as applied to this insurance policy, Patient A's "cost sharing" amount should be \$8,000 (20% of \$40,000) and Patient B's "cost sharing" should be \$10,000 (the cap, because 20% of \$60,000 is \$12,000, which exceeds the \$10,000 maximum cap). That is because the statute states that the patient's "cost-sharing requirement *shall be the same requirement* ... that would apply if such services were provided by ... a participating [*i.e.*, in-

network] provider." 42 U.S.C. § 300gg-112(a)(1) (emphasis added). The statute therefore authorizes PHI to collect \$8,000 from Patient A, and \$10,000 from Patient B. 42 U.S.C. § 300gg-135(a)(1).

164. Under the regulation, by contrast, the insurer instead consults its own secret data in order to determine the QPA. Suppose in this example that the QPA is just \$16,000. In that case, the regulation states that both patients' "cost sharing" is just \$3,200 (i.e., 20% of \$16,000). That is because the regulation, unlike the statute, states that "cost sharing" should be calculated "as if the total amount" that PHI "would have ... charged" was "the [QPA]." 45 C.F.R. § 149.130(b)(2). This regulation deviates from Congress's express directive and is arbitrary and capricious.

165. The Departments gave two explanations for this deviation, neither of which is satisfactory. *First*, the Departments claimed that this re-write is "consistent with the statute's general intent to protect participants, beneficiaries, and enrollees from excessive bills, and to remove the individuals as much as possible from disputes between plans and issuers and providers of air ambulance services." *IFR I*, 86 Fed. Reg., at 36,884.

166. *Second*, the Departments claimed that "using the QPA is one method of ensuring that any coinsurance or deductible is based on rates that would apply for the services if they were furnished by a participating provider, given that the QPA is generally based on median contracted rates." *Id.*

167. Both of these explanations disregard the plain text of the statute, which provides that the patient's "cost-sharing requirement," for an out-of-network provider's services, "*shall be the same requirement* that would apply if the services were provided by ... a participating provider." 42 U.S.C. § 300gg-112(a)(1). The statute states that the "requirement" shall be "the same." The statute does not authorize the Departments to create an entirely new method of

determining a new and different cost-sharing amount for out-of-network providers. The Departments exceeded their authority by doing so.

XIII. Plaintiffs Are Harmed By the Challenged Regulations

168. The regulations challenged here cause procedural injury to Plaintiffs because they deprive Plaintiffs of "the arbitration process established by the Act," which is a "procedural right" that is designed to "protect [Plaintiff's] concrete interests" in receiving compensation for their services. *TMA*, 2022 WL 542879, at *4.

169. The regulations challenged here also cause economic injury to Plaintiffs in at least two ways. First, Plaintiffs will soon be participating in IDRs that will determine Plaintiffs' compensation, from health plans and insurers, for Plaintiffs' out-of-network services. The challenged regulations will cause these IDRs' determinations to be lower than they otherwise would be. That is a direct and immediate financial injury to Plaintiffs. Second, over the long term, the challenged regulations will "systematically reduce out-of-network reimbursement compared to" the results of IDR processes without the challenged regulations. *TMA*, 2022 WL 542879 at *5. That systematic reduction will cause Plaintiffs additional economic injury because it will "drive out-of-network reimbursement rates to the QPA as a de facto benchmark." *Id.*

CLAIMS FOR RELIEF

I. COUNT I: The Implementing Regulations Should Be Set Aside Because the Agencies Failed to Follow Notice-and-Comment Procedures

(5 U.S.C. §§ 553, 706)

(Asserted by Both Plaintiffs)

170. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

171. The APA requires federal agencies to provide public notice of proposed rulemakings and an opportunity for comment, unless the agencies "for good cause" find that notice

and comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). This bedrock procedural protection of the APA is designed to ensure that members of the public have notice of proposed regulations that might affect their interests and an opportunity to present their views to the agency, both to inform and improve the agency's decision-making and to promote public confidence in the administrative process.

172. Agencies may dispense with notice-and-comment rulemaking only if "the agency for good cause finds ... that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(B); *see id.* § 553(d)(3). Otherwise, the APA requires the Departments to provide public notice of proposed rulemakings, and they must allow and consider public comments.

173. In promulgating both IFR Part I and IFR Part II, the Departments failed to follow notice-and-comment rulemaking.

174. The Departments did not satisfy the high bar necessary to establish good cause.

175. The Departments had sufficient time to formulate proposed rules and provide notice and opportunity for comment.

176. Congress itself determined that the Departments would have six months to promulgate the challenged regulations in IFR Part I and a full year to promulgate the challenged IDR Part II regulations.

177. The Departments knew that their regulations would apply to plan years starting on or after January 1, 2022, and that the first arbitrations will not occur until March 2022 at the earliest.

178. In setting deadlines for the final IDR rules, Congress determined that there would be sufficient time to set up the IDR process if the IFR Part II rules were promulgated, in final form,

by December 27, 2021. If more time were necessary, Congress would have set an earlier deadline, a later date to begin the IDR Process, or would have relieved the Defendants of their APA-based duty to comply with notice-and-comment rulemaking.

179. The Departments issued IFR Part II on October 7, 2021—approximately three months before the statutory deadline. They could have used those three months to provide notice and comment. They also could have started notice-and-comment rulemaking for IFR Part II during the preceding nine months.

180. The failure to provide for notice and comment predictably led to a set of regulations with enormous flaws threatening substantial disruption to the provision of emergency services across the country, and material harm to individual providers, as described throughout this Complaint.

181. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside 45 C.F.R. §§ 149.130, 149.140, 149.510, and 149.520, because these regulations were issued "without observance of procedure required by law," *id.*, namely, the notice-and-comment procedure required by 5 U.S.C. § 553; (2) that this Court enjoin the Departments and Department Officials from enforcing these regulations; (3) that this Court issue a declaratory judgment instructing IDR entities to decide IDRs based solely on the statutory text; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the IDR entity applied the challenged regulations and selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

II. COUNT II: The QPA Presumption Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, and Contrary to the Statute

(5 U.S.C. § 706)

(Asserted by Both Plaintiffs)

182. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

183. The QPA Presumption is contained in the six regulatory provisions set forth in paragraph 83.

184. The QPA Presumption is final agency action subject to review under the APA. 5 U.S.C. § 704. The regulations were published as an Interim Final Rule. That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is a regulation from which legal consequences will flow.

185. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

186. The QPA Presumption should be set aside, under the APA, because it is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706, and because these regulations deviate from Congress's clear direction that the QPA is just one of many factors that the IDR entity "shall consider" when "determining which offer is the payment to be applied." 42 U.S.C. § 300gg-112(b)(5)(C)(i).

187. By tying the IDR entity's hands in this way, the QPA Presumption abrogates the discretion that Congress deliberately granted to the IDR entity (and not to the Departments). Congress provided that the IDR entity—not the Departments—would have the power to "determine[]... in accordance with the succeeding provisions of this subsection, the amount of payment ... for such services." 42 U.S.C. § 300gg-112(b)(2)(A). By selecting in advance one factor (the QPA) that "must" be given presumptive effect, and by requiring a heightened

explanation whenever the IDR entity deviates from the QPA Presumption, the regulations usurp the discretion that Congress granted to the IDR entity.

188. The QPA Presumption must also be set aside as arbitrary and capricious, because: (1) the QPA is determined in an arbitrary and capricious manner, for the reasons set forth below in Counts IV-VI, and (2) the IDR entity and the provider do not receive the information necessary to assess whether the QPA was correctly determined or to assess whether the QPA reflects typical contract negotiations for the specific services at issue, for the reasons set forth below in Count III. In other words, the Departments "entirely failed to consider an important aspect of the problem," in contravention of the requirements of the Administrative Procedure Act. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

189. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside the QPA Presumption pursuant to the APA, 5 U.S.C. § 706(2); (2) that this Court issue a declaratory judgment instructing IDR entities to decide IDRs based on a consideration of all the factors enumerated in the statutory text; and (3) that this Court issue a declaratory judgment stating that IDR decisions, in which the IDR entity applied the QPA Presumption and selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

III. COUNT III: The Regulation Prescribing What Information the Payor Must Provide About the QPA (45 C.F.R. § 149.140(d)(2)) Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

(5 U.S.C. § 706)

(Asserted by Both Plaintiffs)

190. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

191. The regulation prescribing the information that the health plan or insurer must disclose about the QPA—45 C.F.R. § 149.140(d)(2)—is final agency action subject to review

under the APA. 5 U.S.C. § 704. This regulation was published as an "Interim Final Rule." That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

192. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

193. The regulation prescribing the information that the health plan or insurer must disclose about the QPA—45 C.F.R. § 149.140(d)(2) is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706, because it deviates from Congress's clear direction that the IDR entity "shall" consider "the qualifying payment amounts (as defined in subsection (a)(3)(E))." 42 U.S.C. § 300gg-112(c)(5)(C). That is a statutory command requiring the IDR entity to actually verify that the dollar amount submitted by the insurer, as "the QPA," was calculated correctly in accordance with the statutory directives. The statute does *not* permit the IDR entity to simply take the insurer's word for it that the insurer has done all these calculations correctly. Yet that is exactly what the Department's regulation contemplates, as the Departments made clear in IFR Part II: "[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly...." 86 Fed. Reg., at 55,996.

194. This regulation is also arbitrary, capricious, and an abuse of discretion because it fails to provide for meaningful disclosure regarding how the QPA was determined.

195. The purpose of the QPA—according to the Departments—is to "reflect[] market rates under typical contract negotiations" for the specific services for which the IDR entity is

charged with making a determination as to the appropriate payment amount. *IFR Part I*, 86 Fed. Reg. at 36,889.

196. The Departments acknowledged in IFR Part I that much more information, about the QPA determination, would be necessary in order for the QPA to serve its intended purpose. "The Departments recognize that" providers "need transparency regarding how the QPA was determined." *IFR Part I*, 86 Fed. Reg. at 36,898. In order to "decide whether to initiate the IDR process and what offer to submit [to the IDR entity]," a provider "must know not only the value of the QPA, but also certain information on how it was calculated. The Departments seek to ensure transparent and meaningful disclosure about the calculation of the QPA...." *Id*.

197. The information required to be disclosed, under this regulation, is insufficient to enable the provider or the IDR entity to verify that the QPA was determined in accordance with the statute. The information is also insufficient to enable the IDR entity to assess whether the QPA "reflects market rates under typical contract negotiations" for the specific services at issue before the IDR entity.

198. For these reasons, Plaintiffs respectfully request: (1) that this Court issue a declaratory judgment and injunction, requiring the Departments to promulgate a new regulation that requires meaningful disclosure of how the QPA was determined³¹; and (2) that this Court issue a declaratory judgment instructing IDR entities not to give any weight to a QPA, unless the IDR entity finds that the insurer's disclosures, to the IDR entity and to the provider, are sufficient to (a) enable the IDR entity to verify that the QPA was determined in accordance with the statute; and (b) enable the IDR entity to assess whether the QPA "reflects market rates under typical contract

³¹ PHI does not request that the Court set aside 45 C.F.R. § 149.140(d)(2) on this ground, because to do so would make the violation even worse, by eliminating even this limited disclosure of information.

negotiations" for the specific services at issue before the IDR entity; and (3) that this Court issue a declaratory judgment stating that IDR decisions, in which the IDR entity applied the challenged regulation and selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

IV. COUNT IV: The Regulation Governing Which Entity's Rates Are Included, in the QPA Calculation (45 C.F.R. § 149.140(b)(1)) Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute.

(Asserted by Both Plaintiffs)

199. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

200. The regulation governing the rates to be included in the QPA calculation—45 C.F.R. § 149.140(b)(1)—is final agency action subject to review under the APA. 5 U.S.C. § 704. This regulation was published as an "Interim Final Rule." That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of providers, group health plans, and issuers, and is one from which legal consequences will flow.

201. The regulation that governs the rates to be included in the QPA calculation—45 C.F.R. § 149.140(b)(1)—impermissibly deviates from the statute by permitting a plan sponsor to use, in the QPA calculation, all of the contracted rates of its *plan administrator*.

202. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

203. The regulation that governs the rates to be included in the QPA calculation is also arbitrary and capricious and an abuse of discretion. It is arbitrary and capricious for the

Departments to permit plan sponsors to pick and choose whose rates to use in the QPA calculation (the sponsor or the administrator) at the sponsor's own discretion, without disclosure to the provider or the IDR entity.

204. The "administrator" of a group health plan is, in many cases, a *different* entity from the plan's "sponsor." Many employers will, for example, contract with a third party administrator to administer the group health plans that they sponsor.³²

205. The statutory language, quoted above, does not call for the QPA to be determined based on the plans administered by the plan *administrator*. On the contrary, the statute refers to the plan *sponsor*. 42 U.S.C. § 300gg-111(a)(3)(E)(i).

206. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside 45 C.F.R. § 149.140(b)(1), pursuant to the APA, 5 U.S.C. § 706(2); (2) that this Court enjoin the Departments and Department Officials from enforcing this regulation; (3) that this Court issue a declaratory judgment instructing IDR entities not to give any weight to a QPA that is calculated based on this regulation; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the IDR entity applied the challenged regulation and selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

V. COUNT V: The Regulation Prescribing the Geographic Regions Used to Determine the QPA Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

(5 U.S.C. § 706)

(Asserted by Both Plaintiffs)

207. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

³² See 29 CFR § 2510.3-16.

208. The regulation governing the geographic regions used to calculate the QPA—45 C.F.R. § 149.140(a)(7)—is final agency action subject to review under the APA. 5 U.S.C. § 704. This regulation was published as an "Interim Final Rule." That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

209. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

210. The regulation governing the geographic regions used to calculate the QPA—45 C.F.R. § 149.140(a)(7)—is arbitrary, capricious, and an abuse of discretion because it will include, in the QPA calculation, contracted rates that applied in vastly distant and different geographic regions from the specific region in which the items and services at issue were provided.

211. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside 45 C.F.R. § 149.140(a)(7), pursuant to the APA, 5 U.S.C. § 706(2); (2) that this Court enjoin the Departments and Department Officials from enforcing this regulation; (3) that this Court issue a declaratory judgment instructing IDR entities not to give any weight to a QPA that is based on rates agreed to outside the specific State in which the services were provided; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the IDR entity applied the challenged regulation and selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

VI. COUNT VI: The Regulation that Excludes Case-Specific Agreements from the QPA Calculation Should Be Set Aside, Under the APA, Because It Is Arbitrary,

Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

(5 U.S.C. § 706)

(Asserted by Both Plaintiffs)

212. Plaintiffs incorporate and re-allege all of the foregoing paragraphs.

213. The regulation excluding case-specific agreements from the QPA calculation—45 C.F.R. § 149.140(a)(1)—is final agency action subject to review under the APA. 5 U.S.C. § 704. This regulation was published as an "Interim Final Rule." That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

214. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

215. This regulation is contrary to the statutory text because it explicitly excludes, from the QPA, any "single case agreement, letter of agreement, or other similar arrangement . . . for a specific participant or beneficiary in unique circumstances." 45 C.F.R. § 149.140(a)(1). Such an agreement, according to the Departments, "does not constitute a contract." *Id.* This misunderstands what the statutory term "contracted rate" means. A "contract" is "[a]n agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law." Black's Law Dictionary (11th ed. 2019).

216. The regulation is also arbitrary and capricious. A "single case agreement" is the rate that the insurer agreed to pay, and the provider agreed to accept, for a single case. By arbitrarily

excluding case-specific agreements from the QPA determinations, the Departments have excluded a very large number of the rates agreed to by providers and plans and insurers that should be included in order to make the QPA better achieve the goal that the Departments themselves set, which is to approximate the "market rate."

217. For these reasons, Plaintiffs respectfully request: (1) that this Court set aside 45 C.F.R. § 149.140(a)(1), pursuant to the APA, 5 U.S.C. § 706(2); (2) that this Court enjoin the Departments and Department Officials from enforcing this regulation; (3) that this Court issue a declaratory judgment instructing IDR entities not to give any weight to a QPA that excludes case-specific rates; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the QPA was calculated excluding case-specific rates and the IDR entity selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

VII. COUNT VII: The Regulation That Includes Hospital Contracted Rates in Air Ambulance QPAs Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

(5 U.S.C. § 706)

(Asserted by PHI)

218. PHI incorporates and re-alleges all of the foregoing paragraphs.

219. The regulation that includes hospital contracted rates in the QPAs for independent air ambulance providers—45 C.F.R. § 149.140(a)(12)—treats *all* air ambulance providers as the same "provider specialty," regardless of the providers' business models and other services. 45 C.F.R. § 149.140(a)(12) ("with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty"). This regulatory carve-out applies *only* to air ambulance services—for all other kinds of services, the term "provider specialty" is defined

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to mean "the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice." *Id.*

220. This regulation is final agency action subject to review under the APA. 5 U.S.C. § 704. This regulation was published as an "Interim Final Rule." That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

221. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

222. This regulation is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706, because it deviates from Congress's clear direction. The No Surprises Act provides that the QPA, in any given dispute, should include only those contracted rates that are "recognized" by the insurer as being "provided by a provider *in the same or similar specialty*" as the specific provider involved in the dispute at issue. 42 U.S.C. § 300gg-111(a)(3)(E)(i) (emphasis added).

223. Independent air ambulance providers, and hospital air ambulance providers, are not "recognized" in the industry as being "the same or similar specialty." On the contrary, these types of providers are "recognized" as being very different from each other in important ways that directly and materially affect the contracted rates that these providers would and could agree to with health plans and insurers.

224. The regulation is also arbitrary and capricious. In the analogous case of freestanding emergency departments, the Departments correctly recognized that such facilities are not in the

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same "provider specialty" as a full hospital's emergency room department. *Supra*, ¶ 146. Thus, the regulation "applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record." *Anna Jaques Hosp. v. Sebelius*, 583 F.3d 1, 7 (D.C. Cir. 2009).

225. The Departments' rule-making failed to provide a "rational connection between the facts"—which show a stark difference in "specialties" between independent air ambulance companies and hospitals—and "the choice made" to implement a regulatory carve-out that defines these businesses as all having the same "specialty." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The regulatory carve-out also "fail[s] to consider an important aspect of the problem," namely, that many hospitals offer air ambulance services at *below cost* and some hospitals may agree to "contracted rates" that are never actually paid (because these hospitals do not in fact operate any air ambulances). *Id.* The Departments' approach "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

226. For these reasons, PHI respectfully requests: (1) that this Court set aside 45 C.F.R. § 149.140, pursuant to the APA, 5 U.S.C. § 706(2); (2) that this Court enjoin the Departments and Department Officials from enforcing this regulation; (3) that this Court issue a declaratory judgment instructing IDR entities not to give any weight to a QPA that includes rates with providers, such as hospitals, that are not independent air ambulance providers; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the QPA was calculated excluding case-specific rates and the IDR entity selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

VIII. Count VIII: The Implementing Regulation Defining the Patient's "Cost Sharing" For Air Ambulance Services (45 C.F.R. § 149.130) Should Be Set Aside Under the

APA Because It Is Arbitrary, Capricious, Contrary to Law, In Excess of Statutory Limits, and Contrary to the Statute

(5 U.S.C. § 706)

(Asserted by PHI)

227. PHI incorporates and re-alleges all of the foregoing paragraphs.

228. The regulation governing how a patient's "cost sharing" is calculated—45 C.F.R. § 149.130—is final agency action subject to review under the APA. 5 U.S.C. § 704. This regulation was published as an "Interim Final Rule." That publication marks the consummation of the Departments' collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is one from which legal consequences will flow.

229. Under Section 706 of the APA, a district court shall "hold unlawful and set aside agency action . . . found to be" either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

230. The Act provides: "[T]he cost-sharing requirement with respect to [air ambulance services provided by an out-of-network provider] shall be the same requirement that would apply if such services were provided by ... a participating [i.e., in-network] provider." 42 U.S.C. § 300gg-112(a)(1).

231. The regulation deviates from the statute by defining the amount of "cost-sharing" as follows: "The cost-sharing requirement must be calculated *as if* the total amount that would have been charged for the services by a participating [i.e., in-network] provider were equal to the lesser of the [QPA] or the billed amount for the services." 45 C.F.R. § 149.130(b)(2).

232. The No Surprises Act did not authorize the Departments to engage in rulemaking that would define "cost sharing" in a manner different from the statute.

233. This regulation is also arbitrary and capricious. The agency did not provide sufficient and acceptable reasons for enacting this new method of calculating the patient's cost-sharing amount.

234. For these reasons, PHI respectfully requests: (1) that this Court set aside 45 C.F.R. § 149.130, pursuant to the APA, 5 U.S.C. § 706(2); (2) that this Court enjoin the Departments and Department Officials from enforcing the regulation; and (3) that this Court issue a declaratory judgment declaring that PHI may bill patients for the amount of "cost sharing" provided in the statute.

IX. Count IX: The Implementing Regulations Violate the U.S. Constitution Because They Take PHI's Property and Services Without Just Compensation

(U.S. Const., Amend. 5)

(Asserted by PHI)

235. PHI incorporates and re-alleges all of the foregoing paragraphs.

236. The Due Process Clause of the Fifth Amendment to the U.S. Constitution provides: "No person shall be . . . deprived of life, liberty, or property, without due process of law." The Takings Clause of this Amendment provides: "[N]or shall private property be taken for public use, without just compensation."

237. The implementing regulations challenged here constitute a "taking" of PHI's property, of PHI's services, and of PHI's pre-existing rights to obtain reasonable compensation.

238. *Property*. The implementing regulations challenged here (in combination with preexisting statutory and regulatory regimes that require PHI to respond to emergency calls) constitute a "taking" of PHI's physical property—its bases, aircraft, and supplies—by requiring PHI to use that property to provide services to patients without "just compensation." *Sierra Med. Servs. All. v. Kent*, 883 F.3d 1216, 1224-25 (9th Cir. 2018) (noting that healthcare providers have property

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interests "in their ambulances, equipment, wages, supplies, insurance, goodwill, and ambulatoryservice and employment contracts").

239. PHI has made substantial investments in its properties, with the expectation that it could obtain compensation for its use of those properties under existing law. PHI's expenditures include, but are not limited to, the acquisition and maintenance of aircraft; the acquisition, construction and improvement of airbases; the purchase of consumables including medical supplies, parts and fuel; and investments in regulatory compliance, safety, and billing systems.

240. *Services.* The implementing regulations challenged here (in combination with preexisting statutory and regulatory regimes that require PHI to respond to emergency calls) also constitute a "taking" of PHI's services. *Ex Parte Brown*, 393 S.C. 214, 711 S.E.2d 899 (2011) (services of court-appointed counsel was property that implicated Takings Clause).

241. *Pre-existing state causes of action*. The No Surprises Act, in combination with the implementing regulations, constitutes a taking of PHI's pre-existing state-law causes of action to recover reasonable compensation for PHI's services.

242. Under well-established Supreme Court precedent, the government may effect a taking through regulation of property that "goes too far." *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922); *see also Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 321-32 (2002).

243. The Supreme Court applies a three-pronged test to determine whether regulatory activity constitutes a "taking": (1) "[t]he economic impact of the regulation on the claimant," (2) "the extent to which the regulation has interfered with distinct investment-backed expectations," and (3) "the character of the governmental action." *Penn Cent. Transp. Co. v. New York*, 438 U.S. 104, 124 (1978). Any one of these so-called "*Penn Central* factors," standing alone, can suffice to

show that the government has effected a "taking." *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005 (1984). The No Surprises Act, and its implementing regulations, implicates all three when combined with pre-existing statutory and regulatory regimes that require PHI to respond to emergency calls.

244. *First,* the implementing regulations, challenged here, impose a significant economic impact on PHI, which is one of the "[p]rimary" factors in the analysis. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538-39 (2005). The Act forbids PHI from seeking to recover reasonable compensation from the patient, which is a significant source of leverage that PHI uses to negotiate reasonable compensation from private insurers. *E.g., supra*, ¶46. And the implementing regulations limit PHI's compensation to the IDR process, in which the arbitrary (and very low) QPA will be given dispositive weight. Finally, the Act freezes this artificially low rate in place—allowing only for inflation-indexed increases in whatever QPAs are calculated today, based on 2019 rates. The result will be systematic under-compensation for PHI's services at confiscatory rates. The "financial burden" on PHI will be "considerable" to say the least. *E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998) (plurality op.).

245. Turning to the second *Penn Central* factor, the implementing regulations challenged here deprive PHI of its "distinct investment-backed expectations" of a return on its investments. 438 U.S. at 124. PHI has made enormous investments in its physical capital (bases, aircraft) and human capital—recruiting, retaining, and training its employees. Neither PHI nor its employees had any expectation, when making these investments, that their returns would be confiscated by the federal government's poorly designed and confiscatory regulations.

246. *Third*, the "character of" the implementing regulations also indicates that the Departments have effected a "taking" of property and services. The "character" of the

implementing regulations runs directly contrary to the fundamental purpose of the Takings Clause, which is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960). The basic objective of the Act is to relieve patients of the direct burden of paying unanticipated costs for out-of-network air ambulance services. PHI applauds and supports that general purpose. But rather than spread across the public the burdens that will result from a system in which patients are not obligated to pay the full cost of the services they obtain, the implementing regulations instead seek to force *providers* to bear almost all of those costs.

247. The implementing regulations do not provide "just compensation" for these takings of PHI's property and services.

248. Instead, the implementing regulations provide for confiscatory rates. *See Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307-308 (1989); *Jersey Cent. Power & Light Co. v. FERC*, 810 F.2d 1168, 1175 (D.C. Cir. 1987) (*en banc*); *Guar. Nat. Ins. Co. v. Gates*, 916 F.2d 508, 515 (9th Cir. 1990) (holding unconstitutional rate regulation that did not guarantee "constitutionally required 'fair and reasonable return'"). The Act limits PHI's compensation to the payment determination of the IDR entity, which does not account for the provider's right to a reasonable return. *See, e.g.*, 42 U.S.C. § 300gg-112(b)(5)(C) (failing to instruct IDR entity to consider adequacy of provider's financial return); 45 C.F.R § 149.510(c)(4)(ii)(A) (making QPA presumptively controlling factor).

249. The implementing regulations will result in payment determinations that fail even to cover PHI costs of operating many of airbases—let alone provide a just and reasonable return. *Cf. Michigan Bell Telephone Co. v. Engler*, 257 F.3d 587, 593 (6th Cir. 2001) (regulated entities

"are not required to subsidize their regulated services with income from rates either deemed to be competitive, or with revenues generated from unregulated services").

250. PHI does not "opt in" to the No Surprises Act's ratemaking scheme, including as a condition of participating in an elective government program. Rather, PHI will be subject to the NSA by virtue of offering its air ambulance services to private customers. In some jurisdictions, PHI also cannot exit the market in response to the confiscatory rates imposed by the implementing regulations. *E.g.*, Ariz. Rev. Stat. Ann. § 36-2238 ("An ambulance service . . . shall not abandon or discontinue any service to any portion of the service area established under the certificate without an order from the department, unless the certificate has expired, becomes invalid or is suspended or revoked."); *see also* 12 Va. Admin. Code 5-31-480 (requiring 90 days' notice to terminate service).

251. For these reasons, PHI respectfully requests: (1) that this Court issue a judgment declaring that the No Surprises Act and its implementing regulations violate the Takings Clause and Due Process Clause because (in combination with pre-existing statutory and regulatory regimes that require PHI to respond to emergency calls) they effect "takings" without providing for "just compensation"; (2) that this Court enjoin the Departments and Department Officials from enforcing the implementing regulations challenged here; (3) that this Court issue a declaratory judgment instructing IDR entities to decide IDRs based solely on the statutory text; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the challenged regulations were applied and the IDR entity selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

X. Count X: The No Surprises Act, and Its Implementing Regulations, Violate Due Process Because the IDR Process Is Fundamentally Unfair And Does Not Permit Providers to Challenge Confiscatory Rates

(U.S. Const., Amend. 5)

(Asserted by PHI)

252. PHI incorporates and re-alleges all of the foregoing paragraphs.

253. The Due Process Clause, of the Fifth Amendment of the U.S. Constitution, provides: "No person shall be . . . deprived of life, liberty, or property, without due process of law."

254. PHI is entitled to the protections of the Due Process Clause in the IDR Process.

255. PHI has a property right in its air ambulance services, as well as its state-law causes of action to obtain reasonable compensation for those services. These property rights are protected by the Due Process Clause.

257. The foregoing entitlements, to payment for services, are a species of property protected by the Due Process clause. *See Goldberg v. Kelly*, 397 U.S. 254, 262 & n.8 (1970).

258. Under the regime put in place by the No Surprises Act, these payments constitute a critical—indeed the principal—revenue stream supporting PHI's air ambulance operations.

259. Having granted PHI a property right, the federal government is barred by the Due Process Clause from depriving PHI of meaningful due process to protect that right. *See, e.g., Cleveland Bd. of Educ. v. Loudermill,* 470 U.S. 532, 541 (1985) ("[I]t is settled that the "bitter with the sweet" approach misconceives the constitutional guarantee. . . . [T]he Due Process Clause provides that certain substantive rights—life, liberty, and property—cannot be deprived except pursuant to constitutionally adequate procedures. The categories of substance and procedure are distinct. Were the rule otherwise, the Clause would be reduced to a mere tautology. 'Property' cannot be defined by the procedures provided for its deprivation any more than can life or liberty.").

260. The implementing regulations, challenged here, deprive PHI of due process because they are fundamentally unfair for the reasons stated in the foregoing paragraphs, and summarized below.

261. *First*, the IDR entity is required to give presumptive (and in many if not all cases, dispositive) weight to the QPA, which is a deeply flawed measure that has almost no relevance to the costs or the value of the services PHI provided.

262. Second, the implementing regulation calculates the QPA in a fundamentally unfair manner. The regulation excludes, from the QPA calculation, all of the many single-case agreements between the insurer and providers, which constitute the majority of private-insurer reimbursements to PHI and other independent air ambulance providers and are therefore powerful and relevant evidence of the reasonable compensation for such services. The QPA also includes rates agreed to by providers (like hospitals and hospital groups) that provide air ambulance services as a "loss leader," i.e., below their own costs. The QPA also includes rates agreed to in vastly

different geographic regions, that may not be relevant to the market value of the specific services, provided by PHI, that are at issue in the IDR Process.

263. *Third*, the IDR Process does not give the provider the opportunity to obtain and present information that must in fairness be considered by a decisionmaker before giving any weight to "the QPA" submitted by the insurer. There is no discovery of this information, and no power is given to the IDR entity to compel the insurer to provide it. Indeed, the implementing regulations do not even provide PHI or the IDR entity with information sufficient to check the private insurer's math, let alone assess whether the QPA is a fair reflection of typical contract negotiations.

264. On information and belief, no federal law has ever required a party to submit to an adjudication, of its claim for reasonable compensation for its goods or services rendered, in which neither that party *nor even the decisionmaker* is given an opportunity to examine the evidence used to calculate the presumptively dispositive factor in the decision-making process.

265. *Fourth,* the implementing regulations unconstitutionally deprive PHI of its due process right to challenge the payment amount as less than a just and reasonable return. *Michigan Bell Telephone Co. v. Engler*, 257 F.3d 587, 593 (6th Cir. 2001) ("The Due Process Clause requires a mechanism through which a regulated utility may challenge the imposition of rates which may be confiscatory."); *see also Guar. Nat. Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) ("We agree that Chapter 784 is unconstitutional. Neither Chapter 784 nor the Nevada Insurance Code of which it is a part provides any mechanism to guarantee a constitutionally required fair and reasonable return."); *Jersey Cent. Power & Light Co. v. FERC*, 810 F.2d 1168, 1186 (D.C. Cir. 1987) (*en banc*) ("Quite clearly, the Commission may not maintain a system of rules that provides

no opportunity at all for . . . allegations to be raised, heard, considered, and made the subject of findings.").

266. The implementing regulations do not direct the IDR entity to consider what would constitute a just and reasonable return when determining payment amounts. *See* 42 U.S.C. § 300gg-112(b)(5)(C). The QPA, to which IFR Part II grants presumptive weight, *e.g.*, 45 C.F.R § 149.510(c)(4)(ii)(A), does not depend at all on the provider's financial return or its costs. 42 U.S.C. § 300gg-111(a)(3)(E)(i) (defining QPA as median of contracted rates); 45 C.F.R § 149.140(c).

267. The IDR entity's payment determination is exempt from judicial review absent extremely limited exceptions. 42 U.S.C. § 300gg-111(b)(5)(E)(i)(I), (II). None of those exceptions appears to entitle PHI to set aside the IDR entity's decision on the basis that the rate is confiscatory.

268. For these reasons, PHI respectfully requests: (1) that this Court issue a judgment declaring that the implementing regulations, challenged here, violate PHI's Due Process rights; (2) that this Court enjoin the Departments and Department Officials from enforcing the implementing regulations challenged here; (3) that this Court issue a declaratory judgment instructing IDR entities to decide IDRs based solely on the statutory text; and (4) that this Court issue a declaratory judgment stating that IDR decisions, in which the challenged regulations were applied and the IDR entity selected the offer submitted by the payor, are void and without effect and must be re-opened and started anew.

PRAYER FOR RELIEF

For the foregoing reasons, Plaintiffs respectfully request that the Court provide the declaratory and injunctive relief set forth in each Count above, and summarized as follows:

A. A judgment declaring that the challenged regulations are arbitrary and capricious; are in excess of statutory authority and limits; and were issued without the required notice-and-comment procedure;

B. A judgment declaring that the challenged regulations violate the Fifth Amendment to the U.S. Constitution;

C. An injunction setting aside the challenged regulations, and forbidding the Departments and Department Officials from enforcing them;

D. A judgment declaring that IDR entities must make their determinations based solely on the statutory text, and without regard to the regulations challenged here;

E. A judgment declaring that IDR decisions, in which the IDR entity applied the challenged regulations, are void and without effect and must be re-opened and started anew; and

F. Any other relief the Court determines to be just and proper.

Date: April 29, 2022

By: __/s/ Chrisandrea Turner_____

Chrisandrea Turner STITES & HARBISON, PLLC 250 W. Main St., Ste. 2300 Lexington, KY 40507 859-226-2261 <u>clturner@stites.com</u> *Counsel to Plaintiffs*

____/s/ Stephen Shackelford, Jr._____

Stephen Shackelford, Jr. (*pro hac vice to be submitted*) Steven M. Shepard (*pro hac vice to be submitted*) SUSMAN GODFREY LLP 1301 Ave. of the Americas, Fl. 32 New York, NY 10019 Case: 6:22-cv-00095-REW-HAI Doc #: 1 Filed: 04/29/22 Page: 79 of 79 - Page ID#: 79

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JS 44 (Rev. 04/21)	CIV		FR SHFFT	Ŭ	0	
The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. <i>(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)</i>						
I. (a) PLAINTIFFS			DEFENDANTS			
PHI HEALTH, LLC,; and EMPACT MIDWEST LLC.			SEE ATTACHED			
(b) County of Residence of First Listed Plaintiff <u>Maricopa County, 1</u> (EXCEPT IN U.S. PLAINTIFF CASES)			AZ County of Residence of First Listed Defendant Washington, D.C. (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.			
(c) Attorneys (Firm Name, A	Address, and Telephone Number)		Attorneys (If Known)			
See attachment.						
II. BASIS OF JURISD	ICTION (Place an "X" in One Box Only)	III.			Place an "X" in One Box for Plaintiff	
1 U.S. Government Plaintiff	3 Federal Question (U.S. Government Not a Party)	c	(For Diversity Cases Only) PT Citizen of This State			
2 U.S. Government Defendant	4 Diversity (Indicate Citizenship of Parties in In		Citizen of Another State	2 2 Incorporated and Prof Business In A		
		C	Citizen or Subject of a Source		6 6	
IV. NATURE OF SUIT	(Place an "X" in One Box Only) TORTS		FORFEITURE/PENALTY	Click here for: <u>Nature of Si</u> BANKRUPTCY	uit Code Descriptions. OTHER STATUTES	
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	310 Airplane 365 Persona 315 Airplane Product Produc Liability 367 Health 320 Assault, Libel & Pharma 330 Federal Employers' Product Liability 368 Asbest 340 Marine Injury 345 Marine Product Liability Liability 948 Asbest 350 Motor Vehicle 370 Other F 355 Motor Vehicle 371 Truth in Product Liability 385 Propert Ja60 Other Personal Propert Injury 385 Propert 360 Other Personal Injury - Product Medical Malpractice Propert 440 Other Civil Rights Habeas Co 441 Voting 463 Alien I 442 Employment 510 Motion 443 Housing/ Sentence Accommodations 530 Genera 445 Amer. w/Disabilities - 540 Manda Other 555 Prison 448 Education 555 Prison	t Liability Care/ ceutical il Injury Liability os Personal Product ty PROPERTY raud a Lending Personal y Damage y Damage t Liability PETITIONS rpus: Detainee is to Vacate ce l Penalty mus & Other ights Condition Detainee -	625 Drug Related Seizure of Property 21 USC 881 690 Other 710 Fair Labor Standards Act 720 Labor/Management Relations 740 Railway Labor Act 751 Family and Medical Leave Act 790 Other Labor Litigation 791 Employee Retirement Income Security Act 462 Naturalization Application 465 Other Immigration Actions	 422 Appeal 28 USC 158 423 Withdrawal 28 USC 157 INTELLECTUAL PROPERTY RIGHTS 820 Copyrights 830 Patent 835 Patent - Abbreviated New Drug Application 840 Trademark 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY 861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 865 RSI (405(g)) FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff or Defendant) 871 IRS—Third Party 26 USC 7609 	 375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit (15 USC 1681 or 1692) 485 Telephone Consumer Protection Act 490 Cable/Sat TV 850 Securities/Commodities/ Exchange 890 Other Statutory Actions 891 Agricultural Acts 895 Freedom of Information Act 896 Arbitration \$95 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes 	
V. ORIGIN (Place an "X" in One Box Only) I Original Proceeding 2 Removed from State Court 3 Remanded from Appellate Court 4 Reinstated or Reopened 5 Transferred from Another District (specify) 6 Multidistrict Litigation - Direct File Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):						
VI. CAUSE OF ACTION 5 U.S.C. §§ 553 & 706 Brief description of cause: Certain provisions of Interim Final Rule Part II, implementing the No Surprises Act and creating the "QPA Presumption," violate the Administrative Pr						
VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND:						

VIII. RELATED CAS IF ANY	SE(S) (See instructions):	JUDGE		DOCKET NUMBER
DATE		SIGNATURE OF ATTORNEY OF RECORD		
Apr 29, 2022	/s/ Chrisandrea Turner			
FOR OFFICE USE ONLY				
RECEIPT#	MOUNT	APPL VING IFP	IUDGE	MAG IUDGE

JS 44 Reverse (Rev. 04/21)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below. United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box. Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked. Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)

- III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: <u>Nature of Suit Code Descriptions</u>.
- V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.

Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction. Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

List of Attorneys for Plaintiff

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Chrisandrea Turner Dustyn B. Jones Emily Startsman Stites & Harbison, PLLC 250 W. Main St., Ste. 2300 Lexington, KY 40507 (859) 226-2300

Defendants

United States Department of Health and Human Services;

United States Department of Labor;

United States Department of the Treasury;

United States Office of Personnel Management;

United States Employee Benefits Security Administration, Internal Revenue Service, Becerra, Xavier (in his official capacity as Secretary of Health and Human Services);

Yellen, Janet (in her official capacity as the Secretary of the Treasury);

Walsh, Martin J. (in his official capacity as Secretary of Labor);

Ahuja, Kiran (in her official capacity as Director of the Office of Personnel Management);

Khawar, Ali (in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration); and

Rettig, Charles (in his official capacity as Commissioner of Internal Revenue)