

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS**

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 closely related to another action pending before this Court: *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.) (the “TMA Decision”). Plaintiff respectfully requests assignment of this matter to Judge Kernodle, who authored the TMA Decision.

INTRODUCTION

1. 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.

2. The No Surprises Act, as relevant here, creates an “Independent Dispute Resolution” (IDR) process, in which out-of-network providers of emergency medical services, such as LifeNet, can obtain an order, from an IDR entity, directing the patient’s health plan or health insurer to pay the provider a certain amount for the services provided to the patient. IDR proceedings are already beginning across the country.

3. This Court’s *TMA* Decision struck down those parts of Defendants’ implementing regulations that imposed a “QPA Presumption” on the IDR Process. 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. The regulations’ QPA Presumption “places 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. This Court set aside the regulations’ QPA Presumption for two independent reasons: first, it “rewrites clear statutory terms” of the No Surprises Act, *id.*, and second, it was promulgated without the notice-and-comment procedure that the APA requires, *id.* at *14.

4. Despite this Court’s holding in *TMA*, the Defendants continue to apply the QPA Presumption to air ambulance providers including LifeNet—making this lawsuit necessary. Defendants are apparently relying on one sentence in their regulations, which was not expressly

struck down by *TMA*. LifeNet requests that this Court act swiftly to vacate this sentence, as well, and for the same reasons as in *TMA*.

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PARTIES

5. 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.

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

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

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

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

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

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

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

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

JURISDICTION AND VENUE

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

15. 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.

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

FACTUAL BACKGROUND

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

17. 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

18. 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.

19. 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.

20. 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 (health plan or insurer) agreed to pay for air ambulance services in 2019 in the geographic area in which the services at issue were provided.² 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

² If the insurer did not have sufficient agreements, in 2019, to calculate a median rate (i.e., the insurer had fewer than three such rates) then the insurer is permitted to instead consult a public “database.” 42 U.S.C. § 300gg-111(a)(3)(E)(iii)(I).

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

21. 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).

22. 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 QPA Presumption.

23. The principal provisions of IFR Part II relating to the IDR Process are codified in 45 C.F.R. § 149.510.³ Section 149.510 applies, in full, to any IDR that is *not* an air ambulance IDR.

³ 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.

24. 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).*⁴

25. 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).

26. 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).*

III. IFR Part II’s QPA Presumption Clearly Rewrites the Statute

27. The Departments’ QPA Presumption is codified in five parts of 45 C.F.R. § 149.510 and in one sentence of 45 C.F.R. § 149.520, as shown in the following chart. The five parts of Section 149.510 (shown in the first five rows of the chart) were expressly vacated by the *TMA* decision. The one sentence from Section 149.520 (shown in the sixth and final row of the chart) was not expressly vacated by *TMA*:

⁴ 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 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.”

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

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

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

29. The QPA Presumption deviates from the statute. The No Surprises Act provides that the IDR entity, conducting an air ambulance IDR, “shall . . . tak[e] into account” a list of *nine* “considerations” specified in the statute. 42 U.S.C. § 300gg-112(b)(5)(A). Only *one* of those

considerations is the QPA. The plain text of the statute does *not* give the QPA any greater weight than the other eight factors that the IDR entity “shall take into account.”

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

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

IV. The Departments’ QPA Presumption Was Issued Without Notice and Comment

32. IFR Part II took effect immediately—*i.e.*, on October 7, 2021—and is, in general, applicable with respect to plan, policy, or contract years beginning January 1, 2022.

33. IFR Part II represented the end of the Departments’ collective decision-making process.

34. Although the Departments placed language in IFR Part II, indicating that they invite comments on certain aspects of the published regulations, that language does not create a formal legal obligation on the Departments to review and consider such comments, much less to revise the rules based on any comments received.

35. The Administrative Procedure Act (APA) required the Departments to provide public notice of the proposed regulations and an opportunity for comment, unless the Departments “for good cause” found that notice and comment “are impracticable, unnecessary, or contrary to

the public interest.” 5 U.S.C. § 553(b)(B). The Departments would then have been required to provide a meaningful response to substantive comments received.

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

37. The Departments could have complied with the APA and provided the public with notice and an opportunity to comment on IFR Part II.

38. “[I]f the Departments had provided notice and comment,” then LifeNet and other affected air ambulance providers “could have submitted the specific reasons and authorities for why they believed the Rule is inconsistent with the Act, how the Rule would impact them as providers, and how the Rule could be drafted to track the statutory text more closely.” *TMA*, 2022 WL 542879, at *13.

39. The Department’s excuses for not allowing notice and comment on the IFR Part II regulations do not suffice to show “good cause.” *See id.* at *12 (“the Court finds that the Departments lacked good cause to bypass notice and comment”).

V. Defendants Continue to Apply the QPA Presumption to Air Ambulance IDRs, Despite this Court’s Opinion and Order in *TMA*

40. This Court’s *TMA* Decision struck down all five aspects of the QPA Presumption that are found in Section 149.510.

41. None of the *TMA* plaintiffs specifically requested that the Court strike down the one sentence in Section 149.520 that refers to the QPA Presumption. That sentence reads: “This [additional] information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.” 45 C.F.R. § 149.520(b)(2).

42. However, the *TMA* decision did strike down a sentence in Section 149.510 that is *identical* to this sentence in Section 149.520. The two sentences are shown in the chart below:

45 C.F.R. § 149.510(c)(4)(iii)(C) (bold language vacated by TMA)	45 C.F.R. § 149.520(b)(2) (not expressly vacated by TMA)
Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.	Additional information. Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

43. On April 12, 2022, Defendants issued updated “guidance” to IDR entities. That guidance instructs IDR entities to continue to apply the QPA Presumption to air ambulance IDRs:

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

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

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

Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities, at 22 (Apr. 12, 2022), available at <https://www.cms.gov/sites/default/files/2022-04/Revised-IDR-Process-Guidance-Certified-IDREs.pdf>.

44. Applying the QPA Presumption only to air ambulance IDRs is arbitrary, irrational, and deviates from the statute. The statutory text indicates that the QPA should be used in the same way in air ambulance IDRs as in all other IDRs, *i.e.*, as one factor among many to be considered.

The relevant statutory text, regarding the consideration to be given to the QPA by the IDR entity, is *identical* for all IDRs:

42 U.S.C. § 300gg-111(c)(5)(C) (IDRs for all other items and services, besides air ambulances)	42 U.S.C. § 300gg-112(b)(5)(C) (air ambulance IDRs)
<p>(C) Considerations in determination</p> <p>(i) In general</p> <p>In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider--</p> <p>(I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and ... [additional circumstances].</p>	<p>(C) Considerations in determination</p> <p>(i) In general</p> <p>In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR air ambulance service shall consider--</p> <p>(I) the qualifying payment amounts (as defined in section 300gg-111(a)(3)(E) of this title) for the applicable year for items or services that are comparable to the qualified IDR air ambulance service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR air ambulance service; and ... [additional circumstances].</p>

VI. The QPA Presumption Is Harming and Will Continue to Harm LifeNet

45. By “put[ting] a thumb on the scale in favor of the QPA,” the QPA Presumption causes a procedural injury to LifeNet. *TMA*, 2022 WL 542879, at *4. The QPA Presumption deprives LifeNet of “the arbitration process established by the Act,” a “procedural right” that is designed to “protect [LifeNet’s] concrete interests” in receiving compensation for its services. *Id.*

46. The QPA Presumption also causes economic injury to LifeNet. In calendar year 2021, LifeNet 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. LifeNet expects it will conduct many such flights in 2022, as well. LifeNet’s right to compensation from the plan or insurer, for many of those 2022 emergency flights, will be governed by the No Surprises Act and by the QPA Presumption challenged in this

action. LifeNet reasonably expects that some and perhaps all of these services will soon be the subject of IDR proceedings. The application of the 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 over the long term because the QPA Presumption will “drive out-of-network reimbursement rates to the QPA as a de facto benchmark.” *Id.*

CLAIMS FOR RELIEF

I. COUNT I: The 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)

47. Plaintiff incorporates and re-alleges all of the foregoing paragraphs. Plaintiff also incorporates all of this Court’s findings and holding in the *TMA* decision.

48. 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 an Interim Final Rule. That publication marks the consummation of the Departments’ collective decision-making, establishes the rights and obligations of air ambulance providers, group health plans, and issuers, and is a regulation from which legal consequences will flow.

49. 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).

50. The QPA Presumption is contained in the six provisions listed above in paragraph 27.

51. The 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).

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

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

II. COUNT II: The QPA Presumption Should Be Set Aside Because the Agencies Failed to Follow Notice-and-Comment Procedures

(5 U.S.C. §§ 553, 706)

54. Plaintiff incorporates and re-alleges all of the foregoing paragraphs. Plaintiff also incorporates all of this Court’s findings and holding in the *TMA* decision.

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

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

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

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

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

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

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

PRAYER FOR RELIEF

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

- A. A judgment vacating the QPA Presumption (specifically, the six regulatory provisions identified, in bold, in the chart appearing at paragraph 27);
- B. A judgment declaring that the QPA Presumption is arbitrary and capricious; is in excess of statutory authority and limits; and was issued without the required notice-and-comment procedure;
- C. A judgment declaring that IDR entities should not apply the QPA Presumption in any IDRs;
- D. A judgment declaring that air ambulance IDR decisions, in which the IDR entity applied the QPA Presumption when determining which offer to select, are void and without effect and must be re-opened and started anew; and
- E. Any other relief the Court determines to be just and proper.

Dated: April 27, 2022

BY:

_____*/s/ Stephen Shackelford, Jr.*_____

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