IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES,
909 N. Washington Street, Suite 410
Alexandria, VA 22314,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201,

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201,

U.S. OFFICE OF PERSONNEL MANAGEMENT,
1900 E Street NW
Washington, DC 20415,

KIRAN AHUJA, in her official capacity as Director of the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

LAURIE BODENHEIMER, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management,
1900 E Street NW
Washington, DC 20415,

U.S. DEPARTMENT OF LABOR,
200 Constitution Avenue NW
Washington, DC 20210,

MARTIN J. WALSH, in his official capacity as Secretary of Labor,
200 Constitution Avenue NW
Washington, DC 20210,

Civ. No. 1:21-cv-3031

U.S. EMPLOYEE BENEFITS SECURITY ADMINISTRATION,
200 Constitution Avenue NW
Washington, DC 20210,

ALI KHAWAR, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration,
200 Constitution Avenue NW
Washington, DC 20210

U.S. DEPARTMENT OF THE TREASURY,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

JANET YELLEN, in her official capacity as Secretary of the Treasury,
1500 Pennsylvania Avenue NW
Washington, DC 20220,

LILY L. BATCHELDER, in her official capacity as Assistant Secretary of the Treasury (Tax Policy),
1500 Pennsylvania Avenue NW
Washington, DC 20220,

INTERNAL REVENUE SERVICE,
1111 Constitution Avenue NW,
Washington, DC 20224,

CHARLES RETTIG, in his official capacity as Commissioner of the Internal Revenue Service,
1111 Constitution Avenue NW,
Washington, DC 20224,

and

DOUGLAS W. O'DONNELL, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service,
1111 Constitution Avenue NW
Washington, DC, 20224,

Defendants.

COMPLAINT

Plaintiff the Association of Air Medical Services (AAMS) brings this complaint against the U.S. Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of Health and Human Services; the U.S. Office of Personnel Management; Kiran Ahuja, in her official capacity as Director of the U.S. Office of Personnel Management; Laurie Bodenheimer, in her official capacity as Associate Director, Healthcare and Insurance, in the U.S. Office of Personnel Management; the U.S. Department of Labor; Martin J. Walsh, in his official capacity as Secretary of Labor; the U.S. Employee Benefits Security Administration; Ali Khawar, in his official capacity as the Acting Assistant Secretary for the Employee Benefits Security Administration; the U.S. Department of the Treasury; Janet Yellen, in her official capacity as Secretary of the Treasury; Lily L. Batchelder, in her official capacity as Assistant Secretary of the Treasury (Tax Policy); the Internal Revenue Service; Charles Rettig, in his official capacity as Commissioner of the Internal Revenue Service; and Douglas W. O'Donnell, in his official capacity as Deputy Commissioner for Services and Enforcement in the Internal Revenue Service (collectively, Defendants), and alleges as follows:

INTRODUCTION

1. This is an action under the Administrative Procedure Act to set aside interim final rules (the Rules or IFRs) issued by the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, and the Office of Personnel Management (collectively, the Departments) to implement the No Surprises Act, Pub. L. No. 116-260, 134 Stat. 1182, div. BB, tit. I (2020). The Rules are inconsistent with the statute's text and purpose and impose through administrative fiat policies that Congress expressly considered and rejected.

2. Indeed, the Chairman and the Ranking Member of the House Ways and Means Committee recently described the Rules as reflecting "an approach that Congress did not enact in the final law" and "in a very concerning manner." *See, e.g.*, Exhibit 1 (Oct. 4, 2021 letter). More

than 150 additional members of Congress from both parties have similarly stated that the Departments' approach 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." Exhibit 2 (Nov. 5, 2021 letter).

3. The administrative overreach in the IFRs promises to impact one segment of the healthcare sector differently from all others: the air ambulance industry. The air ambulance industry fills a critical need in the American healthcare system because the faster a person who suffers a traumatic injury or other medical emergency reaches a hospital, the better the overall outcome.[1] Yet more than 85 million Americans—greater than one quarter of the Nation's population—live further than a one-hour drive from the nearest Level 1 or Level 2 trauma center.[2] For those Americans, lifesaving emergency medical care is not a guarantee. Nor is the situation improving. Nineteen rural hospitals closed in the United States in 2020, and more than 180 rural hospitals have closed since 2005—about a 10% decrease.[3] The sad reality is that access to hospitals is decreasing for most Americans living, visiting, or traveling through rural areas at great distances from trauma

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[1] Hannah Pham et al., *Faster On-Scene Times Associated with Decreased Mortality in Helicopter Emergency Medical Services (HEMS) Transported Trauma Patients*, 2 Trauma Surgery & Acute Care Open 1, 4 (2017) ("It is imperative that trauma victims receive care as soon as possible, whether it be prehospital or definitive care. From our observations, we have identified that faster time of arrival on-scene and departure from scene are directly related to decreased mortality."); Patrick Schoettker et al., *Reduction of Time to Definitive Care in Trauma Patients: Effectiveness of a New Checklist System*, 34 Injury 187, 187 (2003) ("[P]rolonged time to definitive care has been identified as an issue preventing optimal care of injured patients. Early transfer of severely injured patients to a major trauma centre has been shown to be associated with better survival.").

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

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

centers. If air ambulances stopped operating, many patients could not receive emergency or definitive care within the time required to ensure an optimal outcome.[4]

4. Air ambulances are on standby 24 hours a day, seven days a week, and they respond when they are called. They play no role in deciding which patients to transport. First responders (such as police and firefighters) and physicians (typically at community hospitals) decide when patients should be airlifted to a facility, and it is they who call air ambulances when necessary. Air ambulances respond to these time-sensitive emergency calls and carry out the transport so long as conditions are safe for air travel. And they do so without regard to a patient's ability to pay, insurance coverage, or insurance-network status.

5. While air ambulances are essential and life-saving tools, their use also comes at a cost. To provide these services, air ambulance providers must make substantial investments in aircraft, air bases, medical personnel, medical products and equipment, and regulatory compliance measures. These fixed costs are unavoidable and incurred regardless of whether an air ambulance completes zero transports in a day or several of them. Because air ambulances are typically responding on-demand to unplanned medical emergencies, they cannot schedule or predict the timing of specific transports. For similar reasons, it can be challenging for an air ambulance provider to reliably project its future volume of transports over time.

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[4] David Michaels, et al., *Helicopter Versus Ground Ambulance: Review of National Database for Outcomes in Survival in Transferred Trauma Patients in the USA*, 4 Trauma Surgery and Acute Care Open 1, 3 (2019) ("After adjusted analysis, we found that helicopter use is associated with decreased mortality in trauma patients. The higher level of care provided by helicopter medical personnel and the faster on-scene arrival of air transport is still associated with better outcomes compared with ground transportation."); Pham, *supra*, at 3 ("The faster the [helicopter EMS] is able to reach the scene, the faster critically injured patients will receive medical care. It is evident that trauma is time sensitive, especially in its earliest moments, and [helicopter EMS] provides a faster method of reaching and caring for severely injured patients.").

6. These unique characteristics of air ambulance operations deter group health plans and issuers from entering into network contracts with independent air ambulance providers, notwithstanding the providers' best efforts to negotiate such contracts. Under ordinary circumstances, group health plans and issuers steer increased patient volume to "in-network" providers in exchange for the network providers accepting discounted rates. But this network contracting model is a poor fit for the air ambulance industry; air ambulance providers deliver emergency transports on call, and they cannot pick and choose their patients. Group health plans and issuers, in turn, have no ability to steer increased patient volumes in return for discounts. Despite air ambulance providers' good-faith attempts to negotiate network contracts with group health plans and issuers, payers often refuse to offer rates sufficient to offset the significant fixed costs of air ambulance operations. As a result, air ambulance companies are often forced to stay "out of network." And out-of-network air ambulance providers must then negotiate billing arrangements with issuers on a case-by-case basis.

7. This case concerns the No Surprises Act, through which Congress sought to restructure this inefficient process that effectively placed patients in the middle of payment disputes between health plans or issuers and air ambulance providers. Prior to the Act, when a plan or issuer failed to negotiate or adequately reimburse a provider, the patient would receive a bill for the unpaid balance of the invoice not covered by her insurance—a so-called balance bill.

8. Through the Act, Congress required plans and issuers to come to the negotiating table with air ambulance providers to reach a fair and reasonable rate for these critical services. Barring that, Congress provided that the dispute would be resolved through an efficient independent dispute resolution (IDR) process in which an independent entity would consider the information enumerated in the statute and then select the appropriate rate from one of the offers submitted by the parties. Through this design, Congress strongly incentivized providers and payers to resolve disputes amongst themselves or to submit the most reasonable offer.

9. Congress's design, however, was swiftly undone by the Departments through the IFRs. In July 2021, the Departments issued Interim Final Rule Part I without notice and comment. *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021) (attached as Exhibit 3). In October 2021, they followed up with Interim Final Rule Part II, again without notice and comment. *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (attached as Exhibit 4). Critical elements of the IFRs diverge wildly from the structure Congress created with the Act and must be vacated in part.

10. *First*, IFR Part II deems the "qualifying payment amount" (QPA) (which is determined by plans and issuers) presumptively dispositive of the payment dispute and *requires* the IDR entity to select the offer that is closest to that amount. 86 Fed. Reg. at 56,104. It does so notwithstanding the statute's enumerated list of circumstances that the IDR entity "shall consider," only one of which is the QPA. Public Health Service Act (PHSA) § 2799A-2(b)(5)(C). To overcome the IFR's presumption, a provider must offer information that "clearly demonstrates" that the QPA is "materially different" from the "appropriate out-of-network rate." 86 Fed. Reg. at 55,984. In this way, the Departments have adopted an IDR process that is not actually "independent" and flouts the process that Congress enacted; indeed, it is not a meaningful dispute resolution process at all.

11. The Departments are transparent on that point too, explaining that they wanted to "allow for predictability" and "certainty" by "encourag[ing] plans, issuers, providers, and facilities to make offers that are closer to the QPA" and to "avoid the Federal IDR process altogether." 86 Fed. Reg. at 56,061. But an IDR process rigged simply to reaffirm the QPA is neither an independent process nor faithful to Congress's directive to consider multiple enumerated factors in making a decision.

12. *Second*, Part I compounds this error by intentionally depressing the QPA for air ambulance services in a manner contrary to the statutory language and wholly divorced from

market realities. Under the statute, the QPA is supposed to reflect the median of the "contracted rates recognized by the plan" offering the "same or similar" service provided by a provider in the "same or similar specialty" and "geographic region." PHSA § 2799A-1(a)(3)(E)(i)(I). IFR Part I defies this language in three interrelated ways: (1) it excludes most categories of agreed-upon payments between air ambulance providers and health plans; (2) it fails to distinguish between hospital-based air ambulance services and independent air ambulance services; and (3) it relies on overbroad geographic regions.

13. First, while IFR Part I defines a "contracted rate" as the amount "a group health plan has contractually agreed to pay," it specifies arbitrarily that a contract between an air ambulance provider and a plan "for a specific participant . . . does not constitute a contract." 86 Fed. Reg. at 36,953. This exception conflicts with the statute, which reaches *all* "contracted rates," and it arbitrarily excludes from calculation of the QPA the single-case rates for air ambulance services that are actually negotiated "under such plans or coverage." PHSA § 2799A-1(a)(3)(E)(i)(I).

14. Excluding single-case agreements and other types of historical payments results in intentional QPA deflation. Single-case rates are, by definition, contracted rates. The single case rate represents what the group health plan or issuer actually will pay and the provider will accept. The circumstances under which they are negotiated make them a market rate, particularly given the limited history of network contracting in the air ambulance industry.

15. Second, IFR Part I fails to distinguish between hospital-based air ambulance providers and independent air ambulance providers for purposes of calculating the QPA. Eliminating single-case agreements and treating these different providers the same will further deflate the QPA. That is because hospital-based air ambulance providers' rates comprise a larger number of the contracted rates in the QPA analysis. In-network agreements with payers are, in general, reached more often for hospital-based air ambulance providers because the hospitals enter into global agreements for all of their service lines (including air ambulance) which can cross-subsidize the

cost of the air ambulance services. Hospitals can also negotiate volume discounts across the full suite of hospital services that independent air ambulance providers simply do not offer. Indeed, sometimes the negotiated in-network rates are altogether illusory, negotiated by hospitals that do not even conduct air ambulance transports. In-network rates negotiated for hospital-based air ambulance services, such as they are, therefore do not cover "similar" specialty services (*id.*) or reflect market conditions for independent air ambulance providers. The Departments accounted for this distinction for other types of providers, for example, by treating hospital-based and freestanding emergency departments separately. 86 Fed. Reg. at 36,892. But when it came to the air ambulance industry, the Departments arbitrarily chose to depress air ambulances' QPAs by treating all providers the same.

16. Third, the Departments exacerbated these distortions by arbitrarily defining "geographic region" to mean Census-defined metropolitan statistical areas (which are derived without any consideration of the factors that actually affect air ambulance services or pricing), extending the relevant geographic regions for determining region-specific QPAs by hundreds of miles, far beyond what common sense and experience support.

17. The Departments' arbitrary approach to defining the QPA reflects an arbitrary, counter-textual decision to depress the QPA for air ambulance services, in contravention of the regime that Congress adopted. Indeed, the Departments readily concede in IFR Part I that they have purposefully adopted standards designed to deflate the QPA below actual "contracted rates recognized by the plan or issuer" for air ambulance services reimbursed "under such plans or coverage" (PHSA § 2799A-1(a)(3)(E)(i)(I)). *See* 86 Fed. Reg. at 36,891. That approach is inconsistent with both the statutory text and purpose, and if not vacated, will diminish the availability of air ambulance services, with devastating consequences for individuals in need of those services.

18. In sum, the Departments tasked with implementing the Act have turned the statutory text on its head. They adopted a policy that was rejected by Congress in the Act itself to

administratively deflate the amount an out-of-network provider can hope to get from a group health plan or issuer by excluding ubiquitous types of "contracted rates" from consideration in the QPA. And they have dictated the outcome of the IDR process by making the QPA presumptively dispositive, forcing the provider to take that purposefully deflated rate. In so doing, the Departments have gutted the IDR process that Congress created and jeopardized the ongoing viability of air ambulance providers generally. Without adequate payments to cover their fixed costs, air ambulance providers will be driven out of the market. These harms are imminently approaching, with the IFRs' requirements set to apply to plan years beginning January 1, 2022.

19. Congress did not intend to cripple the air ambulance industry like this. The Act was supposed to remove patients from the payment disputes between group health plans or issuers and providers and to give both sides the necessary tools to reach prompt and reasonable resolutions of those disputes. The IFRs twist Congress's balanced design into an indefensibly one-sided scheme that disfavors air ambulance providers. They are arbitrary and contrary to law and should be swiftly set aside in part.

PARTIES

20. Plaintiff the Association of Air Medical Services is the international trade association that represents over 93% of air ambulance providers in the United States. Together, AAMS's 300 members operate more than 1,000 helicopter air ambulances and 200 fixed wing air ambulance services across the United States. AAMS represents every emergency air ambulance care model, including hospital-based aircraft, independent aircraft at bases in rural areas far from hospitals, and many hybrid variations. AAMS represents and advocates on behalf of its members in a variety of forums. As part of that mission, AAMS brings litigation, including the instant action, on behalf of its members to challenge government action that will harm them.

21. Defendant U.S. Department of Health and Human Services is the federal department charged with substantial responsibility for public health.

22. Defendant Xavier Becerra is the Secretary of Health and Human Services. The Secretary of Health and Human Services is the official charged by law with administering the Public Health Service Act. He is sued in his official capacity only.

23. Defendant U.S. Office of Personnel Management is the federal agency charged with administering the Federal Employees Health Benefit Program.

24. Defendant Kiran Ahuja is the Director of the U.S. Office of Personnel Management. She is sued in her official capacity only.

25. Defendant Laurie Bodenheimer is the Associate Director, Healthcare and Insurance, in the Office of Personnel Management. She is sued in her official capacity only.

26. Defendant U.S. Department of Labor is the federal department with substantial responsibility for labor issues.

27. Defendant Martin J. Walsh is the Secretary of Labor. The Secretary of Labor is an official charged by law with administering the Employee Retirement Income Security Act of 1974 (ERISA). He is sued in his official capacity only.

28. Defendant U.S. Employee Benefits Security Administration (EBSA) is an agency within the U.S. Department of Labor. The EBSA has delegated authority for administering ERISA.

29. Defendant Ali Khawar is the Acting Assistant Secretary for the Employee Benefits Security Administration. He is sued in his official capacity only.

30. Defendant U.S. Department of the Treasury is the federal department with substantial responsibility for managing federal finances and for enforcing finance and tax laws.

31. Defendant Janet Yellen is the Secretary of the Treasury. The Secretary of the Treasury is the official charged by law with administering the Internal Revenue Code. She is sued in her official capacity only.

32. Defendant Lily L. Batchelder is Assistant Secretary of the Treasury (Tax Policy). She is sued in her official capacity only.

33. Defendant Internal Revenue Service (IRS) is a federal agency within the Department of the Treasury. The IRS has delegated authority for administering the Internal Revenue Code.

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

35. Defendant Douglas W. O'Donnell is the Deputy Commissioner for Services and Enforcement in the Internal Revenue Service. He is sued in his official capacity only.

JURISDICTION AND VENUE

36. AAMS brings this suit under the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201.

37. The court's jurisdiction is invoked under 28 U.S.C. § 1331.

38. Venue is proper in this district under 28 U.S.C. § 1391(e) because at least one defendant resides in this district and a substantial part of the events or omissions giving rise to the claim occurred in this district.

FACTUAL ALLEGATIONS

A. The air ambulance industry

39. The air ambulance industry is an integral part of the emergency medical system. Air medical services are often the only lifeline that critically ill and injured patients have to definitive care, especially in rural areas.

40. Traumas, stroke, heart attacks, burns, and high-risk neonatal or pediatric cases account for 90 percent of all helicopter air ambulance transports. Without helicopter air ambulances, more than 85 million Americans would not be able to reach a Level 1 or 2 trauma center within an hour when these emergent circumstances arise.

41. Air ambulance providers play no role in determining whether or when to transport a patient. Instead, first responders, like local police and fire departments, or treating physicians, decide when a patient needs to be transported.

42. Air ambulance providers do not question a first responder's or physician's request for services; indeed, in many states, emergency medical services providers have a duty to respond imposed as a condition of licensure. Thus, air ambulance providers determine only whether aviation conditions are safe to fly the patient.

43. At the outset, air ambulance providers are never aware of a patient's ability to pay or their health insurance status. Instead, the goal is to efficiently provide the highest quality of transport safety and patient care and to respond to transport requests within minutes.

44. Air ambulance providers operate under an incredibly complex regulatory regime, with regulatory obligations flowing from numerous federal and state authorities. Air ambulances typically must maintain an air carrier certificate from the Federal Aviation Administration (FAA) to conduct on-demand operations under 14 C.F.R. Part 135 (called a Part 135 certificate), maintain a state-issued ambulance license, and meet the conditions of participation for Medicare, Medicaid, and other federal and state healthcare programs. The Part 135 certificate authorizes the air ambulance to engage in air transportation, while the state ambulance license is necessary for providing medical ambulance operations and billing for the services rendered.

45. The overlap between federal and state regulatory authority is important because more than 33% of helicopter air ambulance flights will cross a state border and nearly all cross a county or municipal boundary. Nearly all fixed-wing air ambulances cross state borders. Seamless interstate delivery of services is possible in part because the Airline Deregulation Act preempts many state laws relating to air carriers. *See* 49 U.S.C. § 41713(b).

46. The delivery of on-demand, heavily regulated, life-saving air ambulance services in emergencies requires substantial investments in specialized aircraft, air bases, technology, personnel, and regulatory compliance systems. For example, to maintain a 24-hour on-demand service, an air ambulance provider would need to have on staff at least 4 pilots, 4 nurses, 4 paramedics, and a mechanic. These costs remain the same regardless of how many transports a provider makes. Variable costs—like fuel and consumed medical supplies—are an important but relatively small proportion of a provider's costs.

47. Though an air ambulance provider's costs are mostly fixed, the volume of emergent and unplanned transports, particularly in rural areas, can vary greatly across both geography and time for reasons outside the air ambulance provider's control. A rural community without a hospital may only need a helicopter air ambulance on an infrequent basis, but, when the need arises, it is most often critical. And it is increasingly critical given that 138 rural hospitals have closed since 2010. *Rural Hospital Closures*, Cecil G. Sheps Ctr. for Health Servs. Rsch. (visited Nov. 15, 2021), perma.cc/LE9K-U3QX.

48. Because of the emergent and unplanned need for services, transport volume can be unpredictable. Regardless, issuers or group health plans cannot steer patients toward particular air ambulance providers in exchange for discounted rates like they can by putting a particular physician or hospital in their network to encourage patients to choose those providers. These structural features of air ambulance operations provide a natural disincentive for issuers and group health plans to contract with air ambulance providers.

49. The structure of air ambulance providers also affect their ability to procure network contracts. Air ambulance services are not typically offered as a public service, like police and fire department services are. Some air ambulances are operated by a hospital or a community organization or split between two or more such entities. But most air ambulances are operated by

standalone operators that hold both federal and state authorizations and are not affiliated with a single hospital or community organization.

50. These differences in structure have naturally driven how air ambulance providers negotiate rates for services. For example, entities that bill through a hospital system commonly enter into a network agreement with an issuer based on a much broader universe of hospital-based services that the hospital system offers and can take into account the universe of hospital services when negotiating payment. A negotiating hospital is not likely to focus on a discrete and comparatively small service line like air ambulance when negotiating a global agreement; indeed, they sometimes agree to an air ambulance rate even when they do not offer the service. As a result, air ambulance transport rates in hospital contracts are often far lower than the true cost of providing care in the area. Hospital-contract rates are thus a factually insupportable comparator for rates that independent air ambulance service providers could agree to.

51. Group health plans have, at various times, offered to bring air ambulance providers in-network by offering to pay at rates equal to Medicare rates. But Medicare rates are often significantly below the cost of providing air ambulance services. Xcenda, *Air Medical Services Cost Study Report* 15 (Mar. 24, 2017), perma.cc/H4M3-W93D; *see also* Gov't Accountability Off., *Air Ambulance: Data Collection and Transparency Needed to Enhance DOT Oversight* 13-14, 16-18 (July 2017), perma.cc/3XGW-JNGA. An air ambulance provider that was paid only on Medicare rates could not generate sufficient revenue to cover its costs. Indeed, in areas with a high percentage of Medicare and Medicaid patients, air ambulance bases have been forced to close.

B. The No Surprises Act

52. The disincentives for group health plans and issuers to bring air ambulance providers in network have historically placed patients and air ambulance providers in an untenable situation. Patients needed the emergency air ambulance transport, and air ambulance providers had a duty to provide it as safely and efficiently as possible without regard to the patient's ability to

pay. Those same features of the air ambulance industry made it exceedingly difficult for air ambulance providers (especially independent ones) to procure network contracts that would enable them to cover their high fixed costs and meet all federal and state regulatory requirements.

53. By keeping air ambulance service providers out of network, group health plans and issuers left patients with the responsibility to pay out-of-pocket substantial portions of the bill for critical air ambulance services. If the patient could not afford the bill, the burden of covering the cost would fall on the air ambulance provider, jeopardizing its ability to recoup sufficient revenue to cover its costs and maintain its ongoing operations.

54. Patients also found themselves in the middle of payment disputes. It was common for a group health plan or issuer to send a below-cost payment for the air ambulance services to the patient and then instruct the provider to bill the patient. That practice put the patient in the position of conducting a three-way arbitration of the payment amount.

55. Congress sought to address the problem of placing patients in the middle of what is, at bottom, a payment dispute between the patient's group health plan or issuer and the provider.

56. On December 27, 2020, the President signed the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 into law. The No Surprises Act (or the Act) was enacted as Title I to Division BB of the Consolidated Appropriations Act, 2021.

57. The Act generally obligates group health plans and issuers to apply the same cost-sharing levels to out-of-network and in-network emergency services, prevents emergency service providers from holding a patient liable for the balance of a bill, and provides an independent dispute resolution process for group health plans and issuers and out-of-network providers to reach a fair payment amount.

58. Given the unique nature of air ambulance services, Congress addressed such services on their own, separate from all other services. Section 105 of the Act includes provisions specific to air ambulance services. It includes the same provisions three times over—by amending

the Public Health Service Act, the Employee Retirement Income Security Act (ERISA) of 1974, and the Internal Revenue Code—so that it reaches commercially insured patients whether enrolled in private sector group health plans or health insurance coverage. It also amended the Federal Employees Health Benefit (FEHB) Program Act to require carriers offering FEHB plans and providers serving FEHB-insured patients to comply with the substantive obligations of the Act with respect to FEHB plans.[5]

59. The Act is designed to establish parity between in-network and out-of-network providers from the patient's perspective. It thus provides that when a participant enrolled in a relevant group health plan or insurance product "receives air ambulance services from a nonparticipating provider" and "if such services would be covered if provided by a participating provider," then:

> (1) the cost-sharing requirement shall be the same for the nonparticipating provider as for a participating provider, and any coinsurance or deductible shall be based on rates applicable to a participating provider;
>
> (2) any cost-sharing amounts will be counted towards the in-network deductible and in-network out-of-pocket maximum in the same way as if it were furnished by a participating provider; and
>
> (3) the plan or issuer shall (A) send an initial payment or notice of denial of payment to the provider within 30 calendar days after the provider transmits its bill and (B) pay a total plan payment to the provider equal to the determined out-of-network rate less the amount of any patient cost-sharing or any initial payment to the provider.

See PHSA § 2799A-2(a).

[5] For ease, we cite to the provisions amending the Public Health Service Act only, by citing to the PHSA itself. The provisions enacted into ERISA and the Internal Revenue Code are the same in all material respects.

60. The Act then establishes a two-stage process for resolving disputes about the applicable out-of-network rate for an air ambulance provider. The parties first engage in open negotiations and, if negotiations fail, they enter the IDR process to have a neutral party independently determine the amount owed.

61. First, there are private negotiations between the provider and the group health plan or issuer. Within 30 days after the provider receives an initial payment or notice of denial of payment, the provider or group health plan or issuer may "initiate open negotiations . . . for purposes of determining, during the open negotiation period, an amount agreed on by such provider, and such plan or coverage for payment (including any cost-sharing) for such service." The open-negotiation period lasts for 30 days following the date of initiation of open negotiations. PHSA § 2799A-2(b)(1)(A).

62. Second, if no payment determination is reached by the close of the open-negotiation period, the parties can proceed through the IDR process wherein a neutral party will decide the amount owed. Either the provider or the group health plan or issuer may "initiate the independent dispute resolution process" within the four days following the close of the open-negotiations period by submitting a notification to the other party and to the relevant Secretary. PHSA § 2799A-2(b)(1)(B).

63. The parties must then agree to use a particular certified IDR entity within three business days or the Secretary will select one. PHSA §§ 2799A-2(b)(4)(B), 2799A-1(c)(4)(F).

64. The statute then provides for a "final offer" or "baseball-style" determination of the payment amount. That is, within 10 days after selection of the IDR entity, each party must "submit to the certified IDR entity" "an offer for a payment amount for such services furnished by such provider" along with any information requested by the IDR entity and any information relating to the offer the party wants to submit. PHSA § 2799A-2(b)(5)(B).

65. The IDR entity must then, within 30 days following its appointment, "select one of the offers submitted" by the parties to be the payment amount for the services. PHSA § 2799A-2(b)(5)(A).

66. The statute describes in detail what the IDR entity must consider in determining the payment amount. *See* PHSA § 2799A-2(b)(5)(C). It does not state or imply that any particular factor is the primary or presumptive factor. Instead, it provides that the IDR entity "*shall consider*" "the qualifying payment amounts" for the applicable year for "comparable" services "in the same geographic region" *and* "information on any [additional] circumstance" listed in the statute or requested by the IDR entity. *See id.* § 2799A-2(b)(5)(C)(i)(I), (II) (emphasis added).

67. The statute enumerates the relevant additional circumstances, in addition to the QPA and information the IDR entity requests, that it "shall consider." Those include:

> (I) The quality and outcomes measurements of the provider that furnished such services.
>
> (II) The acuity of the individual receiving such services or the complexity of furnishing such services to such individual.
>
> (III) The training, experience, and quality of the medical personnel that furnished such services.
>
> (IV) Ambulance vehicle type, including the clinical capability level of such vehicle.
>
> (V) Population density of the pick up location (such as urban, suburban, rural, or frontier).
>
> (VI) 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 and the plan or issuer, as applicable, during the previous 4 plan years.

PHSA § 2799A-2(b)(5)(C)(ii).

68. The "qualifying payment amount" is also defined in the statute. PHSA § 2799A-2(c)(2) (incorporating PHSA § 2799A-1(a)(3)). It is generally the "median of the contracted rates

recognized by the plan or issuer" "for the same or a similar item or service" as of January 31, 2019, that are offered in the same insurance market (i.e., the individual market, large group market, small group market, or self-insured group health plan market) and in the same geographic region, increased by the consumer price index. *Id.* § 2799A-1(a)(3)(E)(i).

69. The statute further directs the Secretaries to determine "the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in rural and underserved areas, including health professional shortage areas" and that they may "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." PHSA § 2799A-1(a)(2)(B).

70. When the group health plan or issuer lacks sufficient information to determine a median contracted rate, the statute authorizes the plan or issuer to determine the QPA through resort to information from a third-party database (*e.g.*, FAIR Health). PHSA § 2799A-1(a)(3)(E)(iii).

71. The statute prohibits the IDR entity from considering certain specific factors—the usual and customary charges of the provider, the amount that the provider would have billed the patient absent the ban on balance billing, or the reimbursement rate that would be paid under governmental health programs. PHSA § 2799A-2(b)(5)(C)(iii).

72. Aside from the prohibition on considering certain factors, the No Surprises Act does not deem any other circumstances presumptively reasonable or owed more weight. Instead, the IDR entity is required to consider them all. This was purposeful. Congress specifically considered and rejected a proposal that would have mandated that payment be "the recognized amount," i.e., an amount set by state law or the median contracted rate. *See* Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020) (proposing new PHSA § 2719A(f)).

73. Instead, under the No Surprises Act, after considering the QPA, the additional circumstances, and any requested information, the IDR entity then selects one of the party's offers to be the rate for the service.

74. The statute requires the group health plan or issuer to pay the amount owed to the provider (less any cost-sharing or initial payment amounts) not later than 30 days after the IDR entity makes its independent determination. PHSA § 2799A-2(b)(6).

75. To ensure that disputes over payment remain between the provider and the group health plan, the statute also bars air ambulance providers from billing a plan participant for more than the cost-sharing amount if she has air ambulance benefits. In other words, the statute prohibits "balance billing." The statute provides that, when a participant has air ambulance benefits under her plan, an air ambulance provider "shall not bill" the participant "for a payment amount for such service furnished by such provider that is more than the cost-sharing amount for such service." PHSA § 2799B-5.

76. To ensure the timely implementation of the Act, Congress directed the Secretaries of Health and Human Services, of the Treasury, and of Labor to engage in rulemaking by specified statutory deadlines.

(a.) By July 1, 2021, the Secretaries were to "establish through rulemaking" the "methodology" to "use to determine the qualifying payment amount"; the "information" the plan or issuer must "share with the nonparticipating provider … when making such a determination"; the "geographic regions . . . taking into account access to items and services in rural and underserved areas"; and "a process to receive complaints of violations." PHSA § 2799A-1(a)(2)(B). In setting "the geographic regions" the rulemaking is required to "tak[e] into account access to items and services in rural and underserved areas, including health professional shortage areas" (*id.* § 2799A-1(a)(2)(B)(iii)) and may "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" (*id.* § 2799A-1(a)(2)(B)).

(b.) Within one year of enactment, i.e., December 27, 2021, the Secretaries were to "establish by regulation one independent dispute resolution process" under which "a certified IDR entity . . . determines . . . the amount of the payment under the plan or coverage" for qualified air ambulance services. *Id.* § 2799A-2(b)(2)(A).

C. The Interim Final Rules

77. To implement the Act, the Departments issued two interim final rules without a notice-and-comment period. But the voluminous IFRs are "interim" in name only. They could have been developed and issued only through a coordinated inter-agency process driven to conclusion by the Executive Office of the President and are thus plainly the consummation of the Departments' collective decision-making process. They create rights and impose obligations on air ambulance providers, group health plans, and issuers. While the Departments invited comment on certain aspects of the IFRs, they are not under any binding legal obligation to review and consider comments, much less issue final, superseding rules. Indeed, the Departments designed the IFRs to operate ad infinitum by enacting a QPA-calculation methodology that adjusts with the consumer price index (86 Fed. Reg. at 36,894) and a fee structure for IDR entities that the Departments will "review and update . . . annually" (86 Fed. Reg. at 56,005).

1. IFR Part I: Qualifying payment amount methodology

78. On July 13, 2021, the Departments issued the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021). 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.

79. Among other things, IFR Part I generally addresses the calculation of the QPA pursuant to Congress's directive to issue regulations on methodology by July 1, 2021. *See* PHSA § 2799A-1(a)(2)(B).

80. In particular, IFR Part I purports to establish the methodology for calculating the QPA for air ambulance services.

81. In the preamble, the Departments posit that the "statutory intent" of the Act was to "ensur[e] that the QPA reflects market rates under typical contract negotiations." 86 Fed. Reg. at 36,889. But in practical effect, the IFR administratively deflates the QPA well below what market conditions actually produce.

82. IFR Part I defines the "same or similar item or service" as a service "billed under the same service code." 86 Fed. Reg. 36,954. For air ambulance services, there are generally two air mileage service codes—A0435 (fixed-wing) and A0436 (rotary-wing). *Id.* at 36,895, 36,955.

83. Though it defines a "provider in the same or similar specialty" generally as "the practice specialty of a provider, as identified by the plan consistent with the plan's usual business practice," it sets a completely different definition for air ambulance services: "with respect to air ambulance services, *all* providers of air ambulance services are considered to be a single provider specialty." 86 Fed. Reg. 36,954 (emphasis added).

84. It defines a "geographic region" "[f]or air ambulance services" as "one region consisting of all metropolitan statistical areas . . . in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up." 86 Fed. Reg. at 36,954. When a plan does not have "sufficient information" to calculate the median contracted rate, then the geographic region becomes "one region consisting of all metropolitan statistical areas . . . in each Census division and one region consisting of all other portions of the Census division." *Id.*[6]

[6] There are only nine Census divisions: Pacific, Mountain, West North Central, East North Central, Middle Atlantic, New England, South Atlantic, East South Central, and West South Central.

85. The plan must then calculate the "median contracted rate" by "arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity . . .) in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number." 86 Fed. Reg. at 36,954. For purposes of contracted rates, the health plan only looks at rates it has "contractually agreed to pay a . . . provider of air ambulance services for covered items or services," expressly excluding any "single case agreement, letter of agreement, or other similar arrangement . . . for a specific participant or beneficiary in unique circumstances" as "not constitu[ting] a contract." *Id.* at 36,953. The preamble to the rule does not justify this exclusion.

86. The plan then calculates the QPA by increasing the median contracted rate consistent with the consumer price index and then multiplying it by the number of "loaded miles," *i.e.*, the number of miles the individual is transported. 86 Fed. Reg. at 36,955.

87. If the plan lacks sufficient information to calculate a median contracted rate, then the plan may determine the QPA via third-party database. 86 Fed. Reg. at 36,895-36,897.

2. IFR Part II: IDR process

88. On October 7, 2021, the Departments issued the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021). IFR Part II took effect on October 7, 2021, and is, in general, applicable to plan, policy, or contract years beginning January 1, 2022, though a handful of requirements took effect immediately. 86 Fed. Reg. at 55,980.

See Census Regions and Divisions of the United States, Census.gov (last visited Oct. 29, 2021), https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.

89. Among other things, IFR Part II generally addresses the IDR dispute resolution process pursuant to Congress's directive to issue a single set of regulations on the process within one year. *See* PHSA § 2799A-2(b)(2)(A).

90. IFR Part II flips the statutory IDR process on its head by giving the QPA nearly conclusive weight in an IDR entity's decision. Specifically, IFR Part II dictates that "[t]he certified IDR entity *must* select the offer closest to the qualifying payment amount" unless one of two circumstances occurs: "[1] 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 [2] if the offers are equally distant from the qualifying payment amount but in opposing directions." 86 Fed. Reg. at 56,104 (emphasis added). "In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer." *Id.*

91. To rebut the IFR-created presumption that the offer closest to the QPA should be the rate, IFR Part II requires the submission of additional information, including "information on the size of the provider's practice," "information on the practice specialty," "information on the coverage area of the plan, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured," and "[t]he qualifying payment amount." 86 Fed. Reg. at 56,103.

92. IFR Part II then relegates the remaining factors Congress required the IDR entity to consider to afterthoughts, merely permitting submission of information concerning the "additional circumstances" that the statute expressly requires the IDR entity to consider in every case. IFR Part II

- lists the statutory factors—"the level of training, experience, and quality and outcomes measurements of the provider"; "[t]he acuity of the participant . . . or the

complexity of furnishing the qualified IDR item"; "[d]emonstration of good faith efforts (or lack thereof) made by the provider . . . or the plan to enter into network agreements with each other" (*see* PHSA § 2799A-2(b)(5)(C)(ii));

- adds two circumstances—"[t]he market share held by the provider . . . or that of the plan in the geographic region" and the "[t]he teaching status, case mix, and scope of services of the facility"; and
- allows for "[a]dditional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors" on which consideration is barred.

Id. at 56,104.

93. But IFR Part II limits consideration of these additional circumstances and information only for purposes of rebutting the IFR-created presumption of choosing the QPA and only if it satisfies a heightened credibility standard. *Id.*

THE INTERIM FINAL RULES ARE UNLAWFUL

94. The Interim Final Rules are contrary to law and arbitrary and capricious. The purpose of the Act was to protect patients from surprise medical bills from out-of-network providers by limiting their cost-sharing to in-network levels and removing patients from payment disputes between plans and providers.

95. Congress intended to facilitate negotiations between the provider and the group health plan or issuer to resolve payment disputes and, when that does not work, to allow an independent entity to decide the payment amount by selecting between each party's final offer. This structure forces providers and group health plans or issuers to reach reasonable and efficient outcomes through rational business and legal judgments that account for available information about market rates, out-of-network payments, operating costs, and the IDR entity.

96. The Act does not authorize the Departments to artificially deflate payment amounts

from group health plans or issuers to air ambulance service providers in a manner entirely out of step with the history and economics of the air ambulance industry. That, however, is what the Departments have done through the IFRs. And they have done so in ways that directly contravene the statute.

97. IFR Part II dictates the outcome of the IDR process by making a purposefully deflated QPA—calculated exclusively by the group health plan or issuer—the presumptively correct payment amount. IFR Part I ensures that the QPA for air ambulance is at an artificially low rate by excluding from consideration the case-specific or other agreed-upon rates actually negotiated for covered air ambulance services and refusing to distinguish between hospital-based and non-hospital-based providers. The rule also extends the relevant geographic region without justification to certain Census-defined levels. These choices and the presumption defy the statute and squarely conflict with the Act's goal of facilitating reasonable and efficient outcomes while protecting patients from being put in the middle.

A. IFR Part II is unlawful.

98. Through IFR Part II, the Departments effectively nullify the statutory IDR process that Congress envisioned, replacing it instead with nearly insurmountable deference to the QPA.

99. The Act provides for a "final offer" or "baseball style" determination of the payment amount by a certified independent dispute resolution entity after considering various factors listed in the statute. Final-offer dispute resolution "is designed to not only persuade parties to settle their disputes to avoid unpredictable and uncompromising hearings, but also to submit reasonable proposals before the hearing." Matt Mullarkey, Note, *For the Love of the Game: A Historical Analysis and Defense of Final Offer Arbitration in Major League Baseball*, 9 Va. Sports & Ent. L.J. 234, 245 (2010). The "all-or-nothing approach is designed to promote reasonable offers because every dollar that a [claimant] adds to his proposal moves up the midpoint and decreases his chance of winning." *Id.* In final-offer resolution, there is typically no written opinion or reasoning

behind the decision, further encouraging the push for reasonableness between the parties. *Id.* at 238.

100. Congress's design was thus to encourage payers and air ambulance providers to resolve their monetary disputes through negotiations between each other to avoid having to risk it all in an IDR determination with little guidance as to what a particular IDR entity would view as the reasonable payment amount. And, even if the parties could not reach an agreement through negotiations, final-offer dispute resolution creates strong incentives for both sides to put forth their most reasonable offer and then for the certified IDR entity to choose the one that it deems most reasonable. The need to make a reasonable offer is reinforced by the statute's obligation on the losing party to bear the costs of the IDR process.

101. IFR Part II unapologetically vitiates this design and, in so doing, conflicts with the statutory language.

102. The statute provides that the IDR entity shall, "taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such services determined under this subsection for purposes of subsection (a)(3)." PHSA § 2799A-2(b)(5)(A). The "considerations specified in subparagraph (C)" that the IDR entity "*shall consider*" are numerous—the QPA, the provider's quality and outcomes measurements, the medical personnel's level of training, experience, and quality, the acuity of the individual and complexity of service, ambulance vehicle type, population density of the pick up location, and each party's demonstration of good faith efforts to reach a contracted rate. *Id.* § 2799A-2(b)(5)(C). The statute treats each of these factors equally, with no weight placed on any particular one. But, under IFR Part II, these statutorily mandated factors are rendered nearly meaningless.

103. IFR Part II irrevocably slants the "independent" dispute resolution by dictating outcomes. It demands that the certified IDR entity "*must* select the offer closest to the qualifying

payment amount," subject only to two narrow exceptions: if "[1] the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate, or if [2] the offers are equally distant from the [QPA] but in opposing directions." 86 Fed. Reg. at 56,104 (emphasis added). Then the IDR entity "must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services." *Id.*

104. According to the preamble, "emphasizing the QPA will allow for predictability" because "even before beginning negotiations, all parties involved will know that the QPA is the primary factor that the certified IDR entity will always consider (while other factors may be considered, depending on the circumstances)." 86 Fed. Reg. at 56,061. In the Departments' view, "[t]his certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor" and "may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period." *Id.*

105. IFR Part II thus writes the independent dispute resolution process out of the statute. No longer does the IDR entity determine *independently* a reasonable payment amount based on various inputs that the statute requires it to consider. Instead, the IDR entity is forced to choose the QPA in nearly all cases, despite that the QPA is effectively set by the payer itself.

106. If Congress intended the QPA to be practically dispositive, it would have said so. Indeed, it could have chosen to simply mandate the QPA as the payment amount. *See* Ban Surprise Bill Act, H.R. 5800, 116th Cong. § 2(a) (2020) (proposing new PHSA § 2719A(f)). It did not. It chose final-offer dispute resolution and called for open-ended consideration of a number of specified factors. The Departments, however, have disregarded that directive, casting aside all considerations other than the QPA in the vast majority of cases. Independent dispute resolution was not intended to be perfectly predictable, nor to force the parties to accept the QPA, especially a QPA

so unreliably derived. By strictly curtailing the IDR entity's ability to independently select the amount of payment, IFR Part II contravenes Congress's design.

107. It is no answer to say that a provider has a narrow escape hatch from the QPA by providing evidence to "clearly demonstrate[] that the qualifying payment amount is materially different from the appropriate out-of-network rate." 86 Fed. Reg. at 56,104. It is instead circular. The statute defines the "out-of-network rate" as the amount that the parties negotiate or the IDR entity selects for the service at issue. PHSA § 2799A-1(a)(3)(K). A party cannot logically provide evidence to "clearly demonstrate" that the "qualifying payment amount is materially different" from the amount the parties have not yet had a chance to negotiate or the IDR entity has not yet determined. In practical effect, the Departments have ensured that the QPA will end matters, an outcome that Congress could have adopted but instead rejected.

B. IFR Part I is unlawful.

108. IFR Part I dictates a QPA that is, by the Departments' own admission, administratively deflated for independent air ambulance service providers but will ensure that patients are not "required to pay higher cost-sharing amounts." *See* 86 Fed. Reg. at 36,891.

109. The statutory starting point for calculating the QPA requires taking "the median of the contracted rates recognized by the plan or issuer" as of 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." PHSA § 2799A-1(a)(3)(E)(i)(I).

110. By its plain terms, the contracted rates contemplated by § 2799A-1(a)(3)(E)(i)(I) include case-specific contracts for covered services. IFR Part I, however, excludes a wide range of relevant contracts from the calculation of the median contracted rate and instead focuses only on a small portion of inapposite payment arrangements. The QPA, for example, excludes historic out-of-network payments made under the patient's health plan, letters of agreement, arrangements

used to supplement a payer's network, incentive-based and retrospective arrangements, and single case agreements. Yet these are all "contracted rates recognized by the plan or issuer" for covered services from which Congress directed the calculation of median reimbursement. *Id.*

111. The Departments acknowledged in IFR Part I that only 25% of air ambulance transports in 2012 and 31% in 2017 were made under a traditional in-network contract. 86 Fed. Reg. at 36,923. Yet under the IFRs, this unrepresentative sample of transports drives the QPA for *all* transports. The Departments' unexplained decision to disregard the majority of actual contract rates is arbitrary and contrary to law. Given these unlawful exclusions, the Departments have ensured that the methodology will not produce QPAs that actually reflect how payers and providers have historically resolved payments via negotiation.

112. The statute further directs that the rulemaking must determine "the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in rural and underserved areas, including health professional shortage areas." PHSA § 2799A-1(a)(2)(B)(iii). And the rulemaking "may . . . 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." *Id.* § 2799A-1(a)(2)(B).

113. For purposes of air ambulance services, however, the agency gives no meaning to the requirement that the service be the "same" and the "provider [be] in the same or similar specialty" nor does it adequately consider "facility type." PHSA §§ 2799A-1(a)(3)(E)(i)(I), 2799A-1(a)(2)(B). IFR Part I simply deems hospital-based and independent non-hospital-based air ambulance providers to be a "single provider specialty." 86 Fed. Reg. at 36,891. Yet the history and structure of the industry does not support treating these two vastly different service providers as the same. The Departments know this. The preamble to IFR Part I specifically explains that the

Departments "understand that hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers." *Id.* But they refused to treat these distinct types of providers differently due solely to cost-sharing considerations: "The Departments, however, are of the view that because participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider, they should not be required to pay higher cost-sharing amounts (such as coinsurance or a deductible) solely because the air ambulance provider assigned to them has negotiated higher contracted rates in order to cover its higher costs, or because it has a different revenue model, than other types of air ambulance providers." *Id.*

114. That is unsupportable. *First*, the judgments made for hospital-based air ambulance providers negotiating global agreements for numerous hospital service lines do not reflect the economic considerations that would determine a reasonable rate for an independent air ambulance provider negotiating for only air ambulance services. Air ambulance service providers that bill only for air ambulance services must ensure that rates with group health plans or issuers are sufficient to maintain services in a community. Otherwise, they cannot cover their costs. Treating these two admittedly distinct types of providers as commanding the same negotiated rates is arbitrary and capricious.

115. *Second*, the arbitrariness of the Departments' conclusion is confirmed by its treatment of hospital-based emergency departments differently from standalone emergency departments. 86 Fed. Reg. at 36,892. The Departments explained: "where a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute." *Id.* The Departments' inexplicable

decision to treat air ambulance service providers differently from hospital-based and freestanding emergency departments is arbitrary and capricious.

116. *Third*, the statute does not tie a patient's cost-sharing amount to the QPA. *See* PHSA § 2799A-2(a)(1). Instead, it directs that cost-sharing for air ambulance services be "based on rates that would apply for such services if they were furnished by such a participating provider[.]" *Id.* Congress knew how to tie cost-sharing to the QPA because it did so for emergency services, requiring cost-sharing to be calculated based on the "recognized amount," which specifically includes the QPA as one base for its calculation. *See id.* § 2799A-1(a)(1)(C)(iii), (a)(3)(H). That Congress did not do so for air ambulance services shows that it rejected intertwining patient cost-sharing and the QPA and that such concerns about patient cost-sharing cannot support the Departments' efforts to depress air ambulance reimbursements.

117. *Finally*, IFR Part I arbitrarily ignores Congress's directive to consider service providers by "geographic region." Where there are an insufficient number of contracts to determine the QPA based on state lines, IFR Part I requires the QPA to be determined using all metropolitan statistical areas in a Census division or all other areas in that Census division. But Census divisions are large. *See Census Regions and Divisions of the United States*, Census.gov (last visited Oct. 29, 2021), perma.cc/4QWX-7738. This requirement would mean that a contracted rate from Alaska or Hawaii could dictate the QPA for a medical air transport in California; or a contracted rate in Florida could dictate the QPA in Washington, D.C. By requiring calculation tailored to a "geographic region," Congress cannot have meant to have geographically and economically unique markets dictate payments in completely different markets that are thousands of miles, and even oceans, apart. The over-broadening of the 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 contracts and agreements from the QPA calculation. IFR Part I is thus contrary to law.

118. Put together, the Interim Final Rules take a statute intended to protect patients by removing them from payment negotiations between providers and payers and transform it into a rate-setting rule that will ensure that air ambulance providers receive artificially low rates (indeed, lower than the health plans paid previously) and drive them out of business, jeopardizing the access to emergency healthcare services by the very patients Congress sought to protect. The IFRs are arbitrary and capricious and contrary to law.

C. The IFRs harm air ambulance providers, including AAMS's members

119. As participants in the air ambulance industry, AAMS's members will be directly injured by the IFRs. Many of AAMS's members have been unable to procure in-network agreements with health plans or issuers in areas where they operate, and they are therefore subject to the No Surprises Act. The IFRs supplant the Act by purposefully depressing the QPA and then pushing AAMS's members into a one-sided dispute resolution process designed to impose the QPA. The natural and intended outcome of the implementation of the IFRs will be a reduction in payment to AAMS's members that could force its members out of the market altogether and, as a result, reduce access to critical emergency services for patients. These injuries are actual and imminent because the IFRs become effective for plan years starting January 1, 2022.

120. One publicly available data point that demonstrates the injury the IFRs will inflict on air ambulance providers is a report issued by FAIR Health—a non-profit claims database that CMS has certified as a Qualified Entity (QE) for the CMS QE Program. *See* FAIR Health, *Air Ambulance Services in the United States: A Study of Private and Medicare Claims* (Sept. 28, 2021), perma.cc/2EA6-PK8E. FAIR Health has determined that "[t]he average estimated allowed amount" for the base rate for an air ambulance transport is $18,668. *Id.* at 2 & n.1. The Act authorizes group health plans and issuers to use third-party databases such as FAIR Health to determine the QPA when the plan or issuer lacks sufficient information to calculate a median in-network rate. As such, FAIR Health is marketing its "average estimated allowed amount" and underlying

data to plans and issuers for that purpose, and their use of the FAIR Health information is imminent given the historically limited network contracting between plans and issuers and air ambulance providers.

121. PHI Health, LLC (PHI) is an AAMS members that will be directly injured by the IFRs. *See* Exhibit 5 (Foster Declaration). PHI delivers rotor-wing air ambulance services from 77 air bases located in 15 states and fixed wing air ambulance services from 3 air bases in California and Missouri. *Id.* ¶ 2. PHI expects that the IFRs will drive payments by group health plans or issuers to a level at or below the QPA because the IFRs eliminate any rational business reason for plans or issuers to enter into a network contract with an air emergency ambulance provider at a rate exceeding the plan's or issuer's QPA. *Id.* ¶ 11. PHI estimates that, if all plans and issuers began paying $18,668 or less for the base rate for out-of-network air ambulance transport beginning on January 1, 2022, then most of PHI's air bases would experience reductions in revenue. *Id.* ¶ 16. Indeed, PHI expects that the "reductions in revenue would be so great that as many as 33 of [PHI's] air bases would cease to cover their costs, and it would become necessary for [PHI] to close or consolidate some or all of those air bases as soon as possible in calendar year 2022," causing an irreparable injury. *Id.* ¶¶ 16-19.

122. Global Medical Response, Inc. (GMR) is an AAMS member that will be directly injured by the IFRs. *See* Exhibit 6 (Preissler Declaration). GMR delivers rotor-wing and fixed-wing air emergency ambulance services from 340 air bases located in 28 states. *Id.* ¶ 2. GMR likewise has concluded that the IFRs will drive payments by group health plans or issuers to a level at or below the QPA. *Id.* ¶ 11. GMR estimates that, if all plans and issuers began paying $18,668 or less for the base rate for out-of-network air ambulance transport beginning on January 1, 2022, then most of GMR's air bases would experience reductions in revenue. *Id.* ¶ 16. GMR anticipates that up to 10% of GMR's total annual emergency transports for all air bases in calendar year 2022 will be paid by reference to the FAIR Health database or other QPA equivalent. *Id.* ¶ 17. If group

health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the base rate when paying for 10% of GMR's total annual transports for all air bases, then "most of GMR's bases would experience reductions in revenue for calendar year 2022." *Id.* ¶ 18.

123. Air Methods Corporation (AMC) is an AAMS member that will be directly injured by the IFRs. *See* Exhibit 7 (Portugal Declaration). AMC delivers rotor-wing air ambulance services from 257 air bases located in 42 states and fixed-wing air ambulance services from 27 air bases located in 15 states. *Id.* ¶ 2. AMC has concluded that, if all plans and issuers began paying $18,668 or less for the base rate for out-of-network air ambulance transport beginning on January 1, 2022, then eighty percent of AMC's air bases would experience reductions in revenue. *Id.* ¶ 16. AMC estimates that up to 7% of AMC's total annual transports in calendar year 2022 will be paid by reference to the FAIR Health database or other QPA equivalent. *Id.* ¶ 17. If group health plans and issuers use the FAIR Health average estimated allowed amount of $18,668 as the base rate when paying for 7% of AMC's total annual transports for each air base, then "eighty percent of AMC's bases would experience reductions in revenue for calendar year 2022." *Id.* ¶ 18.

CLAIMS FOR RELIEF

Count I
Administrative Procedure Act
IFR Part II - arbitrary, capricious, and contrary to law weighting of QPA

124. AAMS incorporates and re-alleges the foregoing paragraphs as though fully set forth herein.

125. IFR Part II is final agency action subject to review under the APA. 5 U.S.C. § 704. IFR Part II 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.

126. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

127. It likewise authorizes courts to set aside agency action "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

128. IFR Part II violates these APA requirements. It squarely conflicts with the provisions of the statute establishing the IDR process, which require equal consideration of all the enumerated factors, and it is therefore in excess of statutory limits.

129. IFR Part II is also arbitrary and capricious because it gives presumptively dispositive weight to a QPA that itself is calculated in an arbitrary and capricious manner, as described herein.

130. Accordingly, those elements of the Interim Final Rule Part II that require IDR entities to give presumptively dispositive weight to the QPA must be set aside. 5 U.S.C. § 706(2).

Count II
Administrative Procedure Act
IFR Part I - arbitrary, capricious, and contrary to law derivation of QPA

131. AAMS incorporates and re-alleges the foregoing paragraphs as though fully set forth herein.

132. IFR Part I is final agency action subject to review under the APA. 5 U.S.C. § 704. IFR Part I 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.

133. The APA empowers courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

134. It likewise authorizes courts to set aside agency action "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

135. The Interim Final Rule Part I violates these APA requirements. IFR Part I conflicts with the relevant provisions of the statute, and it is therefore in excess of statutory limits, by excluding swaths of case-specific contracts and agreements from the definition of "contracted rates."

136. The preamble to IFR Part I also recognizes, but then disregards, the critical differences between hospital-based and independent air ambulance service providers, justifying its decision to treat them the same based purely on a desire to reduce patient cost-sharing. That reasoning fails to "articulate . . . a 'rational connection between the facts found and the choice made,'" "offer[s] an explanation for its decision that runs counter to the evidence before the agency," "fail[s] to consider an important aspect of the problem," and "relie[s] on factors which Congress has not intended it to consider." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

137. Further, by lumping independent and hospital-based air ambulance providers together, while not doing so in similar cases (like hospital-based and freestanding emergency facilities), it "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).

138. IFR Part I also broadly construed the geographic region to reach the Census-division level, potentially allowing contracted rates in Hawaii to dictate rates in rural Washington. By doing so, the agency "failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. And it did so without "articulat[ing] . . . a 'rational connection between the facts found and the choice made'" because the only justification is lack of sufficient volume of contracted rates—a problem the agency created for itself by defining "contracted rates" to exclude substantial volumes of contracts contrary to the statute. *Id.*

139. Accordingly, those elements of the Interim Final Rule Part I that govern QPA determinations for air ambulance services must be set aside. 5 U.S.C. § 706(2).

PRAYER FOR RELIEF

AAMS respectfully requests that the Court enter judgment in its favor and that the Court:

(a.) Vacate the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021):

- Section 54.9816-8T(c)(4)(B)(ii)'s direction that "[t]he 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. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer."

(b.) Vacate the following elements of the interim final rule entitled *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021):

- Section 54.9816-6T(a)(1)'s direction that "[s]olely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract."
- Section 54.9816-6T(a)(7)(ii)'s provision that "[i]f a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region

described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605)."

- Section 54.9816-6T(a)(12)'s provision that "except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty."

(c.) Issue a declaratory judgment that these portions of the interim final rules were issued in violation of the Administrative Procedure Act;

(d.) Enjoin Defendants from implementing, enforcing, or otherwise carrying out these portions of the interim final rules;

(e.) Award AAMS attorney's fees and costs; and

(f.) Award AAMS such other and further relief as the Court may deem just and proper.

Dated: November 16, 2021

Respectfully submitted,

/s/ *Sarah P. Hogarth*
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