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

LIFENET, INC. Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. DEPARTMENT OF LABOR, U.S. DEPARTMENT OF THE TREASURY, OFFICE OF PERSONNEL MANAGEMENT, and the CURRENT HEADS OF THOSE AGENCIES IN THEIR OFFICIAL CAPACITIES, Defendants.	Case No. _____ **ORIGINAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

ORIGINAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

This is an action by LifeNet, Inc. ("LifeNet") challenging, under the Administrative Procedure Act (APA), various regulations that implement the "No Surprises Act" of 2020, Pub. L. 116-260, div. BB, tit. I (Dec. 27, 2020). This action is near-identical to a challenge filed just days ago by the Texas Medical Association ("TMA"): *Texas Medical Ass'n, et al. v. U.S. Dep't Health & Hum. Servs., et al.*, 6:22-cv-00372 (E.D. Tex.) ("*TMA II*"). LifeNet respectfully requests that these two lawsuits be consolidated.

This action, and *TMA II*, are closely related to two prior APA challenges to the earlier version of these regulations, which challenges were brought by the same plaintiffs—LifeNet and TMA. Both of those prior challenges were decided, earlier this year, by Judge Kernodle. Judge

Kernodle agreed with plaintiffs and vacated the earlier version of the regulations. *See LifeNet, Inc. v. United States Dep't of Health & Hum. Servs.*, 22-cv-00162, 2022 WL 2959715, at *1 (July 26, 2022) (Kernodle, J.) ("*LifeNet I*"); *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) (Kernodle, J.) ("*TMA I*"). Rather than appeal from Judge Kernodle's rulings, the defendant Departments instead revised the regulations. But their revisions do not remedy the flaws that Judge Kernodle identified. Because this case is so closely related to Judge Kernodle's prior decisions, Plaintiff respectfully requests assignment of this matter to Judge Kernodle as a related case.

INTRODUCTION

1. This action under the Administrative Procedure Act ("APA") challenges certain provisions of a Final Rule issued by defendants in clear violation of their statutory authority. The rule, entitled "Requirements Related to Surprise Billing," 87 Fed. Reg. 52,618 (Aug. 26, 2022) ("Final Rule"), implements provisions of the federal surprise medical billing law, the No Surprises Act, Pub. L. 116-260 ("NSA").

2. Plaintiff LifeNet is an air ambulance company. LifeNet's planes and helicopters transport hundreds of patients each year—many of whom are suffering medical emergencies and would risk death or further serious injury without LifeNet's services. Defendants are the agencies charged with implementing the No Surprises Act, and the heads of those agencies in their official capacities ("Departments").

3. The No Surprises Act, as relevant here, bars out-of-network medical providers from billing patients, for emergency medical services, in any amount greater than the patients' in-network cost-sharing obligation (e.g., co-pay). Instead, out-of-network providers must negotiate with the patient's insurer to obtain adequate reimbursement.

4. When the provider and insurer cannot agree on an appropriate reimbursement amount, either party may initiate the "Independent Dispute Resolution" (IDR) process. Through that process, the IDR entity determines the dollar amount that the plan or issuer must pay to the provider for the services provided to the patient. IDR proceedings began in March of 2022. Since then, air ambulance providers have initiated thousands of IDRs across the country.

5. A little over two months ago, in *LifeNet I*, this Court struck down those parts of the defendants' implementing regulations that imposed a "QPA Presumption" on the IDR process for air ambulances. This decision followed the Court's earlier holding in *TMA I*, which vacated the QPA Presumption in IDRs for *non*-air ambulance services.

6. The "QPA," or "qualifying payment amount," is "generally" the median in-network rate for the service at issue as agreed to by the specific payor (health plan or insurer). *See TMA*, 2022 WL 542879, at *2. As this Court found, the Old QPA Presumption "place[d] its thumb on the scale for the QPA, requiring arbitrators [i.e., the IDR entities] to presume the correctness of the QPA and then imposing a heightened burden on the remaining statutory factors to overcome that presumption." *Id.* at *8. By doing so, the Old QPA Presumption rewrote the "clear … terms" of No Surprises Act. "Nothing in the Act instructs arbitrators to weigh any one factor or circumstance more heavily than the others." *LifeNet I*, 2022 WL 2959715 at *8–9.

7. On August 26, 2022—just a few months after this Court vacated the Old QPA Presumption—the Departments promulgated the Final Rule that is challenged here. *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (August 26, 2022). That Final Rule enacts a New QPA Presumption in both air ambulance and non-air ambulance IDRs. The New QPA Presumption is a set of requirements that, although no longer labeled as a "presumption," have the same effect.

8. The New QPA Presumption, just like the last version, improperly "places a thumb on the scales" of the IDR process in favor of the QPA. *TMA I,* 2022 WL 542879, at *8. The New QPA Presumption does this in four ways:

(1) It *forbids* the IDR entity from considering the non-QPA statutory factors, which Congress specifically required them to consider, *unless* the IDR entity first (a) determines that the QPA does not "account for" those factors, and (b) explains in writing the basis for that determination;

(2) It *forbids* the IDR entity from considering any of the general non-QPA factors—such as training, experience, ambulance capabilities, etc.—unless the provider makes a heightened showing that these factors were relevant to the specific transport at issue;

(3) It *forbids* the IDR entity from questioning the "credibility" of the QPA, while requiring a "credibility" determination of all non-QPA factors; and

(4) It *requires* the IDR entity to consider the QPA first, and only "then consider" the non-QPA factors.

Taken together, these four aspects of the New QPA Presumption unlawfully elevate the QPA over the other statutory factors and make the QPA the *de facto* benchmark rate. The New QPA Presumption is therefore contrary to the statute, arbitrary, and capricious. The New QPA Presumption will have severe and negative practical consequences, because it will undermine air ambulance providers' ability to obtain adequate reimbursement for their services, to the detriment of those providers and the patients they serve.

9. Plaintiff LifeNet has therefore returned to this Court to compel the Departments to implement the law as Congress wrote it: with the QPA as one of just many factors that must be considered by the IDR entities in making their payment determinations, without any special weight

given to it over and above the other non-QPA factors. This time, LifeNet respectfully requests that the Court not only vacate the New QPA Presumption, but also remand with specific instructions to the Departments, directing them not to impose any further regulations that would elevate the QPA's weight or importance over the other factors that Congress specifically directed IDR entities to consider.

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PARTIES

10. LifeNet, Inc. is a corporation that operates one fixed-wing and two rotor-wing air ambulances from three airbases. LifeNet's air ambulances routinely transport emergency patients located in this District, in Arkansas, and in Louisiana. LifeNet's headquarters are in Texarkana, Texas.

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

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

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

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

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

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

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

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

JURISDICTION AND VENUE

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

20. LifeNet's causes of action are provided by the Administrative Procedure Act, 5 U.S.C. §§ 702-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. 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. LifeNet resides in this District, and a substantial part of the events or omissions giving rise to LifeNet's claims occurred in this District.

FACTUAL BACKGROUND

I. The No Surprises Act Created the IDR Process Without Any "QPA Presumption"

22. 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 Public Health Service ("PHS") Act, 42 U.S.C. §§ 300gg-111 *et seq.*[1]

23. The provisions of the Act at issue here are: 42 U.S.C. § 300gg-111, which governs all emergency medical services, and 42 U.S.C. § 300gg-112, which makes certain modifications for air ambulance service providers.

24. The IDR Process is 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.

[1] The NSA made parallel amendments to provisions of the PHS Act, which is enforced by the Department of Health and Human Services ("HHS"); to the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and to 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.

25. The two sides' offers are submitted simultaneously. Neither party to the IDR is permitted to see the other side's offer or the information submitted by the other party to the IDR entity.

26. In an air ambulance IDR, the No Surprises Act requires that the IDR Entity "shall . . . tak[e] into account" a list of nine "considerations" specified in the statute. 42 U.S.C. § 300gg-112(b)(5)(A). These nine "considerations" are:

a. The "qualifying payment amount" (QPA). 42 U.S.C. § 300gg-112(b)(5)(C)(i)(I). The QPA is generally the median of the rates that the specific payor agreed to pay for air ambulance services in 2019 in the geographic area in which the services at issue were provided. The statutory definition of the QPA is the same, for air ambulance services, as it is for all other items and services. *Compare id. to* 42 U.S.C. § 300gg-111(a)(3)(E).

b. "The quality and outcomes measurements of the provider that furnished such services." 42 U.S.C. § 300gg-112(b)(5)(C)(ii).

c. "The acuity of the individual receiving such services or the complexity of furnishing such services to such individual." *Id.*

d. "The training, experience, and quality of the medical personnel that furnished such services." *Id.*

e. The "[a]mbulance vehicle type, including the clinical capability level of such vehicle." *Id.*

f. The "[p]opulation density of the pick up location (such as urban, suburban, rural, or frontier)." *Id.*

g. "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." *Id.*

h. Any information the IDR Entity requests from the parties to the IDR proceeding. *Id.* (B)(5)(C)(i)(II).

i. Any additional information submitted by either party relating to its offer. *Id.*

II. The QPA Is Calculated By the Payors, In Secret, With Very Little Disclosure to IDR Entities or Providers

27. In July 2021, the Departments issued Part I of their interim final rules, which included regulations regarding (i) how the QPA was to be calculated and (ii) what information payors must disclose about the QPA. *Requirements Related to Surprise Billing; Part I*, 86 Fed. Reg. 36,872 (July 13, 2021) ("*IFR Part I*"). IFR Part I took effect on September 13, 2021, and it applies to plan and policy years beginning on or after January 1, 2022. 86 Fed. Reg. at 36,872. The regulation governing how the QPA is calculated is codified at 45 C.F.R. § 149.140. Subparagraph (d) of that provision governs what information, about the QPA, must be disclosed by the payor to the provider in advance of the IDR process. 45 C.F.R. § 149.140(d).

28. In IFR Part I, the Departments acknowledged 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.*

29. "Transparency regarding how the QPA was determined" is especially important because there is no other meaningful outside check on the accuracy or reliability of QPAs. The Department of Health and Human Services "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 insurance issuers over whom HHS has supervisory authority, each of whom is likely to be calculating hundreds if not thousands of QPAs each year.

A. Calculating a QPA Is Complicated and Requires Independent Judgment

30. Calculating the QPA is not a ministerial task. It requires the exercise of independent judgment to resolve questions on which reasonable people might disagree.

31. In order to calculate the QPA in any given dispute, the payor must answer (at least) the following questions for each contracted rate that the payer includes (or excludes) from the QPA calculation:

(1) Whose contracted rates should be used? The regulation allows a plan *administrator* to use the rates for *all* health plans that the administrator oversees. 45 C.F.R. § 149.140(b)(1). Alternatively, the payor could use the rates of "all group health plans of the plan *sponsor*" (typically, the employer). *Id.* (emphasis added).

(2) What *was* the contracted "rate"? Many payors' 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.[2]

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

[2] 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)").

(4) What is the "geographic area" in which each rate was applied in 2019?

(5) What is the "insurance market" for each rate?

(6) What is the "provider specialty" of the provider that agreed to each rate?

See 45 C.F.R. § 149.140(c). Each of the foregoing questions is likely to require the application of independent judgment by the insurer in order to determine whether the rate should be included in the QPA determination and even to determine what the "rate" actually was.

B. Neither the Provider nor the IDR Entity Is Told How the Payor Calculated the QPA

32. The Departments' regulation providing for disclosure of information relating to QPAs—45 C.F.R. § 149.140(d)—does not require payors to answer *any* of the foregoing questions. The *only* information that the payor must disclose, regarding its secret QPA calculations, 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;
>
> (iii) If a plan or issuer uses an eligible database . . . to determine the qualifying payment amount, information to identify which database was used; and
>
> (iv) 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).[3]

[3] The August 2022 Final Rule also required payors to disclose whether the QPA was based on "downcoding," i.e., a different and reduced service code. 45 C.F.R. § 149.140(d)(1) (as revised in August 2022). "Downcoding" should not typically apply to air ambulance charges.

33. These "disclosures" are likely to be terse and uninformative. Consider, for example, a simplified example of a payor whose QPA is based on three contracted rates: (i) a rate agreed to by an air ambulance company that transports, on average, 250 patients per year; (ii) a rate agreed to by a hospital group that only transports 10 patients per year, and which rate varies greatly based on "incentive" payments depending on when the patient is discharged; and (iii) a rate agreed to by a dentists' office that has no air ambulances and therefore had no incentive to negotiate. Such a payor 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.

34. These disclosures 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.

35. In August 2022, the Departments answered a number of Frequently Asked Questions about implementation of IFR Part I's regulations regarding how to calculate the QPA. DEP'TS, *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* (Aug. 19, 2022).[4] These FAQs acknowledge that payors are not consistently calculating the QPA in accordance with the regulations. Specifically, the Departments conceded that they "have been informed" that payors have not been consistently complying with

[4] https://perma.cc/B7L7-QEKM

how the Departments intended them to calculate QPAs for providers in the "same or similar specialty." *Id.* at 16–17. The Departments also stated that they "have been informed" that some payors "enter $0 in their fee schedule" for certain items and services; the FAQ instructed payors that "$0 does not represent a contracted rate" and thus "plans and insurers should not include $0 amounts in calculating median contracted rates." *Id.* at 17 n.29.

C. The Departments' IFR Part I Regulations Allow Payors to Include, In the QPA, Many Contracted Rates that Are Misleading

36. According to the Departments, the purpose of the QPA is to "reflect[] market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889. But the Departments' regulations allow payors to calculate the QPA in ways that are highly misleading in three ways, described below: (i) QPAs are calculated using rates agreed to with providers that do not even operate air ambulances; (ii) QPAs are calculated using rates agreed to with hospitals, which have an incentive to discount these rates significantly; and (iii) QPAs may be calculated based on rates applicable to very large and diverse geographical regions. The New QPA Presumption nevertheless *requires* the IDR entity to *presume* that the QPA is "credible."

1. QPAs Include Rates Agreed To By Providers That Do Not Even Operate Air Ambulances

37. The Departments' regulations permit payors to include, in the QPA calculation, contracted rates that were agreed to by *providers that do not even operate air ambulances*. *See generally* 45 C.F.R. § 149.140(c) (not requiring that payors exclude, from the QPA calculation, contracted-for rates with providers that never provide the at-issue services).

38. Recently published payor data indicates that many contracted rates, for air ambulance services, were agreed to by providers that do not have air ambulances. The Transparency in Coverage Act required payors to disclose their current in-network rates, for a

variety of services, on July 1, 2022.[5] LifeNet's counsel has retained the expert analysis firm of Dobson DaVanzo to analyze this data. A preliminary analysis of one payor indicates that the *majority* of the payor's contracted rates, for air ambulance services, were agreed to by providers that do not typically operate air ambulances.[6] For example, the data shows contracted rates for air ambulance services with anesthesiologists, students in organized health care education, internists, surgeons, nursing professionals, and dentists. Because these providers do not operate air ambulances, they have no incentive to negotiate for a fair price. The low rates that these providers agreed to accept, for a service they knew that they would never provide, do not "reflect[] market rates under typical contract negotiations." *IFR Part I,* 86 Fed. Reg. at 36,889.

39. The Transparency in Coverage Act disclosures contain rates applicable to plan years beginning on January 1, 2022. The QPA calculations, by contrast, are typically based on *2019* contracted rates. Because the Departments have not required meaningful disclosures by payors, about how their QPAs are calculated, providers and IDR entities can only speculate about how many never-used rates, agreed to by dentists' offices and the like, were used to generate the QPAs.

2. QPAs Include Rates Agreed To By Hospitals, Which Have An Incentive to Price Air Ambulance Services Below Cost

40. Another flaw with the QPA calculation methodology is that the Departments' regulations permit payers to include, in the QPA calculation, contracted rates that were agreed to

[5] *See* Transparency in Coverage Act Final Rules, 45 C.F.R. § 147.211(b)(1)(iii); *see also* FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), *available at* https://perma.cc/B7L7-QEKM; *see generally* D. Gordon, *New Healthcare Price Transparency Rule Took Effect July 1, But It May Not Help Much Yet*, Forbes.com, July 3, 2022, *available at* https://perma.cc/3YHP-TQQQ.

[6] These rates, although low, are nearly all greater than zero. Therefore, these rates would not be excluded from the QPA calculation under the Departments' August 2022 FAQ guidance, which for the first time instructed payors not to include $0 rates.

by *hospitals*. *See* 45 C.F.R. § 149.140(a)(12) ("[A]ll providers of air ambulance services are considered to be a single provider specialty," regardless of the differences between these providers).

41. Hospitals are differently situated from independent air ambulance providers like LifeNet. Hospitals typically negotiate with payers for a large menu of services simultaneously. 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 hospitals (and a small percentage of anticipated revenues).

42. Moreover, hospitals have an economic incentive to offer their air ambulance services at below cost (as a "loss leader") because their transports typically bring patients to the hospital, where those patients then receive additional treatment that generates revenue that is more than sufficient to make up for the hospital's loss on the cost of air transport. By contrast, independent air ambulance providers offer just one service—emergency transport—and cannot agree to reduced transport rates in the expectation of offsetting those losses by charging for other services.

3. QPAs May Include Rates Agreed to In a Very Different Geographic Areas

43. The Departments' regulations also permit payers to include, in the QPA calculation, rates agreed to by air ambulance providers in very different geographic areas within the same Census division.[7] A "Census division," of which there are only nine nationwide, is an enormous

[7] 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" to include the entire Census division. Specifically, the payer is to use its contracted rates in (1) all metropolitan statistical areas

area.[8] For example, the "South Atlantic" Census Division stretches from Delaware down to the Florida Keys.[9] The "Mountain" Census Division extends from Arizona up to Montana.[10] Therefore, a contracted rate from California could dictate the QPA for a medical air transport in Alaska or Hawaii; a contracted rate in the Florida Keys could dictate the QPA in the Shenandoah Valley.

44. In order to evaluate whether a 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?

45. There is no "discovery" available in the IDR Process. Providers and IDR entities have no means, within the IDR Process, to determine the answers to the foregoing questions.

(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).

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

[9] *Id.*

[10] *Id.*

III. The Departments Created One IDR Process in IFR Part II, With Only Slight Differences Between Air Ambulance IDRs and All Other IDRs

46. Congress instructed the Departments to promulgate implementing regulations to govern the IDR Process. Congress actually gave two identical versions of the same instruction: By December 27, 2021 (i.e., within one year of enactment), the Departments were to "establish by regulation" an "IDR process" for "air ambulance services," 42 U.S.C. § 300gg-112(b)(2)(A), and an "IDR process" for all other "item[s] or service[s]," *id.* § 300gg-111(c)(2)(A). Congress instructed the Departments that this IDR Process must enable the IDR entity 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) (emphasis added).

47. On October 7, 2021, the Departments published an 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, including the original QPA Presumption vacated in *TMA I* and *LifeNet I*.

48. The principal provisions of IFR Part II relating to the IDR Process are codified in 45 C.F.R. § 149.510.[11] Section 149.510 applies, in full, to any IDR that is *not* an air ambulance IDR.

49. A second section—Section 149.*520*—applies to air ambulance IDRs. This section simply incorporates, by reference, nearly all of Section 149.510. *See* 45 C.F.R. § 149.520(b)(1).[12]

[11] The Departments also codified these regulations under titles 26 and 29 of the Code of Federal Regulations, which concern ERISA and the Internal Revenue Service. 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.

[12] 45 C.F.R. § 149.520(b)(1) states: "Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except

50. According to the statute, the only difference between air ambulance IDRs and all other IDRs is the list of "additional circumstances" that the IDR Entity is to consider when choosing which offer to select. Some of these "additional circumstances" are different, in an air ambulance IDR—for example, the "population density" at the patient's "pick up location," and the "ambulance vehicle type." 42 U.S.C. § 300gg-112(b)(5)(C)(ii).

51. The regulation—Section 149.520(b)(2)—directs the IDR Entity to consider these different "additional circumstances" in air ambulance IDRs. Otherwise, air ambulance IDRs are to follow the procedures set forth in Section 149.510, which apply to all other IDRs. *See* 45 C.F.R. § 149.520(b)(1).

52. The original version of IFR Part II contained the Old QPA Presumption, which the Departments described as a "rebuttable presumption" that the offer closest to the QPA was the proper payment amount and should be selected by the IDR entity. *See* 86 Fed. Reg. at 56,056–61. "Rather than instructing arbitrators to consider all the factors pursuant to the Act," the Old QPA Presumption "required arbitrators to 'select the offer closest to the [QPA]' unless 'credible' information, including information supporting the additional factors,' 'clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate.'" *LifeNet I* at *2.

53. This Court's *TMA I* and *LifeNet I* Decisions struck down the Old QPA Presumption in IFR Part II. The remainder of IFR Part II remains in effect and governs the IDR process.

IV. The August Final Rule Creates a New QPA Presumption, in Clear Violation of the Statute and This Court's Rulings in *TMA I* and *LifeNet I*

54. On August 26, 2022, two months after this Court's *LifeNet I* decision, the Departments published a Final Rule in the Federal Register entitled *Requirements Related to*

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that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section."

Surprise Billing, 87 Fed. Reg. 52,618 (August 26, 2022).[13] The Final Rule replaces those provisions of IFR Part II that were vacated by *TMA I* and *LifeNet I.* Attached hereto as Exhibit A is a redline comparison showing the changes to the relevant regulatory provisions.

55. In place of the provisions vacated by this Court, the Final Rule enacts a New QPA Presumption. Yet again, the New QPA Presumption requires IDR entities to give the QPA added weight in the IDR process over all the other statutory factors.

56. The New QPA Presumption is codified in four parts of 45 C.F.R § 149.510 and in one part of 45 C.F.R. § 149.520. The following chart quotes each part in the order it appears in Section 149.510:

Regulatory Text (bold language contains the New QPA Presumption)	**Citation**	**Reason Why This Language Creates a New QPA Presumption**
(iii) Considerations in determination. In determining which offer to select: (A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service. (B) The certified IDR entity must **then** consider information submitted by a party that relates to the following circumstances	45 C.F.R. § 149.510(c)(4)(iii)(A)-(B).	This requires the IDR entity *first* to consider the QPA, and only *then* to consider the other statutory factors.
(E) **In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section [i.e., all of the statutory factors *other than* the QPA],** the certified IDR Entity should evaluate whether the information is credible **and relates to the offer submitted by either party for the payment amount for the** qualified IDR item or service that is the subject of the payment determination. **The certified IDR Entity should not give weight to information to the extent it is**	45 C.F.R. § 149.510(c)(4)(iii)(E) 45 C.F.R. § 149.520(b)(3) (near-identical provision applicable to air	This requires the IDR entity to "not give weight" to any statutory factor, besides the QPA, unless the IDR entity first determines that (i) the factor "relates to the offer" and (ii) is not "already

[13] Unless otherwise noted, citations to the Final Rule reference the C.F.R. provisions as set forth in that rule.

Regulatory Text (bold language contains the New QPA Presumption)	**Citation**	**Reason Why This Language Creates a New QPA Presumption**
not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.	ambulances specifically)	accounted for by" the QPA. The IDR entity is required to make a "credibility" determination as to information relating to the other factors, but is *forbidden* to question the "credibility" of the QPA.
(iv) Examples. The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples: …	45 C.F.R. § 149.510(c)(4)(iv)	These five examples each restate the language of 45 C.F.R. § 149.510(c)(4)(iii)(E).
(vi) Written decision. . . . (B) The certified IDR Entity's written decision must include an explanation of their determination, including what information the certified IDR Entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraph (c)(4)(iii)(B) through (D) of this section. **If the certified IDR Entity relies on information described under paragraph (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR Entity concluded that this**	45 C.F.R. § 149.510(c)(4)(vi)	This requires the IDR Entity to do extra work if it "relies on" any of the statutory factors other than the QPA. Specifically, the IDR Entity must somehow explain, in writing, "why" it "concluded that this information was not already reflected in" the QPA.

Regulatory Text (bold language contains the New QPA Presumption)	Citation	Reason Why This Language Creates a New QPA Presumption
information was not already reflected in the qualifying payment amount		

57. Congress's statutory command is clear and unequivocal: the IDR entity "shall consider" each category of additional information, along with the QPA. 42 U.S.C. § 300gg-112(b)(5)(C) ("the certified IDR entity . . . shall consider . . . information on any circumstance described in clause (ii)"). In four different ways, the New QPA Presumption contravenes the statute by giving the QPA greater weight than the other statutory factors.

A. The New QPA Presumption Forbids the IDR Entity from Considering the Non-QPA Factors Unless the IDR Entity First Explains, In Writing, Why It Believes that the QPA Does Not "Account For" this Factor

58. *First,* the New QPA Presumption states that IDR entities may *not* "give weight to" any information, including information relating to the non-QPA factors explicitly listed in the statute, "to the extent that" this information "is already accounted for by the [QPA]." 45 C.F.R. § 149.510(c)(4)(iii)(E) (regulation applicable to non-air-ambulance IDRs); *id.* § 149.520(b)(3) (near-identical provision applicable to air-ambulance IDRs). This is contrary to the statutory command—"the certified IDR entity … shall consider … information on any circumstance described in clause (ii)"—which command is not limited to only those "circumstances" that are not already "accounted for" in the QPA.

59. The Departments nowhere explain *how* the IDR entity is supposed to determine what information is "accounted for" by the QPA. The QPA is just a dollar amount. It is calculated in secret by the payor. The Departments have not required any meaningful disclosure, by the payor, about how the QPA was calculated, nor what rates were used in the calculation. *See supra* ¶¶ 27-45.

60. And yet the New QPA Presumption requires the *IDR entity* to provide the explanation that the Departments have not required from the *payor*. Specifically: If the IDR entity considers any of the non-QPA statutory factors, the IDR entity must also explain in writing "why the certified IDR Entity concluded that this information was not already reflected in the qualifying payment amount." 45 C.F.R. § 149.510(c)(4)(vi). This is an additional burden on the IDR entity that would not exist if the IDR entity were to simply select the offer closest to the QPA.

61. IDR entities are currently paid between $299 and $500 per single IDR.[14] There is no additional pay for taking on the additional burden of explaining the IDR's beliefs regarding what the QPA does not "account for." The obvious economic incentive, created by this regulation, is for IDR entities not to consider any other factor besides the QPA, and thereby avoid this additional burden.

62. The Final Rule also invites payors to make *ex parte* explanations, to the IDR entity, about their QPA calculations and methods, without giving providers any notice or opportunity to respond. Recall that the parties to the IDR do not see each other's submissions and do not have any opportunity to respond to them. The only information the provider receives, about what the payor did to calculate the QPA, are the extremely limited disclosures that the payor is required to make in advance of the IDR. 45 C.F.R. § 149.140(d); *see supra,* ¶¶ 32-35.

[14] CMS.gov, *List of Certified Independent Dispute Resolution Entities* (last visited Sep. 14, 2022), *available at* https://perma.cc/9EWP-G75S.

63. In the new "Example 3," in the Final Rule, the Departments describe an IDR proceeding in which the provider makes additional representations solely to the IDR entity (but *not* to the provider) to the effect that the QPA that the payor has calculated "accounts for the acuity of the patient's condition," which is one of the other, non-QPA statutory factors. 45 C.F.R. § 149.510(c)(4)(vi)(C). The provider has no opportunity to address this point, since the provider is *never told*, before the IDR process, how the QPA has been calculated. *See supra*, ¶¶ 32-35. Yet the Departments, in Example 3, state that the IDR entity in this situation should *disregard* the provider's evidence, regarding the patient's acuity, based on the provider's *ex parte* communication about what the QPA contains: "If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider." 45 C.F.R. § 149.510(c)(4)(iv)(C).

64. This is contrary to the statute, which provides that the IDR entity "shall consider" each category of additional information. 42 U.S.C. § 300gg-112(b)(5)(C) ("the certified IDR entity . . . shall consider . . . information on any circumstance described in clause (ii)"). The statute's command—"shall consider"—is not limited to only those additional factors that are not already "accounted for" in the QPA.

B. The New QPA Presumption Narrows the Non-QPA Statutory Factors to Only Those Factors That Were "Necessary To" the Transport at Issue

65. *Second,* the New QPA Presumption requires the IDR entity to evaluate all information—except the QPA—to determine whether it "relates to the offers submitted." 45 C.F.R. § 149.510(c)(4)(iii)(E); 45 C.F.R. § 149.520(b)(3) (near-identical provision applicable to air ambulance IDRs). The IDR entity may not "give weight to" any other information—including information on the "additional circumstances" that Congress mandated that IDR entities "shall

consider," 42 U.S.C. § 300gg-112(b)(5)(C)(ii)—unless the IDR entity first makes the determination that the information "relate[s] to either party's offer." 45 C.F.R. § 149.520(b)(3).

66. The Final Rule adopts a new—and unduly narrow—interpretation of what it means for non-QPA information to "relate to a party's offer." This is demonstrated by Example 2, which states that the IDR entity should *disregard* credible information, about the provider's "training and experience," if the IDR entity "finds that … the provider's level of training and experience [does not] relate[] to the offer … (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service …. or that the training or experience made an impact on the care that was provided)." 45 C.F.R. § 149.510(c)(4)(vi)(B).

67. To illustrate: Suppose the air ambulance provider invests in the latest defibrillation devices to be used on patients in cardiac distress, and then trains all its personnel in how to use those devices. That is a valuable investment in life-saving care and it should be compensated. There is no way to know in advance which emergency dispatches will require this kind of equipment and training to save the patient's life. But the Department's new regulation will prevent the air ambulance provider from obtaining any compensation for this investment, *except* in those transports in which this equipment and training are actually used.

68. The Department's narrow "relates to the offer" restriction effectively *forbids* the IDR entity from considering any of the *general* non-QPA factors—such as training, experience, prior quality and outcomes measurements, ambulance capabilities, etc.—unless the provider makes a heightened showing that these factors were somehow relevant to the specific transport at issue.

69. The Department's "relates to the offer" restriction is contrary to the statute. The statute requires that the IDR entity (i) *shall* consider the "training, experience, and quality" of the air ambulance's medical crew; (ii) *shall* consider the "clinical capability level" of the air ambulance, and (iii) *shall* consider the "quality and outcomes measurements of the provider." U.S.C. § 300gg-112(b)(5)(C)(ii). There is no statutory basis for the Departments to forbid the IDR entity from considering these factors unless the provider first demonstrates that these factors were "necessary for" or "made an impact on" the specific transport at issue. 45 C.F.R. § 149.510(c)(4)(vi)(B).

70. There is no analogous requirement, in the Final Rule, requiring the IDR entity to make a determination that the *QPA* "relates to the party's offer."

C. The New QPA Presumption Forbids the IDR Entity from Questioning the "Credibility" of the QPA

71. *Third,* the New QPA Presumption forbids the IDR entities from questioning the "credibility" of the QPA.

72. As to all the other, non-QPA statutory factors, the Departments' regulations instruct IDR entities that they may not "give weight to information" relating to those factors "to the extent it is not credible." 45 C.F.R. § 149.510(c)(4)(iii)(E). "Credible information" means "information that upon critical analysis is worthy of belief and is trustworthy." 45 C.F.R. § 149.510(a)(2)(v).

73. But this "credibility" requirement does *not* apply to the QPA. 45 C.F.R. § 149.510(c)(4)(iii)(E) (the IDR entity only needs to "evaluate whether the information is credible" when "weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D)," none of which is the QPA). On the contrary, the IDR entity "must consider" the QPA, regardless of the QPA's credibility. 45 C.F.R. § 149.510(c)(4)(iii)(E)(iv) (each of the "Examples" states that the IDR entity "must consider" the QPA). In their August 2022 rulemaking, the Departments explicitly

directed IDR entities *not* to question the credibility of the QPA. "[I]t is the Departments' . . . responsibility, not the certified IDR entity's, to monitor the accuracy of the plan's or issuer's QPA calculation methodology by conducting an audit . . . ." 87 Fed. Reg., at 52,627 n.31.

74. There is no basis in the statute or common sense to exempt the QPA from a "credibility" requirement that applies to all the other statutory factors. There are ample reasons why the QPA's credibility might be questioned in an air ambulance dispute. For example, if the payor's Transparency in Coverage Act disclosures indicate that the majority of the payor's contracted rates, for air ambulance services, have been agreed to by dentists and other providers that do not typically operate air ambulances, then even a modicum of "critical analysis" would indicate that the median of those rates is not a "trustworthy" benchmark of the market rates for these services. 45 C.F.R. § 149.510(a)(2)(v) (definition of "credible information").

75. By forbidding IDR entities to undertake a "critical analysis" of the QPA, while demanding that analysis for all other statutory factors, the New QPA Presumption puts a thumb on the scale in favor of the QPA.

D. The New QPA Presumption Requires the IDR Entity to Consider the QPA First, and Only "Then" Consider the Other Factors

76. *Fourth,* the New QPA Presumption requires IDR entities to start by "consider[ing] the [QPA] for the applicable year for the same or similar item or service." 42 C.F.R. § 149.510(c)(4)(iii)(A). Only after the IDR entity has first looked to the QPA, may the IDR entity "*then* consider information submitted by a party" concerning the other statutory factors. *Id.* § 149.510(c)(4)(iii)(B) (emphasis added).

77. The statute does not prescribe a procedural order for considering the factors.

78. In their August 2022 rulemaking, the Departments declared that requiring IDR entities to begin with the QPA was "reasonable" because the QPA is the first factor listed in the statute, and because the QPA "must be a quantitative figure," whereas "the information received related to additional circumstances … will often be qualitative and open to subjective evaluation." 87 Fed. Reg. at 52,627; *see also id.* at 52,628. The Departments failed to mention that the other information submitted by the parties may also include quantitative figures, for example, the "contracted rates between the provider or facility … and the plan or issuer … during the previous 4 plan years." 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(V).

79. When combined with the favorable weighting and explanation requirements discussed above, ¶¶ 58-75, this ordering requirement gives further primacy to the QPA and contravenes the text of the No Surprises Act. By forcing the IDR Entity to first consider the QPA, the Final Rule (i) improperly treats the QPA as the principal factor; and (ii) improperly focuses the IDR entity's attention on the QPA.

V. The New QPA Presumption Must Be Vacated Because It is Contrary to the No Surprises Act

80. In the No Surprises Act, 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." 42 U.S.C. § 300gg-112(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." *Id.* (b)(5)(C). The statute has not changed since this Court last considered it in *LifeNet I* just over two months ago. As this Court held, the Departments are not permitted to elevate the QPA above all other statutory factors simply because the QPA "is the first in a list." *TMA I*, 2022 WL 542879, at *8.

81. The Final Rule's New QPA Presumption is contrary to the statute because it (i) imposes an additional burden on the IDR entity to explain in writing why the non-QPA factors are not "accounted for" by the QPA; (ii) *forbids* the IDR entity from considering any of the *general* non-QPA factors—such as training, experience, prior quality and outcomes measurements, ambulance capabilities, etc.—unless the provider makes a heightened showing that these factors were somehow relevant to the specific transport at issue; (iii) forbids IDR entities from questioning the "credibility" of the QPA, while requiring a "credibility" determination for all non-QPA factors; and (iv) requires the IDR entity to consider the QPA first. Taken together, these four requirements yet again put a "thumb on the scale" in favor of the offer closest to the QPA, and thereby contravene the text of the No Surprises Act and this Court's holdings in *TMA I* and *LifeNet I.*

VI. The Revised QPA Presumption Will Harm LifeNet

82. The Final Rule—and thus the New QPA Presumption—will take effect on October 25, 2022, two months after the Final Rule was published in the Federal Register. *See* 45 C.F.R. § 149.510(h) (providing that the provisions of the Final Rule amending 45 C.F.R. § 149.510 will take effect 60 days after the Final Rule's publication in the Federal Register); 45 C.F.R. § 149.520(h) (same for 45 C.F.R. § 149.520); *Final Rule*, 87 Fed. Reg. 52618 (August 26, 2022). All IDRs initiated after that date will be subjected to the defective New QPA Presumption.

83. Many of the emergency air ambulance services that LifeNet provides are subject to the No Surprises Act's IDR process. LifeNet provides emergency air ambulance services in Texas, Arkansas, Louisiana, and Oklahoma. LifeNet has conducted many emergency flights transporting patients who were insured by a commercial (*i.e.*, non-Medicare, non-Medicaid) health plan or health insurer, for which LifeNet was an out-of-network provider and which are subject to the No Surprises Act. LifeNet has provided such services since the start of 2022 and anticipates continuing to provide such services through the remainder of 2022 and beyond.

84. As a "nonparticipating provider" of emergency air ambulance services, LifeNet is directly regulated by the Final Rule. And, as an "object of the Rule, there is 'little question that the [agency] action … has caused [LifeNet] injury.'" *LifeNet I*, 2022 WL 2959715 at *6 (quoting *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 264 (5th Cir. 2015)). In any IDR proceeding under the Final Rule, it is "LifeNet's services [which] will be analyzed and valued in the IDR process pursuant to the Rule" and "it is LifeNet . . . whose training, experience and quality and outcome measurements are to be considered by the arbitrator." *Id.* at *6–7.

85. LifeNet will suffer injury in IDR processes subject to the New QPA Presumption because, in part, the New QPA Presumption "deprives" LifeNet "of the arbitration process established by the Act." *LifeNet I,* 2022 WL 2959715, at *7. By "put[ting] a thumb on the scale in favor of the QPA," the New QPA Presumption causes a procedural injury to LifeNet. *TMA*, 2022 WL 542879, at *4; *see also LifeNet I,* 2022 WL 2959715, at *7. The New QPA Presumption deprives LifeNet of "the arbitration process established by the Act," which is a "procedural right" that is designed to "protect [LifeNet's] concrete interests" in receiving compensation for its services. *TMA*, 2022 WL 542879, at *4.

86. During those IDR processes, it is "LifeNet's services will be analyzed and valued in the IDR process pursuant to the Rule." *LifeNet I,* 2022 WL 2959715, at *7. For example, the arbitrator will be asked to consider the training and experience of the personnel on LifeNet's flights, and LifeNet's quality and outcome measurements. *Id.*

87. Each IDR process results in a determination regarding the value of LifeNet's services. These determinations affect LifeNet's reputation, the market value of LifeNet's services, and the value of the company as a whole.

88. Although LifeNet is compensated for its air ambulance services by Air Methods Corporation ("Air Methods") pursuant to a contract between the two companies, that contract is of limited duration. Section 2.4 of the contract permits either party to terminate the contract "without cause" after the "two-year anniversary of the Commencement Date," which is October 1, 2023. Section 2.3 of the contract permits the contract's earlier termination due to a "financially inviable situation that is beyond the reasonable expectations of either Party."

89. Due, in part, to the low QPAs disclosed thus far by group health plans and health insurance issuers, LifeNet anticipates that in many (if not all) cases, Air Methods will continue to submit offers for LifeNet's services in excess of the QPAs. Should Air Methods terminate the parties' agreement, LifeNet anticipates that LifeNet, too, would submit offers for its services in excess of the QPAs. The New QPA Presumption thus will likely depress reimbursements for LifeNet's services because the New QPA Presumption treats the QPA as a "de facto benchmark." *See TMA*, 2022 WL 542879, at *5. The application of the New QPA Presumption in these IDR proceedings will "systematically reduce out-of-network reimbursement compared to an IDR process without such a presumption," *TMA,* 2022 WL 542879 at *5, which will cause LifeNet significant economic injury because the QPA Presumption will "drive out-of-network reimbursement rates to the QPA as a de facto benchmark." *Id.*

90. The New QPA Presumption creates a significant risk to LifeNet of losing its present contract with Air Methods. The New QPA Presumption threatens to create a "financially inviable situation" that would permit Air Methods to terminate the agreement. In the alternative, the New QPA Presumption increases the likelihood that Air Methods will terminate the contract without cause after October 1, 2023.

91. The lower reimbursement rates, determined by IDRs applying the New QPA Presumption, will immediately cause injury to LifeNet. These lower rates represent a lower dollar valuation for LifeNet's services in the critically important out-of-network commercial payor market. These determinations will instantly devalue LifeNet's services in this market. This injury will be converted into tangible economic injury in the near future, whenever LifeNet's current contract with Air Methods terminates—whether on October 1, 2023, or earlier. By then, the New QPA Presumption will have depressed the value of LifeNet's services in the commercial-payor market, as a result of all the IDR determinations that will have been decided by that point under the New QPA Presumption. By depressing the value of LifeNet's services in the commercial-payor market, this will also depress the dollar amount that AMC (or any other commercial partner) would agree to pay for LifeNet's services.

CLAIM FOR RELIEF

Count I: The New QPA Presumption Contained in 45 C.F.R. § 149.510 and § 149.520 Should Be Set Aside, Under the APA, Because It Is Arbitrary, Capricious, and Contrary to the Statute (5 U.S.C. § 706)

92. LifeNet incorporates and re-alleges all of the foregoing paragraphs. LifeNet also incorporates all of this Court's findings and holdings in the *TMA I* and *LifeNet I* decision.

93. The regulations that govern the IDR Process—45 C.F.R. §§ 149.510 and 149.520—are final agency action subject to review under the APA. 5 U.S.C. § 704. These regulations were published as a 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.

94. 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).

95. The New QPA Presumption is contained in the provisions listed above in the chart contained in paragraph 56.

96. The New QPA Presumption is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. § 706, because it deviates from Congress's clear direction that the QPA is just one of nine 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).

97. By tying the IDR entity's hands in this way, the New 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 giving the QPA the unique and asymmetrical weight over all the other statutory factors, 45 C.F.R. § 149.510(c)(4)(iii)(A)-(B), by selecting in advance one factor (the QPA) be considered first, 45 C.F.R. § 149.520(b)(3), and by requiring the IDR entity to explain why any non-QPA factor is not "accounted for" by the QPA, 45 C.F.R. § 149.510(c)(4)(vi), the New QPA Presumption usurps the discretion that Congress granted to the IDR entity.

98. For these reasons, LifeNet respectfully requests that this Court (i) set aside and vacate the New QPA Presumption, (ii) issue a declaratory judgment instructing IDR entities not to follow the New QPA Presumption in any IDR proceedings, (iii) issue a declaratory judgment that IDR decisions, in which the IDR entity applied the New QPA Presumption in order to select the payor's offer, are void and without effect and must be re-opened and started anew, and (iv) remand

the Final Rule with specific instructions to the Departments to stop directing or encouraging the IDR entities to accord the QPA any additional weight relative to the other statutory factors.

PRAYER FOR RELIEF

For the foregoing reasons, LifeNet respectfully requests that the Court provide the declaratory and injunctive relief set forth in Count I, and summarized as follows:

A. A judgment vacating the New QPA Presumption (specifically, the regulatory provisions identified, in bold, in the chart appearing at paragraph 56);

B. A judgment declaring that the New QPA Presumption is arbitrary and capricious and in excess of statutory authority and limits;

C. A judgment declaring that IDR entities should not apply the New QPA Presumption in any IDRs;

D. A judgment declaring that IDR decisions, in which the IDR entity applied the New QPA Presumption in order to select the payor's offer, are void and without effect and must be re-opened and started anew;

E. A judgment remanding the Final Rule with specific instructions to the Departments to stop directing or encouraging the IDR entities to accord the QPA any additional weight relative to the other statutory factors; and

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

Dated: September 23, 2022

BY:

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