UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS

LIFENET, INC.

Plaintiff,

Case 6:22-cv-00162

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.

PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AND RESPONSE IN OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Plaintiff LifeNet, Inc., respectfully asks the Court to grant Plaintiff's Motion for Summary Judgment (ECF 27) and deny Defendants' Cross-Motion for Summary Judgment (ECF 31).

INTRODUCTION

During the three weeks since this Court granted LifeNet's motion to expedite summary judgment briefing, ECF 25, the public interest in prompt resolution of this case has only grown stronger: As of today, *at least* 289 air ambulance IDRs are already underway using the unlawful QPA Presumption (three of which involve LifeNet's services); 957 have reached the 30-day "open negotiation" period immediately preceding IDR; and 7,189 IDR-eligible claims for air ambulance services have been submitted by air ambulance providers to health insurers. *See* Ex. 1 (updated declaration from Air Methods and LifeNet); Ex. 2 (GMR); Ex. 3 (PHI). LifeNet is grateful to this Court for providing a prompt briefing schedule, and respectfully requests that the Court enter judgment as soon as its schedule permits.

During the same three weeks, the Departments have not made any attempt, in their 56 pages of briefing, to explain why this Court's holding in *TMA* should not apply, in full, to air ambulance IDRs. Nor have the Departments made any attempt to explain why it makes sense for the QPA to be given presumptive weight *only* in air ambulance IDRs, and not in all other IDRs. LifeNet has already explained why this disparate treatment is contrary to the statute (which applies the QPA equally for all IDRs); contrary to the Departments' own regulations (which do the same); and contrary to common sense. *See* ECF 23, 15–17. The Departments' only response is to contend (wrongly) that this Court doesn't have the authority to expect an answer to this question. ECF 31, at 28–29.

¹ Texas Medical Association v. United States Department of Health and Human Services, et al., No. 6:21-CV-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022).

Desperate to escape a decision on the merits, the Departments instead contend that LifeNet lacks standing. Yet LifeNet stands in the same position as Dr. Adam Corley, the individual plaintiff found to have standing in *TMA*—as LifeNet pointed out, *see* ECF 23, at 20, and which the Departments do not dispute, *see* ECF 31, at 15–17 (not mentioning Dr. Corley). The Departments distort Article III standing doctrine beyond recognition when they insist that only an immediate pocketbook injury will open the doors to a federal courthouse. That is not the law, and the Departments cite no case so holding.

Nor should this Court grant the Departments' request for further discovery on standing—a needless excuse for further delay. The Departments come nowhere close to meeting the Rule 56(d) standard—they submit no declaration; they fail to identify any additional relevant discovery; and they have not been diligent. The only specific document they ask to see (LifeNet's contract with Air Methods) has now been provided to them (with only the highly sensitive financial terms redacted) and is being filed as an exhibit to this motion. *See* Third Gaines Declaration, Ex. 1.

The Departments' defense of the QPA Presumption is easily resolved: Every one of the Departments' arguments, here, is substantively identical to an argument that this Court already rejected in *TMA*. Indeed, most of the Departments' brief is a near-word-for-word "copy and paste" of their *TMA* brief. In short: The Departments have nothing new to say that this Court has not already heard, and decided, in *TMA*.

LifeNet respectfully requests that its motion for summary judgment be granted, as soon as the Court's schedule permits, for the reasons already explained by the Court in *TMA*.

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ARGUMENT

I. LifeNet Has Standing

LifeNet's emergency transports of commercially insured patients, which are now subject to the No Surprises Act's IDR process, represent a "critically important market" for LifeNet. ECF 27-2 (First Gaines Decl.), ¶ 2. The valuations that IDR entities place on LifeNet's services in this market matter greatly to LifeNet, *regardless* of whatever dollar payments LifeNet receives from Air Methods under their contract.

Not long from now, that contract will end—either on October 2023 (when either party may terminate it "without cause"),² or even earlier, if the agreed-upon payment amounts become "financially inviable" for Air Methods.³ The QPA Presumption will cause the IDR entities to decrease their valuations of LifeNet's services. The Departments do not dispute this point. Their desire to systematically lower the payments made to providers was one reason why they invented the contrary-to-statute QPA Presumption in the first place. *See* ECF 31 at 5–6, 20–21; *see also* Defendants' Cross-Motion for Summary Judgment, *TMA*, ECF 62, at 10–11, 22, 32, 37 (filed Jan. 10, 2022). The QPA Presumption therefore substantially increases the risk of early contract termination or demands from Air Methods to renegotiate the contract's financial terms.

Contract aside, LifeNet is also injured *today* by the lower valuations that the QPA Presumption causes IDR entities to give to LifeNet's services. LifeNet, like any other for-profit business, must routinely answer the following question: "how much are LifeNet's services worth

² Section 2.4 of the contract permits either party to terminate the contract "without cause" after the "two-year anniversary of the Commencement Date," i.e., October 1, 2023. Third Gaines Decl., Ex. 1 (contract), § 2.4.

³ *Id.* § 2.3 (termination for a "financially inviable situation that is beyond the reasonable expectations of either Party").

in the critically important market of emergency transports of commercially insured patients?" This question will be asked if LifeNet seeks to borrow money or makes capital investments. *See Clinton v. City of New York*, 524 U.S. 417, 431 (1998) (a liability that is *contingent* upon government's later waiver decision is nevertheless an Article III injury, today, because "a substantial contingent liability immediately and directly affects the borrowing power, financial strength, and fiscal planning of the potential obligor"). This question will also be asked when the current contract ends. The first question that Air Methods or any other potential business partner will ask, during negotiations over the terms of a new contract, will be: "how much are LifeNet's services worth?"

The answer to the question "how much are LifeNet's services worth?" now depends entirely on the results of IDRs, because those results are the *only marketplace* for these services. LifeNet can no longer bill the patient directly for anything other than the patient's "cost sharing" (e.g., co-pay) amount. *See* 42 U.S.C. § 300gg-135. The IDRs place a dollar value on LifeNet's emergency transports of commercially insured patients. And the IDRs decided while the Air Methods contract is still in place will directly affect the answer to the question "how much are LifeNet's services worth?"

The results of the IDRs decided today will not vanish into the ether tomorrow; instead, these results will remain: they are recorded in LifeNet's files; in Air Methods' files; in the files of the commercial insurers and health plans who participate in today's IDRs; and in the files of the federal government. Whenever LifeNet is required to answer the key question of any commercial enterprise ("how much are your services worth?"), the results of today's IDRs will form at least part of the answer. And because the results of today's IDRs will be significantly lower, as a result of the QPA Presumption (something the Departments do not dispute), today's results will harm LifeNet when LifeNet is called upon to answer that question. *See Susan B. Anthony List v.*

Driehaus, 573 U.S. 149, 158 (2014) (substantial risk of future harm conferred standing); Clinton, 524 U.S. at 431 (contingent risk of future harm conferred standing); Ass'n of Data Processing Serv. Organizations, Inc. v. Camp, 397 U.S. 150, 152 (1970) (plaintiff had standing to challenge agency ruling because that ruling "might entail some future loss of profits" to plaintiff). The lower valuations, caused by the QPA Presumption, are far more significant to LifeNet than other injuries that have been held to constitute an Article III injury-in-fact, such as a "single unwanted text." Cranor v. 5 Star Nutrition, L.L.C., 998 F.3d 686, 689–90 (5th Cir. 2021).

The Departments ignore this injury; rather, their brief assumes that *only* an immediate injury to the plaintiff's pocketbook, today, can open the doors of a federal courthouse. The Departments do not cite a single case that holds this or anything like it. In *Kitty Hawk*, the challenged regulation affected only certain Postal Service contracts. *Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 459 (5th Cir. 2005). The plaintiff lacked standing because it was *no longer eligible* for those contracts. *Id.* By contrast, LifeNet currently (indeed, routinely) provides air ambulance services that are valued by the IDR process. ECF 27-2 (First Gaines Decl.), ¶¶ 3–4. Three IDRs are currently underway that will place a value on LifeNet's services. Ex. 1, ¶ 3 (Muthia Decl.).

This Court already answered this standing question in *TMA*, when it found that Dr. Corley, the individual plaintiff in *TMA*, had standing. Like LifeNet, Dr. Corley was also compensated for his NSA-covered services by a non-party company that then handled the IDR process. *See* Plaintiffs' Mot., ECF 27, at 20 (describing Dr. Corley's arrangement). The Departments have no answer to this. *See* Defendants' Mot., ECF 31, at 17 n.4 (attempting to distinguish *TMA* plaintiffs but not addressing Dr. Corley's circumstances).

The Departments also contend that LifeNet has not shown "causation" or "redressability." ECF 31, at 16-17. This argument fails because *LifeNet is a regulated entity*. The QPA Presumption will cause today's IDRs to place a lower value on LifeNet's services, and will thereby cause injury to LifeNet today, for the reasons stated above. By contrast, the plaintiff in *Inclusive Communities* was not directly regulated by the challenged regulation. *See Inclusive Communities Project, Inc.* v. *Dep't of Treasury*, 946 F.3d 649, 657 (5th Cir. 2019). Rather, that plaintiff contended that various Treasury regulations increased the plaintiff's costs of finding affordable housing for its clients. The causal chain between Treasury's actions, and the increased costs to plaintiff, was "hazy at best" and "involved ... at least two links." *Id.* at 657. Here, the causal link is direct *and undisputed by the Departments*: the QPA Presumption causes the valuations of LifeNet's present services to be lower than they otherwise would be.

II. The Departments' Belated Request for "Discovery" Should Be Denied

The Departments' belated request for "discovery" regarding standing—a request made, for the first time, in the Departments' cross-motion—should be denied for three reasons. *First*, Rule 56(d) requires a "declaration" showing "that, for specified reasons," the Departments "cannot present facts essential to justify its opposition." The Departments have submitted no "declaration" on this issue at all, much less one that identifies "specified reasons."

Second, the Departments have not shown "a plausible basis for believing that specified facts, susceptible to collection within a reasonable time frame, probably exist," nor "how the emergent facts, if adduced, will influence the outcome of the pending summary judgment motion." Bailey v. KS Mgmt. Servs., L.L.C., 2022 WL 1672850, at *2 (5th Cir. 2022) ("The nonmovant may not simply rely on vague assertions that discovery will produce needed, but unspecified, facts."). The only specific document the Departments mention is LifeNet's contract with Air Methods. ECF

31, at 17. But that contract is not necessary to show that LifeNet has suffered the injury described above (the low valuation of its services, in a "critically important" market). And in any event, LifeNet has now provided the contract (which is also being filed with the Court as Exhibit 1 to the Third Gaines Declaration). The Departments do not identify, with specificity, any other documents or information that they would seek, nor do they give any explanation of how those documents or information could "influence the outcome." *Bailey*, 2022 WL 1672850, at *2.

Third, the Departments have not shown that they "diligently pursued discovery." Id. at *4 (plaintiff showed diligence by repeatedly requesting specific discovery). This Court ordered expedited summary judgment briefing on May 13. See ECF 25. The Departments thereafter made no discovery request of any kind to LifeNet (formal or informal), or to the Court, before filing their cross-motion on June 1. In the context of this action, in which this Court granted an expedited briefing schedule, the Departments' failure to promptly request discovery from LifeNet demonstrates a lack of diligence. See Bailey, 2022 WL 1672850, at *5 ("In other cases where we've found a lack of diligence, it was because the movant failed to conduct discovery during a period in which it was permitted to do so." (collecting cases)).

III. The QPA Presumption Is Contrary to the No Surprises Act's Unambiguous Requirement that the IDR Entity Consider Each Enumerated Factor

"The Departments recognize that this Court reached a contrary conclusion" to their present position in *TMA*. *See* ECF 31 at 22. That concession is entirely proper, because *TMA* fully resolves this case: "the [No Surprises] Act is unambiguous." *TMA* at *7. "The Act plainly requires arbitrators to consider all the specified information in determining which offer to select" because the Act provides that arbitrators "shall consider" that information. *Id.* "Because Congress spoke clearly on the issue relevant here," the Court held in *TMA*, "the Departments' interpretation of the statute is owed no *Chevron* deference." *Id.* And this Court expressly rejected the Departments'

assertion that the Act "instructs arbitrators to weigh any one factor or circumstance more heavily than the others" and imposes a "rebuttable presumption" in favor of the QPA. *Id.* at *8.

The reasoning of *TMA* applies with equal force to air ambulance providers' IDRs. In 42 U.S.C. § 300gg-111(c)(5)(C)(i), Congress directed that the arbitrator "shall consider ... the qualifying payment amounts ... and ... information on any circumstance described in clause (ii)" when setting the out-of-network rate for non-air ambulance providers. And in 42 U.S.C. § 300gg-112, Congress directed that the arbitrator "shall consider ... the qualifying payment amounts ... and ... information on any circumstance described in clause (ii)" when setting the out-of-network rate for air ambulance providers. The relevant dictates in 42 U.S.C. § 300gg-111 and 42 U.S.C. § 300gg-112 are identical.

The Departments state they "respectfully disagree with [TMA's] decision" for "the reasons stated" in their brief. But their brief states no reasons that would justify a different outcome than in TMA. Almost the entirety of Section II of their argument, which concerns the substantive validity of the QPA presumption, is copy-and-pasted from the analogous sections of their brief in TMA. Compare ECF 31 at 18–22 with TMA, ECF 62 at 18–29. The Court has considered those arguments and rejected them. It should do so again.

The only substantive passage in the merits portion of the Departments' brief, which differs in any significant way from their *TMA* brief, is the following:

Plaintiff also contends that the September rule improperly treats the QPA differently from the other statutory factors. Pl.'s Mem. 13. But the No Surprises Act itself directs the arbitrator first to the qualifying payment amount, and then instructs the arbitrator next to consider "additional information" or "additional circumstances" that may warrant the award of a different amount. 42 U.S.C. § 300gg-112(b)(5)(C)(i)(II), (ii). Congress, of course, may "prescribe a structure" for an agency to go about addressing a set of statutory factors, *Ramirez v. ICE*,471 F. Supp. 3d 88, 176 (D.D.C. 2020)

But even though the words are different, the *substance* of this "structural" argument was raised by the Departments in *TMA*,⁴ and rejected by this Court. *TMA* at *8 ("[T]he Departments cite no authority holding that a statutory factor is entitled to more weight simply because it is the first in a list. And subchapter heading[s] cannot substitute for the operative text of the statute. The term 'additional,' moreover, does not justify weighing the other factors less than the QPA." (internal citations and quotation marks omitted)). The Departments offer nothing new to change the Court's conclusion.

IV. The Departments Violated the APA's Procedural Requirements

A. The No Surprises Act Does Not Override the APA's Notice-and-Comment Requirements

The Departments again recycle the same arguments, rejected by *TMA*, concerning the alleged inapplicability of the APA's notice-and-comment procedures. The only substantive addition to the Departments' brief is an acknowledgement that *TMA* joined other courts that had already rejected those arguments:

And the Departments acknowledge, of course, that this Court followed the reasoning of those cases in the *Texas Medical Association* opinion. The Departments respectfully disagree, however with the reasoning of those cases

ECF 31 at 23. Nothing has changed in the months since *TMA*. The Departments "disagree" with every judge to have considered their argument, but they present no new rationale to justify a different outcome.

The APA's notice-and-comment requirements apply unless a statute "expressly" modifies or supersedes them. *TMA* at 22; *see also* 5 U.S.C. § 559 ("Subsequent statute may not be held to

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⁴ See Defendants' Cross-Motion for Summary Judgment, *TMA*, ECF 62 at 23–24 ("Congress can 'prescribe a structure' under which an agency is to address competing considerations, and one way it can do so is by setting forth a sequence in which the agency is to address various factors (quoting *Ramirez*, 471 F. Supp. 3d at 176)).

supersede or modify this subchapter ... except to the extent that it does so expressly."). "But the language cited by the Departments" in TMA, and again in this case, "neither expressly nor implicitly exempts [the Departments] from the APA's notice-and-comment requirement." TMA at *10. The Departments cite the PHISA's, ERISA's and IRC's authorization to "promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter." 42 U.S.C. § 300gg-92; see also 26 U.S.C. § 9833; 29 U.S.C. § 1191c. However, that language does not expressly supersede notice-and-comment rulemaking because it is "silent as to any required procedure for issuing an IFR," does not "provide that notice and comment is supplanted or that good cause is no longer required," and does not "provide alternative procedures that could reasonably be understood as departing from the APA." California v. Azar, 911 F.3d 558, 579 (9th Cir. 2018); see also, e.g., TMA at *10 (rejecting government's argument); Coal. for Parity, Inc. v. Sebelius, 709 F. Supp. 2d 10, 18-19 (D.D.C. 2010) (same); Pennsylvania v. President of United States, 930 F.3d 543, 566 (3d Cir. 2019) (same), rev'd on other grounds, 140 S. Ct. 2367 (2020). The Departments even admitted in their TMA briefs that every court to consider their argument has rejected it. TMA, ECF 112 at 53:12–54:3; see also TMA at *10 (noting same and collecting cases).

The cases cited by the Departments remain inapposite for the reasons identified in *TMA*. *TMA* at *10. In *Asiana Airlines v. FAA*, 134 F.3d 393, 397–98 (D.C. Cir. 1998), and *Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994), "the statutes explicitly directed the agencies to issue interim final rules first, *then* provide a comment period, and *then* issue final rules." *TMA* at *23 (citing *Methodist Hosp. of Sacramento*, 38 F.3d at 1237 and *Asiana Airlines*, 134 F.3d at 397–98). In contrast, in 42 U.S.C. § 300gg-92, Congress supplied

no alternative rulemaking scheme that would authorize the Departments to deviate from the noticeand-comment procedures of the APA.

B. The Departments Lacked Good Cause to Dispense with Notice-and-Comment Rulemaking

When it comes to the good cause exception, the Departments again regurgitate briefing that this Court has already considered and rejected in *TMA*. ECF 31 at 23.

The Departments' only new wording that differs from their *TMA* briefing is the following:

As a coalition of providers warned the Departments, "if the IDR process [were] not ready on the backend by January 1 when the balance billing protections are implemented, then providers [would] be at the mercy of the insurer for reimbursement." Centers for Medicare & Medicaid Servs., *Report: No Surprises Act Listening Session with Providers* at 3 (Apr. 14, 2021) (AR 2492). These circumstances "constitute[] the 'something specific' required to forgo notice and comment." *Biden v. Missouri*, 142 S. Ct. 647, 654 (2022).

ECF 31 at 25 (alterations in original). But even though the words are new, the substance of this argument was also made (and then rejected) in *TMA*. *See* Defendants' Cross-Motion for Summary Judgment, *TMA*, ECF 62 at 33. Moreover, the actual administrative record indicates that this supposed "warning" came, not from a "coalition," but rather from *a single participant* in *one* "listening session" organized by the Departments.⁵

As the Court held in *TMA*, the statutory deadline to implement the IDR process does not provide good cause, and the Departments have also failed to justify their failure to engage in notice-and-comment rulemaking during the more than 15 months between the Act's enactment and the first IDRs. *TMA* at * 11-12; *see also* ECF 31 at 2 (noting arbitrations did not begin until April 2022). The Departments' arguments also contradict each other: although the Departments claim to have dispensed with notice-and-comment in order to protect providers from

⁵ ECF 31, at 25 (AR 2492) (ascribing this view to "[o]ne participant" in the listening session).

⁶ In fact, the Departments now "anticipate that they will issue a final rule by early summer"—even though they only initiated that final rulemaking eight months ago, in October 2021.

underpayment, they also justify their contrary-to-statute QPA Presumption as necessary in order *reduce* providers' compensation. *Compare* 86 Fed. Reg. at 56,044 (claim to be protecting providers) *with* ECF 31 at 5–6, 20–21 (purpose of QPA Presumption is to drive down reimbursement rates).

The Departments' remaining allegations of supposed "good cause," for dispensing with notice-and-comment, are even weaker now than when the Court rejected them in *TMA*. The good cause exception applies when notice-and-comment is "impracticable, unnecessary or contrary to the public interest." 5 U.S.C. § 553(b)(B). The exception "should be read narrowly in order to avoid providing agencies with an escape clause from the requirements Congress prescribed." *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) (quoting *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985)).

The Departments assert that insurers needed lead time to prepare for arbitrations and to set appropriate premiums. ECF 31 at 24-25. But the Departments present no evidence that *TMA*'s change to the IDR process has left insurers unable to navigate arbitrations or has rendered plans insolvent. In any event, the solution to that problem is not to ignore the Departments' obligation to conduct notice-and-comment rulemaking, but rather to have conducted a rulemaking during the 15 months between the Act's passage in December 2020 and the start of arbitrations in April 2022. The Departments squandered nearly 10 months before publishing IFR Part II, which contained the QPA Presumption.

The Departments argue that providers needed advanced warning "of the types of information" to be considered lest arbitrators rule against providers for failing "to provide contemporaneous information supporting the provider's payment claim." ECF 31 at 25 (citing 42 U.S.C. § 300gg-112(b)(5)(B)(i)(II)). But the Departments present no evidence that *TMA*'s changes

to the arbitration process has resulted in default judgments against providers. The provision the Departments cite, moreover, only require the provider to present "such information as requested by the certified IDR entity." 42 U.S.C. § 300gg-112(b)(5)(B)(i)(II). The challenged rule has nothing to do with what information the IDR entity may or may not request (other than forbidding entities from requesting certain categories of information that the statute forbids them from considering). *Compare* 42 U.S.C. § 300gg-112(b)(5)(C)(iii) *with* 45 C.F.R. § 149.510(c)(4)(v).

Finally, the Departments assert that arbitrators needed time to "acquire the necessary expertise," and "[a]ny further delay would not have left the Departments with sufficient time to ensure that certified arbitrators meet the Act's standards for expertise and integrity." ECF 31 at 26. But the Departments have not identified any pitfalls in training arbitrators to apply the new IDR process that the Departments implemented for non-air ambulance providers following *TMA*.

The Departments, in short, have advanced no new arguments to justify a departure from the Court's conclusion in *TMA* that the Departments have failed to carry their burden to show "good cause" for dispensing with notice-and-comment rulemaking. To the contrary, the Departments' arguments have only grown weaker over the past five months.

C. The Departments' Failure to Follow the Required Notice-and-Comment Procedures Was Not Harmless.

Here again, in the "harmlessness" analysis, the Departments repeat the arguments they made in *TMA* and that this Court rejected. ECF 31 at 27.

As this Court noted in *TMA*, "the touchstone [of the harmless error analysis] is whether it is clear that the lack of notice and comment did not prejudice the petitioner." *TMA* at *12 (quoting *City of Arlington v. FCC*, 668 F.3d 229, 244 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013)). But, when it comes to "failure[s] to provide notice and comment," courts "'rare[ly]' find harmless error ... because the 'vast majority of agency rulemaking, which produces nuanced and detailed

regulations[,] greatly benefit[s] from expert and regulated entity participation." *Id.* at *13 (quoting *United States v. Johnson*, 632 F.3d at 932). Indeed, "[a]n utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure." *Safari Club Int'l v. Zinke*, 878 F.3d 316, 335 (D.C. Cir. 2017).

The Departments protest that LifeNet has identified no specific comment it would have submitted had LifeNet been given the opportunity to do so. But "[t]here is no such requirement for harmless error analysis." *California v. Azar*, 911 F.3d at 580. And, as the Court noted in *TMA*, "if the Departments had provided notice and comment, Plaintiffs could have submitted the specific reasons and authorities [raised in their motion for summary judgment] for why they believed the Rule is inconsistent with the Act." *TMA* at *13. The same is true here.

The Departments' assertion of harmless error in this case is even weaker than the position they advanced in *TMA*. In *TMA*, the Departments asserted that TMA *had* submitted comments and thus allegedly had an opportunity to influence their views. *TMA*, ECF 62 at 36. The Departments admit here, however, that Plaintiff "has not participated in the rulemaking proceedings"; instead, they suggest that Plaintiff's views were necessarily represented because "the Association of Air Medical Services" (AAMS) participated. ECF 31 at 28. The Departments cite *no* authority suggesting that soliciting comments from a trade association obviates agencies' duty to consider comments from the association's members.

Moreover, the Departments cite only four purported comments from AAMS at AR 2501, AR 4985, AR 4989, and AR 5782. ECF 31 at 28. None of these directly addresses the QPA presumption.⁷ That silence should come as no surprise. The Departments announced the QPA

⁷ The Departments appear to cite AR 4985 in error. AR 4985 is a May 7, 2021 letter from the Association of American Medical Colleges—not AAMS. Departments may have intended to cite

presumption as a *fait accompli*, when promulgating IFR Part II *after those comments were received*. AAMS (and all other providers) had no notice that the Departments intended to deviate from the statute in this way, and had no opportunity to address the deviation in their informal comments to the Departments. The purpose of *notice* and comment rulemaking is to provide regulated parties with an opportunity to comment (and for the agency to consider those comments) *before* the agency finalizes the proposed rule. 5 U.S.C. § 553 (requiring agency to receive and consider comments *after* providing notice of proposed rulemaking); *see also*, *e.g.*, *CSX Transp.*, *Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079 (D.C. Cir. 2009) (requiring notice of proposed rulemaking, pursuant to "logical outgrowth" test, to have reasonably alerted interested parties to "have filed their comments on the subject during the notice-and-comment period" (citations omitted)). That did not occur here.

Nor—contrary to the Departments' assertion—must Plaintiff show that the Departments' regulations would have been different, if the notice-and-comment procedures had been filed. Such a burden would nullify the APA's notice-and-comment requirements as an agency "could always clam that it would have adopted the same rule even if it had complied with the APA procedures." *Paulsen v. Daniels*, 413 F.3d 999, 1006 (9th Cir. 2005); *see also*, *e.g.*, *Riverbend Farms*, *Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir. 1992) (same); *United States v. Reynolds*, 710 F.3d 498, 517 (3d Cir. 2013) (same); *TMA* at *13. Moreover, this Court already found that the "exhaustive and complex arbitration process," challenged here, "would have changed—even if in small part—had the Departments properly considered Plaintiff['s] objections." *TMA* at *13.

AR 4995, a June 15, 2021, letter from AAMS. That letter also does not address the QPA Presumption.

The Departments' insistence that a forthcoming final rule negates any harm is similarly misplaced. The Fifth Circuit "has twice rejected the argument that a 'post-promulgation comment period cure[s] whatever procedural error may have been committed,' concluding that such a position would 'allow any agency to dispense with pre-promulgation notice and comment whenever it so desired." *TMA* at *14 (quoting *City of Waco v. EPA*, 620 F.2d 84, 86 (5th Cir. 1980) and citing *U.S. Steel Corp. v. U.S. E.P.A.*, 595 F.2d 207, 213–215 (5th Cir. 1979)). *Ex post* consideration of comments does not meet the Departments *pre-promulgation* notice-and-comment obligations under the APA. *See, e.g., id.* And the possible promulgation of a final rule does not answer the harms Plaintiff currently suffers under IFR Part II. Because it is not "clear that the lack of notice and comment did not prejudice" LifeNet, *Johnson*, 632 F.3d at 931, the Court should stand by its conclusion in *TMA* that the Departments' failure to follow the required notice-and-comment procedures was not harmless. *TMA* at *14.

V. The Departments Have Offered No Valid Rationale For Treating Air Ambulances Differently From All Other Emergency Providers

The Departments' differential treatment of air ambulance providers, as compared to all other out-of-network providers, is arbitrary and capricious for the reasons stated in Plaintiff's opening brief. ECF 27 at 15–16. This is Plaintiff's sole new argument; it was (of course) not raised in *TMA*, since at the time of the *TMA* briefing the Departments were still treating air-ambulance providers the same as all other providers for purposes of the QPA Presumption. This is an *alternative* argument only; this Court may resolve this case on the two bases, discussed above, in which this matter is *identical* to the TMA challenge.

As explained in Plaintiff's opening brief, the statute and regulations provide no basis for distinguishing the QPA's use, in air ambulance IDRs, from the QPA's use in all other IDRs. ECF 27 at 15–17. The relevant statutory text is the same and the Departments' rulemaking drew no

distinction. *Id.* at 16. On the merits, the Departments *still* make no attempt to explain why the statute, the published regulation, or basic common sense supports the Departments' current approach, which is to apply the QPA Presumption solely to air ambulance providers.

Rather than defend their current discriminatory treatment of air ambulance providers, the Departments instead contend that this Court cannot review Plaintiff's challenge to this new irrationality. Citing *Auer v. Robbins*, 519 U.S. 452, 459 (1997), and *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016), the Departments argue that Plaintiff cannot challenge the unique application of the QPA presumption to air ambulance providers as arbitrary and capricious under the APA because, at the time they issued IFR Part II, the QPA presumption applied to all providers. Therefore, the Departments have not *yet* discriminated against air ambulance providers, and Plaintiff must first petition the Departments under section 553(e) of the APA to amend 45 C.F.R. § 149.520, in order to bring it in line with 45 C.F.R. § 149.510. Only when the Departments deny that petition, the Departments say, can Plaintiff seek judicial review of the denial.

The Departments miss the point. Plaintiff argues that the agencies' April 12 "Federal Independent Dispute Resolution IDR Process: Guidance for Certified IDR Entities" was arbitrary and capricious. ECF 27 at 15–17. That "April 12 Guidance" was issued *after* this Court vacated the QPA presumption for non-air ambulance providers. And that Guidance directed arbitrators to apply the QPA *only* to air ambulance providers. *Compare* ECF 27-1 at § 6.4 (applying QPA presumption to air ambulance providers) *with id.* at § 6.3 (not applying that presumption to all other providers).

The Departments' April 12 Guidance qualifies as final agency action and is therefore subject to arbitrary and capricious review. *See* 5 U.S.C. § 704. "The Supreme Court has 'long taken' a "pragmatic approach ... to finality,' viewing 'the APA's finality requirement as flexible.""

Texas v. EEOC, 933 F.3d 433, 441 (5th Cir. 2019) (citations omitted). A final agency action marks the "consummation' of the agency's decisionmaking process," Bennett v. Spear, 520 U.S. 154, 178 (1997) (quoting Chicago & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113, (1948)), and is a decision "from which 'legal consequences flow." Id. (quoting Port of Boston Marine Terminal Assn. v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970). The April 12 Guidance meets that test. The April 12 Guidance determined that, notwithstanding the Court's decision in TMA, arbitrators must continue applying the QPA Presumption to air ambulance providers—and to air ambulance providers alone. Absent the April 12 Guidance, arbitrators might reasonably have concluded that the rationale and holding of TMA wiped out the QPA presumption for all providers.

In *Texas v. EEOC*, 933 F.3d at 443, the Fifth Circuit held that a similar EEOC "Guidance" qualified as final agency action subject to APA review. That EEOC Guidance "binds EEOC staff to an analytical method in conducting Title VII investigations," "directs their decisions about which employers to refer for enforcement actions," and "limits discretion respecting the use of certain evidence, mandating that evidence of a racially-balanced workforce cannot overcome a showing of disparate impact." *Id.* at 443. The April 12 Guidance similarly (1) constrains the analytical method to be used when applying the NSA to air ambulance providers, (2) constrains arbitrators' discretion to use evidence other than the QPA, and (3) creates a presumption based on the QPA. These constraints have "legal consequences," *Bennett*, 520 U.S. at 178, and are therefore reviewable.

The April 12 Guidance therefore reverses the agencies' prior statement on the matter: IFR Part II. In IFR Part II, the agencies decided to treat all providers the same with respect to the QPA. See 45 C.F.R. § 149.520(b)(1) (applying same IDR procedures to air ambulance providers—

including QPA Presumption—except for making minor changes, not relevant here, to the specific additional information that the IDR entity should consider). When promulgating IFR Part II, the Departments explained that the "process for a certified IDR entity to select an offer in a dispute related to qualified IDR services that are air ambulance services is essentially the same as" for "services that are not air ambulance services"; and, "[a]s with qualified IDR items or services that are not air ambulance services, the certified IDR entity must begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate for the air ambulance service." Fed. Reg. at 55,998–99. IFR Part II never suggests applying the QPA Presumption differently to air ambulance providers, and certainly does not provide any reasoned basis for doing so.

The April 12 Guidance thus represents a *change* in agency policy, which must pass muster under the arbitrary and capricious standard. "An agency may not, for example, depart from a prior policy *sub* silentio"; it "must" instead "show that there are good reasons for the new policy." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009); *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. at 221–22 (requiring agency to "at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy." (citations omitted)). Here, the April 12 Guidance offered no justification for treating air ambulance providers differently. The April 12 Guidance did not even acknowledge that change. Therefore, the April 12 Guidance was arbitrary and capricious in treating air ambulance providers differently, and it should be set aside.

The two cases cited by the Departments are inapposite. In *Auer v. Robbins*, the respondent had claimed "it was 'arbitrary' and 'capricious' not to conduct amendatory rulemaking" to alter the existing rule after Congress amended the Fair Labor Standards Act (FLSA) to cover public sector employees. *Auer*, 519 U.S. at 459. The respondent did not claim that the existing regulation

was "substantively unlawful" or "violated a clear procedural prerequisite"—simply that the Secretary of Labor should have weighed changing the rule through a process "which might well have resulted in no change." *Id.* In contrast, Plaintiff in this suit does not argue that the Departments should have changed the rules, but rather that the Departments acted arbitrarily and capriciously at the time they imposed the QPA presumption on air ambulance providers.

The Departments also cite *Encino Motorcars, LLC v. Navarro*, 579 U.S. at 221. But the Departments fail to note that the passage they quote is from the parenthetical of a "cf. also" citation to *Auer*. In *Encino* itself, the agencies did "not contest the manner in which petitioner has challenged the agency procedures here," therefore, the Court's "opinion assumes without deciding that the challenge was proper." *Id. Encino* provides no independent support for the Departments' argument.

VI. The Court Should Vacate the QPA Presumption

The Court should (again) vacate QPA Presumption—just as it did in *TMA*. "[B]y default, remand with vacatur is the appropriate remedy' in a case challenging agency action under the APA." *TMA* at *14. (quoting *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021)). As in *TMA*, the "seriousness of the deficiency weighs heavily in favor of vacatur." *Id.* at *14. And, "[f]ailure to provide the required notice and to invite public comment—in contrast to the agency's failure ... adequately to explain why it chose one approach rather than another for one aspect of an otherwise permissible rule—is a fundamental flaw that normally requires vacatur of the rule." *See Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (internal quotation marks omitted).

In arguing against vacatur, the Departments invoke cases presenting (1) "a serious possibility that the [agency] will be able to remedy its failures," *Texas Ass'n of Manufacturers v. United States Consumer Prod. Safety Comm'n*, 989 F.3d 368, 389 (5th Cir. 2021), and/or (2) circumstances suggesting that the agency "may well be able to justify its decision," *Cent. & S. W.*

Servs., Inc. v. EPA, 220 F.3d 683, 692 (5th Cir. 2000). See ECF 31 at 30. But unlike these cases, the provisions challenged by LifeNet conflict "with the unambiguous terms of the Act in several key respects." TMA at *14. There is thus "nothing the Departments can do on remand to rehabilitate or justify the challenged portions of the Rule as written." Id.

The Departments' argument that "vacatur would disrupt the dispute resolution process," ECF 31 at 30, is, at bottom, only "the regulatory uncertainty that typically attends vacatur of any rule," *Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 85 (D.C. Cir. 2020). This Court has already held that vacating the QPA Presumption and remanding for further rulemaking would "not be unduly disruptive," since the "remaining provisions of the Rule and the Act itself provide a sufficient framework for providers and insurers to resolve payment disputes, including specifying what criteria an arbitrator 'shall' consider and those the arbitrator 'shall not.'" *TMA* at *14 (quoting 42 U.S.C. §§ 300gg-111(c)(5)(C), (D)); *see also* 42 U.S.C. §§ 300gg-112(c)(5)(C)(i), (iii) (providing that IDR Entities in air ambulance IDRs "shall" and "shall not" consider certain factors). Moreover, it has now been nearly four months since *TMA* vacated the QPA Presumption for all non-air-ambulance providers, and the Departments' brief fails to identify any specific disruption caused by that decision.

In short: The Departments provide no reason for the Court to depart from its *TMA* approach. The challenged provision should be vacated and remanded to the agency.

CONCLUSION

LifeNet, a regulated party, is affected by the QPA Presumption because the IDR decisions decided under that presumption, today, will devalue LifeNet's services in the "critically important" market for emergency transports of commercially insured patients. Devaluing LifeNet's services causes injury now, and is certain to do so in the future whenever LifeNet is called upon (by a potential business partner, by a bank, or by an insurance company) to show "what its services are

worth." LifeNet therefore has Article III standing to challenge the regulation. That challenge succeeds on the merits for all the reasons given by this Court in *TMA*. The Departments' merits arguments were all rejected by this Court in *TMA*, and have only become less persuasive with the passage of time. LifeNet's motion for summary judgment should be GRANTED, and the Department's cross-motion should be DENIED.

Dated: June 7, 2022

BY: /s/ Steven M. Shepard
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Counsel to Plaintiff LifeNet, Inc.

CERTIFICATE OF SERVICE

I certify that on June 7, 2022, a copy of the foregoing was served on the parties to this

action by electronically filing true and correct copies with the Clerk of the Court using the

ECM/ECF system which automatically sent notification by e-mail of such filing to the counsel of

record.

/s/ Steven M. Shepard

Steven M. Shepard

EXHIBIT 1

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

LIFENET, INC.

Plaintiff,

Case No. 6:22-cv-00162-JDK

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.

DECLARATION OF KOREEN MUTHIAH

- 1. My name is Koreen Muthiah. I am over the age of eighteen. I am employed by Air Methods Corporation. My job title is Vice President of Reimbursement. I have personal knowledge of the matters contained herein.
- 2. Air Methods Corporation together with its affiliates and subsidiaries (collectively "Air Methods Corporation") provides air ambulance services across the United States.
- 3. As of the date of this Declaration, Air Methods Corporation has performed approximately 2,119 emergency air transports for which the right to reimbursement is governed by the No Surprises Act and its implementing regulations. These are services that were provided

to patients with commercial health plans or health insurance policies, for plan or policy years

beginning on or after January 1, 2022, for which our company is an out-of-network provider.

4. As of the date of this Declaration, approximately 347 of these emergency air

transports have become the subject of an "open negotiation notice" initiating the "open

negotiation" period described in the No Surprises Act and its implementing regulations. Of these,

nine were flights on which LifeNet's personnel provided the clinical services.

5. As of the date of this Declaration, approximately 106 of these emergency air

transports have become the subject of an Independent Dispute Resolution ("IDR") notice, initiating

an IDR proceeding. Of these, three were flights on which LifeNet's personnel provided the clinical

services.

I declare under penalty of perjury under the laws of the United States of America that the foregoing

is true and correct. Executed on USWK, 2022 . (date).

Signature:

Printed Name:

Koreen Muthian

EXHIBIT 2

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

LIFENET, INC.

Plaintiff,

Case No. 6:22-cv-00162-JDK

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.

DECLARATION OF GLOBAL MEDICAL RESPONSE, INC.

- 1. My name is Sarah Netherton. I am over the age of eighteen. I am employed by Global Medical Response, Inc. ("GMR"). My job title is Director, Revenue Cycle Strategic Initiatives. I have personal knowledge of the matters contained herein.
 - 2. GMR provides air ambulance services across the United States.
- 3. As of the date of this Declaration, GMR has performed approximately 4,120 emergency air transports for which the right to reimbursement is governed by the No Surprises Act and its implementing regulations. These are services that were provided to patients with commercial health plans or health insurance policies, for plan or policy years beginning on or after January 1, 2022, for which our company is an out-of-network provider.

- 4. As of the date of this Declaration, approximately 420 of these emergency air transports have become the subject of an "open negotiation notice" initiating the "open negotiation" period described in the No Surprises Act and its implementing regulations.
- 5. As of the date of this Declaration, approximately 163 of these emergency air transports have become the subject of an Independent Dispute Resolution ("IDR") notice, initiating an IDR proceeding.

I declare under penalty of perjury u	ınder the l	aws of the Unite	d States of America	that the foregoing
is true and correct. Executed on	6/4/2	2 (dat	e).	

Signature:

Printed Name:

EXHIBIT 3

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

LIFENET, INC.

Plaintiff,

Case No. 6:22-cv-00162-JDK

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.

DECLARATION OF MICHAEL FOSTER OF PHI HEALTH, LLC

- 1. My name is Michael Foster. I am over the age of eighteen. I am employed by PHI Health, LLC. My job title is Chief Financial Officer. I have personal knowledge of the matters contained herein.
 - 2. PHI Health, LLC provides air ambulance services across the United States.
- 3. As of the date of this Declaration, PHI Health, LLC has performed approximately 950 emergency air transports for which the right to reimbursement is governed by the No Surprises Act and its implementing regulations. These are services that were provided to patients with commercial health plans or health insurance policies, for plan or policy years beginning on or after January 1, 2022, for which our company is an out-of-network provider.

- 4. As of the date of this Declaration, approximately 190 of these emergency air transports have become the subject of an "open negotiation notice" initiating the "open negotiation" period described in the No Surprises Act and its implementing regulations.
- 5. As of the date of this Declaration, approximately 20 of these emergency air transports have become the subject of an Independent Dispute Resolution ("IDR") notice, initiating an IDR proceeding.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on $\frac{202}{202}$. (date).

Signature:

Printed Name:

EXHIBIT 4

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

LIFENET, INC.

Case No. 6:22-cv-00162-JDK

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Plaintiff,

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.

THIRD DECLARATION OF LIFENET, INC.

- 1. My name is James L. Gaines. I am over the age of eighteen. I am employed by LifeNet, Inc. ("LifeNet"). My job title is General Counsel. I have personal knowledge of the matters contained herein.
- 2. Attached as Exhibit 1 is a true and accurate copy of LifeNet's contract with Air Methods Corporation ("AMC"), executed on August 24, 2021, together with the subsequent amendments thereto. The only redactions are of specific pricing and other financial information, which are highly commercially sensitive.
- 3. The unreducted portions of the document are also commercially sensitive and for that reason LifeNet respectfully requests that the Court permit them to be filed under seal. The

commercially sensitive information, contained in the unredacted portions, includes: the specific details and structure of LifeNet's and AMC's compensation arrangement; the specific details and structure of LifeNet's and AMC's cooperation, whereby LifeNet provides clinical services and AMC provides the air ambulance vehicle and piloting services; the specific details of LifeNet's and AMC's operations and personnel; and details of the locations served by the parties' services. If these details were to be made public, then that would cause competitive injury to LifeNet. For these reasons, LifeNet and AMC agreed to a confidentiality clause preventing either party from disclosing the agreement (August 24, 2021 contract, section 27.0, page 19).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed in G/G/2022. (date).

Signature:

Printed Name: SAMEL. Games

EXHIBIT 1 FILED UNDER SEAL

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS

LIFENET, INC.

Plaintiff,

Case 6:22-cv-00162

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.

[PROPOSED] ORDER DENYING DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Before the Court is Defendants' Cross-Motion for Summary Judgment. Being fully advised in the premises, the Court finds that the motion should be DENIED as to [Count I and Count II].

It is, therefore, ORDERED that the motion is hereby DENIED as to [Count I and Count II].