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

TEXAS MEDICAL ASSOCIATION, et al.,)
Plaintiffs,)
v.) Case No.: 6:22-cv-00372-JDK
••) Lead Consolidated Case
UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES, et al.,)
Defendants.))

LIFENET'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT

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Plaintiff LifeNet, Inc., respectfully moves for summary judgment on Count I of its complaint. Attached hereto as Exhibits E, F, and G, and incorporated herein by reference, are LifeNet's declarations in support of this motion.

INTRODUCTION

LifeNet joins in full the separate motion for summary judgment filed by the Texas Medical Association ("TMA"). ECF 41 (the "TMA Br."). LifeNet makes three additional arguments:

First, there are no material statutory or regulatory differences, relevant to this case, between the Independent Dispute Resolution ("IDR") process for air ambulance providers and the IDR process for non-air ambulance providers. Nor are there any material differences between how the New QPA Presumption is applied to air ambulance providers, and how it is applied to non-air-ambulance providers. Therefore, all of TMA's arguments are equally applicable to air ambulance providers like LifeNet. See LifeNet, Inc. v. United States Dep't of Health & Hum. Servs., No. 6:22-CV-162-JDK, 2022 WL 2959715, at *8 (E.D. Tex. July 26, 2022) ("LifeNet I") ("[F]or all the reasons stated in TMA, the Court holds that the Rule conflicts with the Act and must be set aside under the APA.").

Second, the Departments' New QPA Presumption is arbitrary and capricious because QPA calculations are afflicted by "ghost rates"—that is, contracted rates agreed to by providers who do not even provide the at-issue service. To take just one local example: Aetna of Texas's recently published data contains hundreds of contracted rates, for air ambulance transport services, which were agreed to by social workers, optometrists, and psychologists. See Ex. E. Such "ghost rates" are not a reliable measure of the market prices for these services because a provider with no air ambulance has no economic incentive to negotiate for an appropriate air-ambulance rate. The Departments knew about this problem but did not address it. Nor did the Departments attempt to

explain why the arbitrator should be forbidden from questioning the credibility of QPAs that are based on "ghost rates."

Third, LifeNet has standing to challenge the New QPA Presumption.

STATEMENT OF THE ISSUE

LifeNet respectfully incorporates TMA's statement of the issue.

STATEMENT OF UNDISPUTED MATERIAL FACTS

LifeNet respectfully incorporates TMA's statement of undisputed material facts. In addition, LifeNet adds the following undisputed material facts relating to air ambulances.

I. The No Surprises Act

In the No Surprises Act, Congress enacted a separate and much shorter statutory provision that governs air ambulance IDRs: 42 U.S.C. § 300gg-112.¹ That separate provision incorporates, by reference, nearly every part of the statutory provision that governs non-air ambulance IDRs: 42 U.S.C. § 300gg-111. The only difference between these two provisions, relevant to this case, is the list of non-QPA statutory factors that the IDR entity "shall consider." The chart below compares these factors for both kinds of IDRs:

"Considerations in determination" for non-	"Considerations in determination" for air
air ambulance IDRs. 42 U.S.C. § 300gg-	ambulance IDRs. 42 U.S.C. § 300gg-
111(c)(5).	112(b)(5)(C).
"[T]he qualifying payment amounts	Substantially the same.
[QPAs] for the applicable year for items or	
services that are comparable to the qualified	
IDR item or service and that are furnished in	

¹ The relevant statutory and regulatory provisions at issue in this case generally appear in triplicate and are identical in all material respects. For ease of reference, this brief—like TMA's brief—cites the PHS Act provisions in 42 U.S.C., and the PHS implementing regulations in 45 C.F.R., which are enforced by the Department of Health and Human Services ("HHS"). The NSA made parallel amendments to the Employee Retirement Income Security Act ("ERISA"), enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), enforced by the Department of the Treasury. The relevant provisions are also codified at 29 U.S.C. § 1185e(c) (ERISA), and 26 U.S.C. § 9816(c) (IRC).

"Considerations in determination" for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5).	"Considerations in determination" for air ambulance IDRs. 42 U.S.C. § 300gg-112(b)(5)(C).
the same geographic regionas such qualified IDR item or service."	
"Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years."	Substantially the same.
Any information the IDR entity requests from the parties.	Same.
Any additional information submitted by a party relating to an offer.	Same.
"The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual."	Substantially the same.
"The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service"	"The training, experience, and quality of the medical personnel that furnished such services."
	"The quality and outcomes measurements of the provider that furnished such services."
"The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided."	The "[a]mbulance vehicle type, including the clinical capability level of such vehicle."
"The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service."	The "[p]opulation density of the pick up location (such as urban, suburban, rural, or frontier)."

Because the statutory provisions are otherwise identical in all relevant respects, each of the statutory arguments made by TMA's brief applies with full force to air ambulance providers and to air ambulance IDRs. All the Court need do is transpose TMA's citations to Section 300gg-111(c) to the same subparagraph of Section 300gg-112(b). *Compare, e.g.*, 42 U.S.C. § 300gg-

111(c)(5)(C) ("the certified IDR entity...shall consider...information on any circumstance described in clause (ii)"), with 42 U.S.C. § 300gg-112(b)(5)(C) (same).

II. The Final Rule, Enacting the New QPA Presumption, Also Affects Air Ambulance Providers

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 Surprise Billing*, 87 Fed. Reg. 52,618 (August 26, 2022). The Final Rule replaces those provisions of the October IFR that were vacated by *TMA I* and *LifeNet I*. Exhibit A to LifeNet's current complaint is a redline comparison showing the changes to the relevant regulatory provisions. *LifeNet v. HHS, et al.*, 6:22-cv-00373, ECF 4 (filed Sep. 26, 2022).

In place of the provisions vacated by this Court, the Final Rule enacts a New QPA Presumption. The New QPA Presumption is to be codified in four parts of 45 C.F.R § 149.510 (which governs all *non*-air ambulance IDRs) and in one part of 45 C.F.R. § 149.520 (which governs air ambulance IDRs, and which adopts nearly all of Section 149.510 by reference). This brief, like TMA's brief, cites the New QPA Presumption's provisions according to these as-yet-to-be-implemented codifications in the Code of Federal Regulations.

The New QPA Presumption affects air ambulance providers in the same way as it affects non-air ambulance providers. Indeed, all of the regulatory citations are exactly the same, except for 45 C.F.R. § 149.520(b)(3), which differs solely because it contains the additional statutory factors that "shall" be considered in an air ambulance IDR. *See supra*, at 3 (chart comparing the statutory factors). The following chart quotes each part of the New QPA Presumption in the order it appears in Sections 149.510 and 149.520:

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 <i>first</i> to consider the QPA, and only <i>then</i> 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 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.	45 C.F.R. § 149.510(c)(4) (iii)(E) 45 C.F.R. § 149.520(b)(3) (near-identical text, applicable to air ambulance IDRs)	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 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).

Regulatory Text (bold language contains the New QPA Presumption)	Citation	Reason Why This Language Creates a New QPA Presumption
(vi) Written decision.	45 C.F.R. § 149.510(c)	This requires the IDR Entity to do extra work
(B) The certified IDR Entity's written	(4)(vi)	if it "relies on" any of
decision must include an explanation of their	(-)()	the statutory factors
determination, including what information the		other than the QPA.
certified IDR Entity determined demonstrated		Specifically, the IDR
that the offer selected as the out-of-network rate		Entity must somehow
is the offer that best represents the value of the		explain, in writing,
qualified IDR item or service, including the		"why" it "concluded
weight given to the qualifying payment amount		that this information
and any additional credible information under		was not already
paragraph (c)(4)(iii)(B) through (D) of this		reflected in" the QPA.
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 information		
was not already reflected in the qualifying		
payment amount		

III. QPAs Are Being Calculated Using "Ghost Rates" Agreed to By Providers that Do Not Even Operate Air Ambulances

In addition to the arguments made in TMA's brief, the New QPA Presumption is also arbitrary and capricious because the Departments do not grapple with the problem of QPAs calculated using "ghost rates," that is, rates agreed to by providers that *do not even provide the service at issue*. A provider who does not own or operate an air ambulance will have no incentive to negotiate for a fair price for this service. Including "ghost rates" in the QPA therefore defeats the supposed purpose of the QPA, which the Departments claim is to "reflect[] market rates under typical contract negotiations." July IFR, 86 Fed. Reg. 36,872, at 36,889 (July 13, 2021).

The Transparency in Coverage Act required payors to disclose their current in-network rates, for a variety of services, on July 1, 2022.² LifeNet's counsel has retained the expert analysis firm of Dobson DaVanzo to analyze this data. Their analysis of one Texas payor—Aetna of Texas—demonstrates that many of that payor's contracted rates, for air ambulance services, were agreed to by providers that do not typically operate air ambulances. *See* Ex. E (DaVanzo Decl.). For example, the data shows contracted rates, for air ambulance transport, which were agreed to by social workers, optometrists, and psychologists. *Id*.

The Dobson DaVanzo analysis is confirmed by another independent analysis firm, Avalere Health. According to Avalere Health, insurers' QPAs are routinely based on contracts with providers who "rarely or never provide" the service in question. Ex. F (Smyser Decl.), Ex. 3.³

The "ghost rate" problem was pointed out to the Departments by at least two commenters.

The Association of Air Medical Services (AAMS) commented, on the October IFR, as follows:

[The Original QPA Presumption is] an unreliable approach because it does not account for critical differences in an entity's structure and contracting practices. For example, a hospital may enter into an agreement with a payer based on a broad range of services, including rates for air ambulance services. In some instances, a hospital may agree to rates for air ambulance services without actually offering the services. Such rates may be far below market, and may be included in the contract without any negotiation because the hospital will never seek payment.

² 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-TOOO.

³ This report is also publicly available online. Avalere Health, *PCP Contracting Practices and Qualified Payment Amount Calculation Under the No Surprises Act*, 1 (August 2, 2022) https://perma.cc/6NJN-ZULQ. Avalere Health concludes that the number of non-specialist providers whose rates are included in the QPA, even though those providers do not actually provide the service at issue, is vastly greater than the number of specialist providers who actually supply the vast majority of these specialty services. *See id.* at 5–6 (noting that primary care physicians massively outnumber "anesthesiologists, emergency physicians, and radiologists," and discussing the reasons why this imbalance means that the QPA is not a credible measure of the market rates for these specialty services).

. . . . It is not rational for the Departments to treat independent rates negotiated at arm's length the same as below-market, ghost rates that are passively accepted by hospitals because they will never be charged to payers.

Ex. F (Smyser Decl.), Ex. 1, at 4 (AAMS Ltr to Hon. Xavier Becerra, et al. (Dec. 6, 2021) (emphasis added)).

Similarly, MedNax—a national medical group comprised of neonatal care providers—commented in response to the October IFR that:

[W]e urge the Departments to fix the Qualifying Payment Amount (QPA) methodology, which is currently based on in-network contracts alone and a myriad of physicians, regardless of whether a physician ever bills for services under a CPT code. This issue of "ghost contracting" frequently occurs in the subspecialty of neonatology. Rather, the QPA should be determined based on a weighted methodology of CPT codes actually used that will allow the IDR entity to have better understanding of prior contracted rates, good-faith negotiations, specialists' medical experience, acuity of patients seen and market share.

Ex. F (Smyser Decl.), Ex. 2, at 1 (MedNax Ltr to Hon. Xavier Becerra, et al. (Nov. 19, 2021) (emphasis added)).

As TMA's brief points out, the Departments' regulations require no meaningful disclosure of what the insurer did to calculate the QPA. TMA Br., at 7 (citing 45 C.F.R. § 149.140(d)). There is no way that a provider or arbitrator can tell, based on the meager disclosures required by the Departments, whether the insurer has calculated its QPA based on "ghost rates."

IV. Facts Relating to LifeNet's Standing

This Court previously determined that LifeNet had standing to challenge the Original QPA Presumption enacted in the October IFR. *See LifeNet I*, 2022 WL 2959715, at *6-*8. LifeNet resubmits, here, substantially the same evidence that LifeNet submitted in its previous action. *See* Ex. G (Gaines Decl.).

LEGAL STANDARDS

LifeNet incorporates by reference the legal standards set forth in TMA's brief.

ARGUMENT

I. LifeNet Incorporates TMA's Merits Arguments

LifeNet incorporates by reference the merits argument set forth in TMA's brief. TMA's arguments apply in full to air ambulance providers once TMA's citations to Section 300gg-111(c) are transposed to the corresponding subparagraphs of Section 300gg-112(b).

II. The New QPA Presumption Is Arbitrary and Capricious Because the Departments Do Not Account for "Ghost Rates"

The New QPA Presumption exempts the QPA from the threshold requirement of credibility. As to all the non-QPA factors, the arbitrator must first determine that the evidence is "credible," *i.e.*, "that upon critical analysis [it] is worthy of belief and is trustworthy." 45 C.F.R. § 149.510(a)(2)(v). But although the Departments required arbitrators to verify the credibility of all this non-QPA information, the Departments forbade the arbitrators from questioning the credibility of the QPA. Instead, the Departments emphasized that it is not the arbitrator's "responsibility" to "monitor the accuracy of the plan or issuer's QPA calculation methodology." *Id.* at 52,627 n.31. The Departments simply declared, by agency fiat, that "the QPA will meet the credibility requirement." 87 Fed. Reg. at 52,627. Although Congress charged the Departments with auditing some subset of insurers' QPA calculations, it does not follow that arbitrators must always treat the QPA amount as credible information, while scrutinizing all other information more closely. *See Chamber of Commerce v. Dep't of Lab.*, 885 F.3d 360, 385 (5th Cir. 2018) ("Illogic and internal inconsistency are characteristic of arbitrary and unreasonable agency action.").

The presumption of QPA credibility is also arbitrary and capricious because the Departments did not grapple with the serious problem of ghost rates—that is, rates agreed to by providers that do not even provide the service at issue. *See supra*, at 6-8 (describing the mounting

evidence of the ghost rate problem, and quoting from two commenters who pointed out this problem to the Departments). The Departments gave no logical reason why arbitrators should be required to treat QPAs as credible, while viewing all other information critically, given that the QPAs may be based on ghost rates. This is an additional reason why the Departments' fiat that the QPA "will mee[t]" the credibility requirement is unsupported and hence arbitrary and capricious. See, e.g., Matter of Bell Petrol. Servs., Inc., 3 F.3d 889, 905–06 (5th Cir. 1993).⁴ Nor did the Departments consider an obvious alternative: permitting arbitrators to take the ghost rate problem into account in deciding how much weight to give the QPA.

In short: by simply ignoring the ghost rate problem in their rulemaking, the Departments acted arbitrarily and capriciously because they failed to consider important aspects of the problem, address obvious alternatives, or articulate satisfactory explanations for their decision. *See Chem. Mfrs. Ass'n v. EPA*, 870 F.2d 177, 264 (5th Cir. 1989).

III. LifeNet Has Standing

LifeNet has standing to challenge the New QPA Presumption, for all of the reasons that this Court previously found that LifeNet had standing to challenge the Old QPA Presumption. *See See LifeNet I*, 2022 WL 2959715, at *6-*8. Specifically: (i) LifeNet is an object of the challenged regulation; (ii) the challenged regulation will cause financial harm to LifeNet; (iii) the challenged regulation deprives LifeNet of procedural rights; and (iv) the challenged regulation causes

⁴ The full quote is as follows: "to the extent the QPA is calculated in a manner that is consistent with the detailed rules issued under the July 2021 interim final rules, and is communicated in a way that satisfies the applicable disclosure requirements, the QPA will meet the credibility requirement" 87 Fed. Reg. at 52,627. The effect of this language is to remove any discussion of ghost rates from the arbitrator's determination. The July IFR can be read to allow insurers to include ghost rates" in their QPAs. And nothing in the July IFR's disclosure requirements obligates the insurers to tell providers or arbitrators that they have done so. *See* 45 C.F.R. § 149.140(d) (meager disclosures, required by the Departments, convey almost no meaningful information about how the QPA was calculated or the contracted rates on which it is based).

immediate reputational harm by devaluing LifeNet's services in the critically important market for commercial out-of-network payor reimbursements.

A. Legal Standard

Standing requires that the plaintiff "have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The standing requirement is not demanding: "A single unsolicited automated call has been found to confer Article III standing." *Shields v. Dick*, No. 3:20-CV-00018, 2020 WL 5522991, at *4 (S.D. Tex. July 9, 2020); *see also Cranor v. 5 Star Nutrition, L.L.C.*, 998 F.3d 686, 688 (5th Cir. 2021) (a single "unwanted text" message).

B. LifeNet Is An Object of the New QPA Presumption

First, LifeNet is an object of the New QPA Presumption. When "a plaintiff is an object of a regulation there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 264 (5th Cir. 2015) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (cleaned up)); *Duarte v. City of Lewisville*, 759 F.3d 514, 518 (5th Cir. 2014); *Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008) ("[S]tanding is usually self-evident when the plaintiff is a regulated party.").⁵

⁵ See also, e.g., Meland v. Weber, 2 F.4th 838, 845 (9th Cir. 2021) (shareholder had Article III standing to challenge state law mandating female representation on corporation's board of directors because shareholder was also "one of the objects" of the law); Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin., 656 F.3d 580, 585–86 (7th Cir. 2011) (individual truckers had standing because they were "objects" of rule requiring on-board recording devices, even though the rule directly regulated only the truckers' employers, the "motor carrier" companies).

LifeNet is a "nonparticipating provider" of air ambulance services, and therefore LifeNet's compensation for its out-of-network transports, for commercially insured patients, is governed by the NSA and its implementing regulations. *See* Ex. G (Gaines Decl.) ¶¶ 2-4.

LifeNet remains an "object of the regulation" even though non-party Air Methods Corporation has contracted to pay LifeNet for LifeNet's air ambulance services. *Id.* ¶ 5 (Gaines Decl.); *see also id.* Ex. 1 (contract between LifeNet and Air Methods). During the IDR process, the arbitrator will consider LifeNet's training, experience, and quality and outcome measurements, and the arbitrator will then place a value on LifeNet's services. *See* 45 C.F.R. § 149.520(b)(2) (arbitrator "shall" consider the "training, experience, and quality of the medical personnel that furnished the air ambulance services"); *see also LifeNet I*, 2022 WL 2959715, at *7 ("It is LifeNet—not Air Methods—whose training, experience, and quality and outcome measurements are to be considered by the arbitrator. LifeNet is therefore a 'nonparticipating provider' under the Act and has standing to challenge the Rule as an object of it." (citations omitted)).!

C. The New QPA Presumption Causes Procedural Injury to LifeNet

Second, the New QPA Presumption imposes a procedural injury on LifeNet. A plaintiff can show a cognizable injury-in-fact if he or she has "been deprived of 'a procedural right to protect [his] concrete interests." *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019); *see also Lujan*, 504 U.S. at 573 n.8. The plaintiff "need not prove that following proper procedure will necessarily create different outcomes," but rather "must merely show a reasonable claim of minimal impact." *TMA*, 2022 WL 542879, at *4 (cleaned up).

Just like the Original QPA Presumption, the New QPA Presumption "deprives" LifeNet "of the arbitration process established by the Act. Rather than having an arbitrator consider all statutory factors as provided by the Act, the Rule puts a substantial 'thumb on the scale' in favor of the QPA." *LifeNet I*, 2022 WL 2959715, at *7 (citations omitted).

D. The New QPA Presumption Causes Economic Harm to LifeNet

Third, the New QPA Presumption causes economic harm to LifeNet because it "will drive out-of-network reimbursement rates to the QPA as a de facto benchmark." Ex. G (Gaines Decl.), ¶ 16. "[I]n many and perhaps all cases" the offer made by Air Methods, for LifeNet's services, will "be above the QPA." *Id.* ¶ 11.

The New QPA Presumption, like the Old QPA Presumption, will have the effect of systemically disfavoring selection of the offers submitted by Air Methods for LifeNet's services, thus resulting in lower out-of-network rates being awarded for LifeNet's services. The Departments concede that this effect—lowering the rates of compensation for providers—is one of the intended effects of the New QPA Presumption. *See* Final Rule, 87 Fed. Reg. at 52,629 (identifying New QPA Presumption as helping to avoid "higher health care costs").

Lower payment determinations, by the arbitrators, will inevitably cause financial harm to LifeNet even though LifeNet's current contract with Air Methods guarantees fixed payments (for now). That contract will expire in less than one year. *See* Ex. G (Gaines Decl.), Ex. 1 (contract), § 2.4 (permitting either party to terminate the contract "without cause" after the "two-year anniversary of the Commencement Date," i.e., on October 1, 2023). Moreover, Air Methods also has the option of terminating the contract earlier, if the fixed payments to LifeNet become "financially inviable." *Id.* § 2.3 (providing for termination without cause if a "financially inviable situation that is beyond the reasonable expectations of either Party" arises). By depressing the value of the compensation Air Methods receives from insurers in the IDR process, the New QPA Presumption creates a "significant risk" of just such a "financially unviable" situation that would cause this contract to be terminated by Air Methods before October 1, 2023. Ex. G (Gaines Decl.) ¶ 12; *see also LifeNet 1*, 2022 WL 2959715, at *7 (E.D. Tex. July 26, 2022) (crediting same).!

Lower reimbursement rates will inevitably harm LifeNet directly whenever its current contract with Air Methods ends. If LifeNet wishes to extend its relationship with Air Methods, it will need to agree to rates that reflect the value of its services under the New QPA Presumption. *See LifeNet I*, 2022 WL 2959715, at *7 (E.D. Tex. July 26, 2022) ("An unviable situation, moreover, would almost certainly result in LifeNet's having to renegotiate its contract for a lower payment amount—or losing the contract altogether.").

E. The New QPA Presumption Causes Immediate Reputational Harm to LifeNet

Contract aside, LifeNet is also injured immediately by the lower valuations that the New QPA Presumption causes IDR entities to give to LifeNet's services. LifeNet, like any other forprofit business, must routinely answer the following question: "how much are LifeNet's services worth?" The answer to that question critically depends on the important market of commercial insurers' reimbursements for emergency transports. *See* Ex. G (Gaines Decl.), ¶ 17 (this is a "critically important market").

This question—what are LifeNet's services worth?—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 LifeNet's current contract with Air Methods ends next year. Indeed, this is the first question that Air Methods or any other potential business partner will ask, during negotiations over the terms of a new contract: "how much are LifeNet's services worth?"

The answer to the question "how much are LifeNet's services worth?" now depends in large part on the results of IDRs, because those results are now the *only* commercial marketplace

for LifeNet's services to commercially insured out-of-network patients. LifeNet can no longer bill such patients directly, for anything other than the patient's "cost sharing" (e.g., co-pay) amount. See 42 U.S.C. § 300gg-135. And there are no other state-law processes available to LifeNet, to obtain compensation from commercial insurers, because all such state laws are preempted by the Airline Deregulation Act. See July IFR, 86 Fed. Reg. at 36,885 & n.37. In short, the NSA's IDR process is the only game in town. Every IDR determination, by placing a dollar value on LifeNet's services, is a relevant piece of data in answering the question of what LifeNet's services are worth.

The results of the IDRs decided today will have a continuing impact on the answer to that question. And because the results of today's IDRs will be significantly lower, as a result of the New QPA Presumption, 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).

To be sure, the immediate harm to LifeNet, from a low dollar valuation in the IDR process, is intangible for now. But a harm does not need to be "tangible" to provide Article III standing. *Cranor*, 998 F.3d at 689-90. In *Cranor*, the Fifth Circuit held that the "nuisance" caused by receiving a "single unwelcome text message" was sufficiently "concrete" to constitute an injury-in-fact. *Id.* Similarly, the inaccurate reporting of credit information—e.g., age and marital status—has been held to be a sufficiently "concrete" injury to confer standing, even absent any reputational harm or monetary loss. *Robins v. Spokeo, Inc.*, 867 F.3d 1108, 1115 (9th Cir. 2017) (on remand from Supreme Court), *cert. denied*, 138 S. Ct. 931 (2018).

Moreover, lower dollar valuations, for LifeNet's services, are analogous to injuries recognized at common law. *See Cranor*, 998 F.3d at 691 (finding Article III standing, in part, because a claim based on a "single unwelcome text message" bore a close relationship to a claim for "public nuisance" as recognized at common law). This inquiry "is focused on types of harms protected at common law, not the precise point at which those harms become actionable" under common law. *Id.* at 693 (emphasis added) (quoting *Krakauer v. Dish Network*, L.L.C., 925 F.3d 643, 654 (4th Cir. 2019)). Lower-than-appropriate dollar valuations of LifeNet's services bear a close relationship to the kinds of injuries recognized at common law for untrue and disparaging statements about another's "chattels or intangible things." Restatement (First) of Torts § 624 (1938); *see also* Restatement (Second) of Torts § 623A-629 (1977).

CONCLUSION

The New QPA Presumption should be vacated, and this matter should be remanded to the Departments with specific instructions that any additional regulations or guidance to arbitrators on the weighing of the statutory factors may not privilege the QPA over the other factors.

Dated: October 12, 2022 Respectfully submitted,

By: /s/ Stephen Shackelford, Jr.

Stephen Shackelford, Jr. (EDTX Bar No.

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CERTIFICATE OF SERVICE

I hereby certify that on October 12, 2022, I electronically filed the foregoing document

with the clerk of the court for the U.S. District Court, Eastern District of Texas, using the electronic

filing system of the court. The electronic case filing system sent a "Notice of Electronic Filing"

to the attorneys of record who have consented in writing to accept this Notice as service of this

document by electronic means.

By: /s/ Stephen Shackelford, Jr.

Stephen Shackelford, Jr.

EXHIBIT E

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

TEXAS MEDICAL ASSOCIATION, et al.,)
Plaintiffs,)) Case No.: 6:22-cv-00372-JDK
v.)) Lead Consolidated Case
UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES, et al.,)
Defendants.)))

DECLARATION OF JOAN E. DAVANZO

- 1. My name is Joan E. DaVanzo, Ph.D., M.S.W. I make this declaration in support of LifeNet, Inc.'s motion for summary judgment. I have personal knowledge of the matters discussed below, and if called as a witness I could competently testify to each of them.
- 2. I am a health care researcher and Chief Executive Officer (CEO) of Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo), a health economics and policy consulting firm located in the Washington DC metropolitan area. The firm was founded in 2007, and over the last fifteen years, the work of our principals has influenced the design of demonstrations and many public policy decisions, and it has appeared in numerous instances in legislation and regulation. Our litigation support efforts have helped courts, plaintiffs, and defendants understand the economic value of various health care matters. We are at the forefront of using administrative data sets to explore payment bundling and other financial issues for both commercial and government clients. We apply decades of experience, access to a broad range of policymakers and subject matter experts, and innovative research techniques to design rigorous and objective analyses that best meet our clients' needs.

- 3. The Transparency in Coverage Act requires payors to disclose their current innetwork rates, for a variety of services, beginning July 1, 2022. At LifeNet's request, Dobson | DaVanzo obtained and analyzed the raw data that was made public by Aetna of Texas ("Aetna TX", and "Aetna TX Raw Data"). Specifically:
- a. Dobson | DaVanzo downloaded and extracted the machine-readable file (MRF) in JSON format for CY 2021 Texas Federal PPO Aetna Advantage data from the In-Network Negotiated Rates & Allowed Amount Files section of the Aetna MRF website.²
- b. After extraction, a Python 3 interpreter with the additional "JSON" community tested module was used for converting the machine-readable data. Once that data was loaded, normalized, and reshaped, Dobson | DaVanzo created two CSV files: (i) a contract-level rate file, containing the underlying fee schedule and negotiated rates, and (ii) a contract-to-provider crosswalk.
- c. Next, using Healthcare Common Procedure Coding System (HCPCS) codes, Dobson | DaVanzo created and filtered (i) the contract-level rate file, in order to isolate the subset of contract rates associated with the four HCPCS codes for air ambulance services.³
- d. Next, Dobson | DaVanzo created a base analytic file, by taking the following three steps:

¹ 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.

² https://health1.aetna.com/app/public/#/one/insurerCode=AETNACVS_I&brandCode=AFEHBPFI/machine-readable-transparency-in-coverage.

³ The four rates are: One-way fixed-wing (A0430); one-way rotary-wing (A0431); fixed-wing per-loaded mile rate (A0435); and rotary-wing per-loaded-mile rate (A0436).

- i. Dobson | DaVanzo merged the subset of the contract-rate file with the contract-to-provider crosswalk, using a contract-level identifier to match providers with contracts;
- ii. Dobson | DaVanzo added provider names and provider specialty information (when available) to this file, using information that was obtained by matching the National Provider Identifiers (NPIs) in the Aetna data with the May 2022 extract of the National Plan & Provider Enumeration System (NPPES) provider information download file;⁴ and then
- iii. Dobson | DaVanzo added to that file the Medicare specialty group categories, applicable to each provider, which were obtained from the Provider Taxonomy Code found in a May 10, 2022 extract of the Medicare Provider and Supplier Taxonomy Crosswalk file.⁵
- 4. Exhibit A to this declaration is a small, randomly chosen subset of the base analytic file, which is intended to illustrate the names and specialty groups of providers for whom the Aetna Raw Data showed air ambulance rates. For each of the randomly chosen providers, Exhibit A contains all underlying fee schedule or negotiated reimbursement rates for air ambulance service codes found in the Aetna Raw Data and associated with that provider. Exhibit A is organized by NPI and known Provider Specialty. The full base analytic file is much larger than Exhibit A, and contains over 5,000 rows of data.
- 5. Exhibit B shows: (1) the total number of unique providers (i.e., NPIs) associated with that provider specialty type, and (2) for each provider specialty type, the median fee schedule rate of each of the four air ambulance service codes.

⁴ https://download.cms.gov/nppes/NPI_Files.html

⁵ https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-provider-and-supplier-taxonomy-crosswalk/data

I declare under penalty of perjury that the foregoing is true and correct. Executed on 10/12/2022

Joan E. DaVanzo

Exhibit A: Extract of Aetna In-Network Underlying Fees Schedule or Negotiated Reimbursement Rate for Contracted Conventional Air Ambulance Services Providers

	National			Fixed-W	ing Rates	Rotary Wing Rates		
#	Provider ID (NPI)	Provider Name	Provider Specialty	Air Service (HCPCS A0430)	Per Statute Mile (HCPCS A0435)	Air Service (HCPCS A0431)	Per Statute Mile (HCPCS A0436)	
1	1003080375	ASHESH PARIKH	Physician/Cardiovascular Disease	\$6,241.42	\$20.48	\$14,392.12	\$44.98	
2	1003129495	MAHSA SHEKARI	Optometry	\$2,095.73	\$34.86	\$2,436.59	\$43.05	
3	1003329319	JAZMINE MADDOX	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98	
4	1003329319	JAZMINE MADDOX	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31	
5	1003329319	JAZMINE MADDOX	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11	
6	1003329319	JAZMINE MADDOX	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08	
7	1003329319	JAZMINE MADDOX	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12		
8	1003337783	PUBLIX SUPER MARKETS, INC	Other Medical Supply Company	\$2,241.73	\$21.08	\$5,075.03	\$44.98	
9	1003337783	PUBLIX SUPER MARKETS, INC	Other Medical Supply Company	\$4,755.24	\$25.00			
10	1003349648	COURTNEY WASHINGTON	Physician/Family Practice	\$3,570.00	\$21.08	\$5,075.03	\$58.11	
11	1003875238	EYE TEL IMAGING LLC	Physician/Ophthalmology	\$4,044.65	\$9.50	\$2,436.59	\$44.98	
12	1003875238	EYE TEL IMAGING LLC	Physician/Ophthalmology	\$4,176.83	\$25.97	\$5,075.03	\$50.00	
13	1003879180	DVA RENAL HEALTHCARE INC	End-Stage Renal Disease Facility	\$3,570.00	\$21.08	\$16,919.72	\$44.98	
14	1003946310	JENNIFER CLEVELAND	Psychologist Clinical	\$2,241.73	\$11.22	\$3,713.85	\$44.98	
15	1003946310	JENNIFER CLEVELAND	Psychologist Clinical	\$3,570.00	\$20.48	\$5,075.03	\$55.31	
16	1003946310	JENNIFER CLEVELAND	Psychologist Clinical	\$4,176.83	\$21.08	\$5,548.74	\$58.11	
17	1003946310	JENNIFER CLEVELAND	Psychologist Clinical	\$4,755.24		\$6,766.06	\$73.08	
18	1003946310	JENNIFER CLEVELAND	Psychologist Clinical	\$6,241.42		\$14,392.12		
19	1013401371	LEANA TALBOTT	Psychologist Clinical	\$3,570.00	\$21.08	\$5,075.03	\$58.11	
20	1013405034	SCHULER DIALYSIS LLC	End-Stage Renal Disease Facility	\$3,570.00	\$34.86	\$5,213.04	\$55.61	
21	1013423227	ANDREW MCLANE	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98	
22	1013423227	ANDREW MCLANE	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31	
23	1013423227	ANDREW MCLANE	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11	
24	1013423227	ANDREW MCLANE	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08	
25	1013423227	ANDREW MCLANE	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12		

	National			Fixed-Wing Rates		Rotary Wing Rates	
#	Provider ID (NPI)	Provider Name	Provider Specialty	Air Service (HCPCS A0430)	Per Statute Mile (HCPCS A0435)	Air Service (HCPCS A0431)	Per Statute Mile (HCPCS A0436)
26	1013442102	MAFON FOMUJANG	Nurse Practitioner	\$2,241.73	\$20.48	\$5,075.03	\$44.98
27	1013442102	MAFON FOMUJANG	Nurse Practitioner	\$3,570.00	\$21.08	\$5,548.74	\$50.00
28	1013442102	MAFON FOMUJANG	Nurse Practitioner	\$4,755.24		\$14,392.12	\$55.31
29	1013442102	MAFON FOMUJANG	Nurse Practitioner	\$6,241.42			\$58.11
30	1013442102	MAFON FOMUJANG	Nurse Practitioner				\$133.26
31	1013551688	PUBLIX NORTH CAROLINA, LP	Other Medical Supply Company	\$2,241.73	\$25.00	\$5,075.03	\$44.98
32	1013948447	GATEWAY COMMUNITY HC	Federally Qualified Health Ctr	\$4,755.24	\$21.08	\$5,075.03	\$44.98
33	1023012481	LAURA PIIPPO	Physician/Ophthalmology	\$3,570.00	\$21.08	\$5,075.03	\$50.00
34	1023096237	BRYAN ODITT	Physician Assistant	\$3,570.00	\$21.08	\$5,548.74	\$44.98
35	1023115417	EMMA GONZALEZ	Optometry	\$4,044.65	\$25.63	\$5,075.03	\$44.98
36	1023495959	NACOGDOCHES DIALYSIS	End-Stage Renal Disease Facility	\$4,755.24	\$21.08	\$6,766.06	\$44.98
37	1023535523	CROWN POINT EYE CARE	Optometry	\$4,755.24	\$34.86	\$6,858.92	\$55.31
38	1023647286	JENNIFER MELENDEZ	Nurse Practitioner	\$4,755.24	\$21.08	\$5,075.03	\$44.98
39	1033382452	STACY GHANAMI	Physical Therapist	\$4,755.24	\$21.08	\$5,075.03	\$44.98
40	1033401351	MAXIM HEALTHCARE SERVICES	Home Health Agency	\$3,570.00	\$21.08	\$5,548.74	\$44.98
41	1043250103	DAN CRISWELL	Physician/Family Practice	\$3,570.00	\$17.60	\$5,075.03	\$50.00
42	1043303274	RIAZ RAHMAN	Physician/Internal Medicine	\$3,570.00	\$21.08	\$5,075.03	\$44.98
43	1043412299	LIFEHME, INC.	Oxygen supplier	\$3,570.00	\$34.86	\$6,766.06	\$55.31
44	1043711195	ALEXIS MONTOYA VILLALPANDO	Psychologist Clinical	\$4,755.24	\$17.60	\$5,548.74	\$140.00
45	1043824717	CHE BEHAVIORAL HEALTH	Licensed Clinical Social Worker	\$3,570.00	\$17.60	\$3,570.00	\$44.98
46	1043824717	CHE BEHAVIORAL HEALTH	Licensed Clinical Social Worker	\$4,755.24	\$20.48	\$4,831.31	\$55.61
47	1043824717	CHE BEHAVIORAL HEALTH	Licensed Clinical Social Worker		\$21.01	\$5,075.03	\$124.30
48	1043824717	CHE BEHAVIORAL HEALTH	Licensed Clinical Social Worker		\$30.00	\$5,213.04	
49	1053052506	APERION CARE NILES LLC	Skilled Nursing Facility	\$3,570.00	\$21.08	\$2,436.59	\$87.59
50	1053345553	CLIFFORD FAGAN	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98

	National			Fixed-W	Fixed-Wing Rates		/ing Rates
#	Provider ID (NPI)	Provider Name	Provider Specialty	Air Service (HCPCS A0430)	Per Statute Mile (HCPCS A0435)	Air Service (HCPCS A0431)	Per Statute Mile (HCPCS A0436)
51	1053345553	CLIFFORD FAGAN	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31
52	1053345553	CLIFFORD FAGAN	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11
53	1053345553	CLIFFORD FAGAN	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08
54	1053345553	CLIFFORD FAGAN	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12	
55	1053360131	TORREY CARLSON	Optometry	\$4,755.24	\$21.08	\$5,075.03	\$44.98
56	1053439125	PROFESSIONAL VISIONCARE, INC	Optometry	\$3,570.00	\$17.60	\$5,075.03	\$21.08
57	1053467431	JACKIE MURPHY	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98
58	1053467431	JACKIE MURPHY	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31
59	1053467431	JACKIE MURPHY	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11
60	1053467431	JACKIE MURPHY	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08
61	1053467431	JACKIE MURPHY	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12	
62	1053735951	COMPREHENSIVE HOSPITALIST SERVICES OF NEW MEXICO LLC	Physician/Hospitalist	\$3,570.00	\$21.08	\$5,075.03	\$14.46
63	1053799064	AKHIL SHENOY	Physician/Internal Medicine	\$6,241.42	\$20.48	\$14,392.12	\$44.98
64	1063000636	TRINA LINDSEY	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98
65	1063000636	TRINA LINDSEY	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31
66	1063000636	TRINA LINDSEY	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11
67	1063000636	TRINA LINDSEY	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08
68	1063000636	TRINA LINDSEY	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12	
69	1063059756	MODUPE OLATUNDE	Nurse Practitioner	\$2,241.73	\$21.08	\$5,075.03	\$43.05
70	1063059756	MODUPE OLATUNDE	Nurse Practitioner	\$3,570.00		\$5,548.74	\$58.11
71	1063059756	MODUPE OLATUNDE	Nurse Practitioner				\$133.26
72	1063089704	SANDRA WINANS	Psychologist Clinical	\$2,241.73	\$11.22	\$3,713.85	\$44.98
73	1063089704	SANDRA WINANS	Psychologist Clinical	\$3,570.00	\$20.48	\$5,075.03	\$55.31
74	1063089704	SANDRA WINANS	Psychologist Clinical	\$4,176.83	\$21.08	\$5,548.74	\$58.11
75	1063089704	SANDRA WINANS	Psychologist Clinical	\$4,755.24		\$6,766.06	\$73.08

	National			Fixed-Wing Rates		Rotary V	Ving Rates
#	Provider ID (NPI)	Provider Name	Provider Specialty	Air Service (HCPCS A0430)	Per Statute Mile (HCPCS A0435)	Air Service (HCPCS A0431)	Per Statute Mile (HCPCS A0436)
76	1063089704	SANDRA WINANS	Psychologist Clinical	\$6,241.42		\$14,392.12	
77	1063450740	TOD GANN	Physical Therapist	\$3,570.00	\$20.48	\$5,075.03	\$44.98
78	1063492338	JOHN MCDONALD	Physician/Pathology	\$4,755.24	\$21.08	\$5,075.03	\$44.98
79	1063669612	LOUISIANA ORTHOPAEDIC SPEC	Clinic or Group Practice	\$4,755.24	\$21.08	\$5,075.03	\$44.98
80	1063793123	SUMMER LAAKE	Nurse Practitioner	\$6,241.42	\$20.48	\$14,392.12	\$44.98
81	1063823425	WALLY OMAR	Physician/Cardiovascular Disease (Cardiology)	\$6,241.42	\$20.48	\$14,392.12	\$44.98
82	1063924397	PUBLIX ALABAMA LLC	Other Medical Supply Company	\$2,241.73	\$21.08	\$5,075.03	\$44.98
83	1063924397	PUBLIX ALABAMA LLC	Other Medical Supply Company	\$4,755.24	\$25.00		
84	1073027843	CLAUDIA STANLEY	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98
85	1073027843	CLAUDIA STANLEY	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31
86	1073027843	CLAUDIA STANLEY	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11
87	1073027843	CLAUDIA STANLEY	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08
88	1073027843	CLAUDIA STANLEY	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12	
89	1073069811	SNG - PASADENA DIALYSIS CTR	End-Stage Renal Disease Facility	\$4,755.24	\$21.08	\$6,766.06	\$44.98
90	1073286472	JENNIFER GONZALEZ	Licensed Clinical Social Worker	\$2,241.73	\$11.22	\$3,713.85	\$44.98
91	1073286472	JENNIFER GONZALEZ	Licensed Clinical Social Worker	\$3,570.00	\$20.48	\$5,075.03	\$55.31
92	1073286472	JENNIFER GONZALEZ	Licensed Clinical Social Worker	\$4,176.83	\$21.08	\$5,548.74	\$58.11
93	1073286472	JENNIFER GONZALEZ	Licensed Clinical Social Worker	\$4,755.24		\$6,766.06	\$73.08
94	1073286472	JENNIFER GONZALEZ	Licensed Clinical Social Worker	\$6,241.42		\$14,392.12	
95	1073776860	SOUTHWEST REGIONAL PCR, LLC	Clinical Laboratory	\$3,570.00	\$17.60	\$4,831.31	\$44.98
96	1073776860	SOUTHWEST REGIONAL PCR, LLC	Clinical Laboratory	\$5,891.50	\$21.08	\$5,075.03	\$124.30
97	1073902771	PRIMROSE DIALYSIS, LLC	End-Stage Renal Disease Facility	\$3,570.00	\$34.86	\$5,213.04	\$55.61
98	1093463838	KIRCHNER WOMENS CLINIC	Physician/Obstetrics & Gynecology	\$2,241.73	\$21.08	\$5,548.74	\$133.26
99	1093708687	DUANE MILLER	Physician/Psychiatry	\$6,241.42	\$20.48	\$14,392.12	\$44.98
100	1093712424	PATRICIA FENDERSON	Physician/Pathology	\$4,755.24	\$21.08	\$5,075.03	\$44.98

Exhibit B: Aetna Median In-Network Underlying Fee Schedule or Negotiated Reimbursement Rate for Contracted Conventional Air Ambulance Services Providers Offering Air Ambulance Services by HCPCS Codes and Provider Specialty

Consider	Specialty	# of	Fixed-Wing		Rotary Wing	
Specialty Code		Unique Providers	Air Service (HCPCS A0430)	Per Statute Mile (HCPCS A0435)	Air Service (HCPCS A0431)	Per Statute Mile (HCPCS A0436)
02	Physician/General Surgery	6	\$1,973.88	\$19.31	\$5,920.55	\$58.11
03	Physician/Allergy/ Immunology	1	\$3,570.00	\$21.08	\$5,075.03	\$14.46
04	Physician/Otolaryngology	1	\$3,807.33	\$23.80	\$10,997.38	\$56.86
05	Physician/Anesthesiology	2	\$4,162.62	\$21.08	\$5,075.03	\$44.98
06	Physician/Cardiovascular Disease (Cardiology)	5	\$6,241.42	\$20.48	\$14,392.12	\$44.98
08	Physician/Family Practice	24	\$3,570.00	\$21.05	\$5,075.03	\$54.06
11	Physician/Internal Medicine	10	\$4,176.83	\$20.48	\$5,075.03	\$44.98
16	Physician/Obstetrics & Gynecology	3	\$2,241.73	\$21.08	\$5,548.74	\$133.26
18	Physician/Ophthalmology	7	\$3,535.00	\$21.01	\$5,075.03	\$44.98
22	Physician/Pathology	39	\$4,755.24	\$21.08	\$5,075.03	\$44.98
26	Physician/Psychiatry	11	\$4,176.83	\$20.48	\$5,075.03	\$44.98
30	Physician/Diagnostic Radiology	4	\$2,241.73	\$17.60	\$5,075.03	\$55.61
35	Chiropractic	2	\$4,044.65	\$21.08	\$5,075.03	\$44.98
36	Physician/Nuclear Medicine	1	\$6,241.42	\$20.48	\$14,392.12	\$44.98
37	Physician/Pediatric Medicine	2	\$3,364.56	\$21.05	\$5,075.03	\$44.98
41	Optometry	35	\$3,570.00	\$21.08	\$5,075.03	\$44.98
43	Certified Registered Nurse Anesthetist (CRNA)	1	\$6,241.42	\$20.48	\$14,392.12	\$44.98
47	Independent Diagnostic Testing Facility (IDTF)	1	\$4,755.24	\$21.08	\$5,548.74	\$143.35
49	Ambulatory Surgical Center	1	\$3,570.00	\$21.08	\$16,919.72	\$44.98
50	Nurse Practitioner	26	\$4,110.74	\$21.08	\$5,075.03	\$50.00
54	Other Medical Supply Company	20	\$3,570.00	\$21.08	\$5,075.03	\$44.98
58	Medical Supply Company with Pharmacist	3	\$3,570.00	\$25.00	\$5,548.74	\$44.98
59	Ambulance Service Provider	9	\$3,570.00	\$21.08	\$5,548.74	\$44.98
61	Voluntary Health or Charitable Agency[1]	1	\$3,570.00	\$20.48	\$5,075.03	\$44.98
62	Psychologist Clinical	34	\$4,176.83	\$20.48	\$5,548.74	\$55.31

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Specialty		# of	Fixed-Wing		Rotary-Wing	
Code	Specialty	Unique Providers	Air Service (HCPCS A0430)	Per Statute Mile (HCPCS A0435)	Air Service (HCPCS A0431)	Per Statute Mile (HCPCS A0436)
64	Audiologist	3	3570	21.08	5075.03	58.11
65	Physical Therapist in Private Practice	6	3570	20.48	5075.03	44.98
69	Clinical Laboratory	12	3807.325	21.08	5075.03	44.98
70	Clinic or Group Practice	6	3570	21.045	5075.03	51.545
71	Registered Dietitian or Nutrition Professional	1	2241.73	21.08	6766.06	44.98
75	Slide Preparation Facility	1	4755.24	21.08	5075.03	44.98
80	Licensed Clinical Social Worker	202	4176.83	20.48	5548.74	55.31
86	Physician/Neuropsychiatry	2	3570	21.08	5075.03	51.545
92	Physician/Radiation Oncology	1	1354.31	17.6	6766.06	58.11
93	Physician/Emergency Medicine	8	4162.62	21.08	5075.03	51.545
97	Physician Assistant	10	4755.24	21.08	5075.03	44.98
A0	Hospital	5	3570	21.08	16919.72	44.98
A1	Skilled Nursing Facility	7	3570	21.08	3713.85	44.98
A4	Home Health Agency	5	3570	21.08	5548.74	44.98
B1	Oxygen supplier	8	3570	34.86	5548.74	44.98
B4	Other Facilty/Center	23	3570	21.08	5213.04	55.61
C5	Dentist	1	4044.65	21.08	5075.03	44.98
C6	Physician/Hospitalist	3	3570	21.08	5075.03	14.46
UN	Unknown	966	4176.83	20.48	5548.74	55.31

EXHIBIT F

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

TEXAS MEDICAL ASSOCIATION, et al.,)
Plaintiffs,)) Case No.: 6:22-cv-00372-JDK
v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,) Lead Consolidated Case)
Defendants.)))

DECLARATION OF JAMES CRAIG SMYSER

- 1. My name is James Craig Smyser. I am over the age of eighteen. I am employed by Susman Godfrey, LLP. My job title is Associate. I have personal knowledge of the matters contained herein.
- 2. Attached as Exhibit 1 is a true and accurate copy of the public comment letter submitted by the Association of Air Medical Services on December 6, 2021 concerning the Interim Final Rule, *Requirements Related to Surprise Billing; Part II*.
- 3. I downloaded this copy from "Regulations.gov" at the following link: https://www.regulations.gov/comment/CMS-2021-0156-5280 on October 10, 2022.
- 4. Attached as Exhibit 2 is a true and accurate copy of the public comment letter submitted by Mednax Services, Inc. on November 19, 2021 concerning the Interim Final Rule, Requirements Related to Surprise Billing; Part II.
- 5. I downloaded this copy from "Regulations.gov" at the following link: https://www.regulations.gov/comment/CMS-2021-0156-2609 on October 10, 2022.

- 6. Attached as Exhibit 3 is a true and accurate copy of "PCP Contracting Practices and Qualified Payment Amount Calculation Under the No Surprises Act," a report by Avalere Health dated August 2, 2022.
- 7. I downloaded this copy from the website of the American College of Radiology (acr.org) at the following link: https://www.acr.org/-/media/ACR/Files/Advocacy/2022-8-15-Avalere-QPA-Whitepaper Final.pdf on October 11, 2022.

I declare under penalty of perjury that the foregoing is true and correct. Executed on October 11, 2022.

Signature:

James Craig Smyser

EXHIBIT 1

Board of Directors

Deborah Boudreaux, MSN, RN, CCRN, C-NPT, LP, CMTE Chair and Region IV Director Teddy Bear Transport

Rene Borghese, MSN, RN, CMTE Vice-Chair Director-At-Large Duke Life Flight

Susan Rivers, RN, BSN, MBA, CMTE Secretary and Region VI Director Carilion Clinic Life-Guard

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Anthony Pellicone Region V Director Northwell Health/ Southside Hospital

Russell MacDonald, MD, MPH, FRCPC Region VII Director Ornge

Graeme Field
Region VIII Director
NSW Air Ambulance Service

James Houser MSN, APRN, FNP-C, NRP, CFRN Director-At-Large STAT MedEvac

Guy Barber Director-At-LargeAir Methods Corporation

Edward Eroe, LFACHE, CAE, CMTE Public Member

Denise Treadwell, CRNP, MSN, CFRN, CEN, CMTE CAMTS Representative AirMed International. LLC

Cameron Curtis, CMM, CAE President and CEO Association of Air Medical Services

ASSOCIATION OF AIR MEDICAL SERVICES



December 6th, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Martin Walsh Secretary U.S. Department of Labor 200 Constitution Ave N.W. Washington, DC 20210

The Honorable Janet Yellen Secretary U.S. Department of the Treasury 1500 Pennsylvania Avenue, N.W. Washington, DC 20220

Dear Secretaries Becerra, Walsh and Yellen:

I write to offer the views of the Association of Air Medical Services (AAMS) on the tri-departmental Interim Final Rule ("IFR"), Requirements Related to Surprise Billing; Part II, as prescribed by the No Surprises Act, Pub. L. No. 116-260 (2020) (the "Act"). AAMS is the international trade association that represents over 93 percent of air ambulance providers in the U.S. Together, our over 300 members operate nearly 1,000 helicopter air ambulances and 200 fixed wing air ambulance services across the U.S. AAMS represents every emergency air ambulance care model, including aircraft based at hospitals, independent aircraft at bases in rural areas far from hospitals, and many hybrid variations.

AAMS strongly supports the purpose of the Act, which is removing patients from payment disputes between healthcare providers and payers, through an independent dispute resolution ("IDR") process, while maintaining patient cost sharing at participating levels. However, we are gravely concerned about the negative consequences that will result from the implementation timeline, cost sharing and payment methodologies, and IDR process, as currently drafted.

We believe the IFR threatens the sustainability of air ambulance services and places traditionally underserved communities at risk of reduced access to care. The qualifying payment amount ("QPA") methodology and the Departments' presumption that the QPA is the appropriate out-of-network rate to be selected in IDR will create a race to the bottom in which existing contracts are destabilized and reimbursement drops to an unsustainable level. Instead of simply removing patients from payer-provider payment disputes, the Departments have put patients at risk by making it harder for air ambulance providers to sustain operations and deliver life-saving care. Air ambulance providers can only operate if they receive fair, adequate payments that cover the costs of delivering services. Fair payments are essential to preserving the emergency medical system that saves American lives every day.

Without adequate reimbursement, air ambulance providers may be forced to exit the market or reduce services, leaving patients in emergent situations with few options. This is not the outcome Congress intended when it passed the Act. We urge the Departments to consider the negative impacts the regulations will have on underserved communities and, instead, take a more equitable approach to ensure that access to care is possible, regardless of location.

In this comment letter, we offer several considerations that the Departments should take into account as you revise the regulation, including recommendations in the following key areas:

- I. Navigating Implementation
- II. Qualifying Payment Amount
- III. Weighting of Factors in IDR
- IV. Transparency in IDR
- V. IDR Entity Certification
- VI. Batching of Claims

I. Navigating Implementation

We appreciate the ambitious timeline that Congress prescribed in the Act and the Departments' efforts to achieve those milestones to protect consumers from surprise bills. However, the IFRs involve significant, industry-wide changes to day-to-day practices that require time, resources, and careful attention to implement correctly. These changes were initiated and adopted without notice and comment. And, where we engaged with Congressional Members during the design and passage of the Act, we have not seen the intent and vision of those Members, nor our discussions, carried through in the Departments' regulations.

We believe the Departments can achieve the goal of the Act if they provide stakeholders more time to understand, test, and provide thoughtful recommendations on the policies. We have just begun to identify the barriers to implementation and are anticipating many more hurdles ahead. To that end, the Departments should engage more deeply with the air ambulance provider community, so that concerns and solutions can be openly shared and addressed.

The Departments should also exercise enforcement discretion as stakeholders work to become compliant with the new requirements, which are far-ranging and complex (e.g., data reporting,

and more). The Departments have demonstrated a willingness to exercise enforcement discretion for group health plans and issuers. They should extend comparable regulatory relief to air ambulance providers that are making good faith, reasonable efforts to implement the Act. We urge the Departments to use their enforcement discretion as the IFRs are implemented; to work with the air ambulance provider community as obstacles are identified; and to provide reasonable and timely clarification, when needed.

II. Qualifying Payment Amount

The QPA methodology described in IFR Part I and reinforced in IFR Part II will have unintended consequences for access to emergency air ambulance services, especially in rural America. The Departments posit that the QPA is a median contracted rate that "generally reflect[s] market rates." The QPA methodology, however, arbitrarily excludes from the median calculation certain types of contracts, like single case agreements and alternative payment arrangements (collectively, "SCAs"), that are commonplace in the air ambulance industry. The magnitude of the exclusion is material; AAMS members representing 236 air bases (approx. 25% of the national air bases) report that, in 2019, 38%-56% of out-of-network claims were resolved through SCAs. The result is that under the QPA methodology, the QPA does not reflect market rates.

The QPA methodology also treats all types of air ambulance providers the same – lumping together in the same category those providers that negotiate with insurers as part of a larger hospital system and those providers that negotiate independently Plus, if there is an insufficient number of contracted rates at the state level to determine a median, then IFR Part I requires the QPA to be determined using all metropolitan statistical areas ("MSAs") in a Census division or all other areas in the Census division. This means that an air ambulance provider's reimbursement may derive from amounts paid several states, or even an ocean, away.

This methodology will depress reimbursement. Congress tasked the Departments with implementing a framework that would remove patients from payment disputes and allow for the swift resolution of disagreements. Instead, the Departments have distorted the statutory framework to reduce payment on a national scale – something Congress considered and rejected. This is not a theoretical problem. We were alarmed to see a now widely-circulated letter by BlueCross BlueShield of North Carolina, which uses the QPA as a lever to immediately terminate and renegotiate provider contracts. We are concerned that this is only the start of contract terminations and that, in straying from Congress's intent, the Departments have put patient access to care at risk. As payers terminate contracts and drive reimbursement to levels at or below the administratively depressed QPA, air ambulance providers will be forced to make difficult, but necessary, business decisions. Our members simply cannot operate where expenses exceed reimbursement. This means that transports may be reduced, including in rural, underserved areas. This is not what Congress intended in implementing the Act.

¹ 86 Fed. Reg. 55,980, 56,060.

² See e.g., J. Lagasse, American Society of Anesthesiologists Accuses BCBSNC of Abusing No Surprises Act, Healthcare Finance (Nov. 23, 2021). Accessible at: https://www.healthcarefinancenews.com/news/american-society-anesthesiologists-accuses-bcbs-north-carolina-abusing-no-surprises-act.

For these reasons and more, we ask that the Departments fix the QPA methodology and we discuss each of the fundamental flaws below.

The QPA Methodology Arbitrarily Excludes Relevant Data: The QPA methodology excludes contracted rates from a wide range of contracts, including SCAs, letters of agreement, arrangements used to supplement a payer's network, incentive-based and retrospective arrangements. Given these broad exclusions, the methodology will not produce QPAs that reflect all contracted rates, nor will it account for the cost of services. Rather, the QPA will reflect the comparatively smaller number of rates from in-network contracts, including contracts that were accepted without vigorous negotiation (as described below). This will exacerbate the historic market conditions that prompted the need for the Act in the first place.

Instead, all contracted rates should be included in the QPA calculation, especially since no reliable database presently exists to determine a median contracted rate for air ambulance services in the case of "insufficient information." There is no existing database that contains a representative number of the air ambulance transports in a given state. AAMS is interested in working with the Departments to create such a database. However, in the interim, the only avenue for generating a fair, reliable QPA is to include all contracted rates in the methodology.

The QPA Methodology Should Differentiate Between Air Ambulance Provider Types: The QPA is the median contracted rate for the "same or similar item or service" rendered by a provider in "the same or similar specialty" in the geographic region. The Departments lump all air ambulance providers into "the same or similar specialty," and fail to draw critical distinctions between those that bill for services through a hospital system and those that do not, emergency rotor-wing and emergency and non-emergency fixed wing providers, and active and shuttered providers. Each of these distinctions can drive the costs of delivering the service, as well as any contracted rate negotiated between the provider and the payer.

This is an unreliable approach because it does not account for critical differences in an entity's structure and contracting practices. For example, a hospital may enter into an agreement with a payer based on a broad range of services, including rates for air ambulance services. In some instances, a hospital may agree to rates for air ambulance services without actually offering the services. Such rates may be far below market, and may be included in the contract without any negotiation because the hospital will never seek payment.

In contrast, providers of air ambulance services who only bill for air ambulance services must ensure that rates are sufficient to maintain services. Otherwise, they cannot cover their costs. It is not rational for the Departments to treat independent rates negotiated at arm's length the same as below-market, ghost rates that are passively accepted by hospitals because they will never be charged to payers.

The Departments acknowledge legitimate differences between independent and hospital providers elsewhere in IFR Part I. Notably, the Departments recognize that standalone emergency departments may have a different relationship to payers when compared to

emergency departments that bill through a hospital system.³ The Departments should similarly recognize the distinctions between air ambulance providers.

The Use of Census Divisions Will Produce Absurd Results: While we appreciate the Departments' efforts to base the QPA on sufficient information, the use of Census divisions in the context of air ambulance services means that a rate from Hawaii or Alaska may dictate the QPA for a pick-up in California. We believe this approach, again, reflects a misunderstanding of the unique nature of air ambulance services. Congress tied payment rates to geography because it understood that healthcare is local or regional and that the unique features of a market varies by geography and economy. The circumstances of a rural county in Alaska should not dictate payments for services in Los Angeles, California. There are better approaches to reaching a sufficient number of rates – such as including SCAs and historic payment rates established in the same market – that do not involve comparing markets that are thousands of miles apart.

The Departments Should Mitigate the QPA's Unintended Consequences: Regardless of whether the Departments address flaws in the QPA methodology, the Departments should, at a minimum, work to mitigate the unintended consequences of the methodology. As a first step, payers should be required to disclose additional information about the limitations of the QPA to providers. As drafted, payers are required to communicate very little information about the QPA to providers and there is no opportunity for providers, or the Departments, to confirm that payers have taken the necessary and correct steps to reach the final amount. The Departments have placed a significant amount of trust in payers to understand and calculate this complex sum, with hardly any oversight or checks and balances.

To promote transparency and confidence in the QPA, payers should disclose: the number of contracts used to calculate the QPA; the rates, types of air ambulance providers, and volumes of claims in the QPA; out-of-network volume and payment amounts; volume and payment amounts for all other arrangements (e.g., SCAs); and a description of each contract omitted from the QPA methodology and the reasons for the omission. Disclosure of this information will allow providers to assess whether payers' calculations were performed correctly and will better equip both parties to evaluate the reasonableness of their positions. If providers have assurance that the amount is accurate and based on a sufficient number and range of contracts, the number of claims brought to IDR will likely be reduced.

In addition, the Departments should instruct IDR entities on the limitations of the QPA. IDR entities should evaluate payments to air ambulance providers with an open mind and with a clear-eyed understanding of what the QPA does and does not represent. The IDR entity should be able to consider the QPA in context and, based on all of the circumstances Congress articulated in the statute, make a sound selection of the appropriate out-of-network rate.

³ 86 Fed. Reg. 36,872, 36,892 (July 13, 2021) ("[W]here a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute.")

III. Weighting of Factors in IDR

IDR Entities Should be Free to Weigh the Circumstances that Congress Mandated for Payment Determinations: The Act establishes certain criteria that an IDR entity must weigh when determining which payment offer to select, including the QPA, the provider or facility's level of training, experience, and quality and outcomes measurements, and more. The IFR, however, ignores these factors and instead requires arbiters to "select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate [.]"⁴ This approach directly conflicts with the process Congress designed.

The Act states that the IDR entity "shall consider" the list of circumstances enumerated, and the QPA is but one of those factors. Congress likely designed the IDR process to consider multiple circumstances because no two patients are alike. The cost of services may vary from case to case based on the severity of the condition, the expertise of the provider/s involved, the patient's underlying conditions, and more. The presumption that the QPA is the appropriate out-of-network rate ignores these realities to the detriment of providers and their patients.

The Departments also add qualifying terms (i.e., "credible information" and "materially different") that are not included in the Act, further diminishing the relevance of the additional circumstances that Congress directed the IDR entities to consider. These qualifiers create a much higher bar for providers to meet and impose an additional step in the resolution process.

The result is that the Departments have transformed the IDR process enacted by Congress into a perfunctory rubber stamp for an administratively depressed QPA. Instead of considering all circumstances mandated by Congress, evaluating the parties' arguments, and reaching an independent conclusion, IDR entities must award the QPA in all but the most exceptional cases. This approach is inconsistent with the statute. If Congress had meant for the QPA to be the appropriate out-of-network rate, then it would have said so. Instead, Congress created an IDR in which the QPA is one of many factors that IDR entities must consider when determining the appropriate out-of-network rate.

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

Congress' design is effective because it offers a dispute resolution process that is *un*predictable. Despite this design, the Departments concluded that "emphasizing the QPA will allow for

⁴ 86 Fed. Reg. 55,980, 55,984.

⁵ Public Health Service Act (PHSA) § 2799A-2(b)(5)(C).

predictability."⁶ The IFR states "[t]his certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor" and "may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period."⁷ Therefore the express purpose of IFR Part II is to destabilize the foundation on which the dispute resolution is built and to render the process effectively meaningless. Congress created an independent dispute resolution process because it wanted an *independent* dispute resolution process, not one in which outcomes were predetermined.

The Departments should revise their regulations to align with the process Congress intended. IDR entities should have the discretion to weigh all of the circumstances mandated by Congress, consider the parties' arguments, and make independent decisions.

IV. Transparency in IDR

The Departments Should Encourage Transparency in IDR: The Departments should make the information that the parties disclose to one another in open negotiations admissible in IDR, require the parties to share their submissions to the IDR entity with one another, and make clear that the only mandatory exemptions of those materials from public disclosure are the ones established by the Freedom of Information Act ("FOIA"). Anything less than maximum transparency in the IDR process will permit parties to game the IDR system by withholding information from both the IDR entity and the public that is material to the decision-making process and integral to a fair resolution on the merits.

Fairness also requires an opportunity to respond to new information that a party withheld during open negotiations, and disclosed for the first time in its submission to the IDR entity. The Act imposes a 10-day statutory deadline for both sides to submit claims and supporting information to the IDR entity. But the Act authorizes the Secretary to modify that deadline for "extenuating circumstances." The Departments should define "extenuating circumstances" to include a submitting party's presentation of information that was not disclosed during open negotiations, and that requires the IDR entity to grant the receiving party at least 5 days to respond to such information. A procedural right to respond to new information will encourage transparency during open negotiations and prevent unfair surprise.

V. IDR Entity Certification

The Departments Should Require that IDR Entities Request Average Non-Contracted Paid Claims Amounts From the Parties: The IFR outlines a process for certifying IDR entities to ensure they carry out their responsibilities. The Act authorizes the Departments to revoke an IDR entity's certification if it demonstrates a pattern or practice of noncompliance. Separately, the Act requires the parties to submit to the IDR entity (i) an offer for a payment amount, and (ii) "such information as requested by the certified IDR entity." Together, these provisions authorize the Departments to require IDR entities to request specific information from parties in IDR as a

⁶ 86 Fed. Reg. 55,980, 56,061.

⁷ Id.

condition of IDR certification.

We recommend that the Departments require IDR entities to request that, with respect to a dispute regarding calendar year 2022, the provider submit the average non-contracted paid claims amount during calendar year 2019 (to be updated by an inflation factor with respect to a dispute regarding a future calendar year). This information is important because it reflects the amounts that payers were willing to offer before the Act was implemented. The information will provide the parties and the IDR entity with a more complete and transparent factual basis for assessing the dispute. The failure to request this information should result in decertification of the IDR entity.

VI. Batching of Claims

The Departments Should Clarify the Definitions Associated with the Batching of Claims; Allow Air Ambulance Providers to Batch Base and Mileage Rates: The Act allows multiple qualified IDR dispute items and services to be considered jointly in one determination if they are: (i) furnished by the same provider or facility; (ii) payment is made by the same health plan or issuer; (iii) items or services rendered are related to the treatment of a similar condition; and (iv) items or services were furnished during the same 30-day period or an alternative period as determined by the Secretary. The IFR refines the definition of "same provider or facility" to include entities that bill with the same National Provider Identifier ("NPI") or Taxpayer Identification Number ("TIN").

However, the Act and IFR do not define "same health plan or issuer." We believe that the Departments intend to refer to a specific health plan in the market and not to a payer's parent organization, which may operate on a regional or national basis. If the Departments were to interpret the definition as applying at the parent organization level, it would create a significant backlog as every claim associated with a national payer is forced to wait out the cooling off period. This would be contrary to Congress's vision of establishing an "efficient" resolution process. We request confirmation of this understanding.

Next, the IFR adds a conflicting definition of "items or services." While the Act defines items or services as related to the treatment of a similar condition, the IFR defines items or services as "billed under the same service code, or a comparable code under a different procedural code systems [.]" Service codes are defined according to CPT, HCPCS, or DRG codes. We believe that the Departments should apply the Act's broader definition, with the aim of enabling the batching of claims to the fullest extent (and thereby reducing the number of IDR proceedings).

Similarly, we request that the Departments clarify the ability to bundle air ambulance base rates and milage rates in one payment determination. Every air ambulance flight is billed with a base rate and loaded miles. Under the current structure, it is not clear whether these amounts may be batched in one resolution. It appears that payers may issue separate QPAs for the base rate and mileage and that these amounts will then the deemed separate items or services. This means that for each air transport, an air ambulance provider might need to initiate two IDR processes for: (i) base rates involving the same NPI, same payer, and in the same 30-day window; and (ii)

⁸ 86 Fed. Reg. 55,980, 55,994.

milage rates involving the same NPI, same payer, and in the same 30-day window.

This approach would create tremendous inefficiencies and essentially double the IDR disputes involving air ambulance providers. Rather, the Departments should clarify that, given the nature of air ambulance services, base and mileage rates go hand-in-hand and should be considered in the same determination.

Thank you for the opportunity to provide comments on the IFR. We believe it is critical to protect patients' use of air ambulance services, both in emergency and nonemergency situations. Air ambulance services are essential to our healthcare system and there must be a reliable mechanism in place to financially support these operations. We are concerned that the IFR will have serious, unintended consequences, particularly for underserved and rural communities, and we urge the Departments to consider our recommendations. If you have any questions, please contact AAMS Vice President of Public Affairs Christopher Eastlee at ceastlee@aams.org.

Sincerely,

Cameron Curtis, CMM, CAE President & CEO

Association of Air Medical

Services

Deborah Boudreaux, MSN, RN, CCRN, C-NPT, LP,

Delbie Boudreaux MSN, RN, LP

CMTE

Chairman and Region IV Director, AAMS

Teddy Bear Transport, Cooks Children Medical

Center

EXHIBIT 2



1301 Concord Terrace Sunrise, FL 33323 800.243.3839 www.mednax.com

November 19, 2021

Via Electronic Submission

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Martin Walsh Secretary U.S. Department of Labor 200 Constitution Ave N.W. Washington, DC 20210

The Honorable Janet Yellen Secretary U.S. Department of the Treasury 1500 Pennsylvania Avenue, N.W. Washington, DC 20220

Dear Secretaries Becerra, Walsh and Yellen:

On behalf of our physicians and the patients and communities we serve, Mednax is providing these comments on the *Requirements Related to Surprise Billing; Part II* Interim Final Rule (IFR).

Mednax is a national medical group, comprised of the nation's leading providers of prenatal, neonatal, and pediatric services. Mednax, through its affiliated professional entities, provides services through a network of more than 2,300 physicians in 39 states and Puerto Rico. Twenty-five percent of premature babies in the U.S. are born in our NICUs.

While we applaud the Departments' goal of putting patient care first, we offer a number of recommendations below to facilitate implementation of the surprise billing protections. Specifically, we urge the Departments to fix the Qualifying Payment Amount (QPA) methodology, which is currently based on in-network contracts alone and a myriad of physicians, regardless of whether a physician ever bills for services under a CPT code. This issue of "ghost contracting" frequently occurs in the subspecialty of neonatology. Rather, the QPA should be determined based on a weighted methodology of CPT codes actually used that will allow the IDR entity to have better understanding of prior contracted rates, good-faith negotiations, specialists' medical experience, acuity of patients seen and market share.



Secretaries Becerra, Walsh and Yellen November 19, 2021 Page 2 of 12

We are gravely concerned about the impact the IFR will have on underserved communities. The IFR as written will have a broad, discriminatory impact and harm patients who reside in traditionally underserved communities, including many rural areas. This will happen very quickly.

Today, Mednax provides highly specialized neonatology care in urban and rural areas alike. In some urban and suburban areas, high patient volume enables us to spread the costs of staffing obstetrics units 24/7 across many cases and sustain reasonable margins. These margins then enable us to provide care in traditionally underserved areas, like rural communities, where because of lower case volumes, professional service reimbursements alone typically do not sustain sophisticated high-cost neonatal care. We also operate in hospitals with high volume, but that are overwhelmingly dependent on Medicaid. We subsidize these services because we are committed to providing broad access to high-quality neonatal care. By subsidizing these services, we are able to deliver the same level of high-quality care where it could not possibly otherwise exist.

We are already hearing from payers who, in anticipation of the power-shift created by this rule, are leveraging the rules to renegotiate contracts. Many of these are contracts that are otherwise not up for renewal at this time. These payers are unilaterally terminating contracts and seeking substantial payment reductions to renew because they expect to be able to pay significantly less for services in 2022 as a result of the manner in which the Departments intend for plans to calculate the QPA, and the outsized role that the Departments envision for the QPA in dispute resolution processes. They are weaponizing the QPA and patient care in many places will be severely compromised or will end.

If payments for our services are wildly reduced, as we expect they may be as a result of these regulations, Mednax, like so many other providers, will need to make quick economic decisions about where we are able to provide services, and where it is no longer economically viable to do so. We will make hard, swift, but necessary business decisions to maintain operations, and these decisions will undoubtedly involve cutting some services, like the services we provide in underserved areas.

The effect of this ruling will also end our many vital support services. We provide enormous clinical oversight, and we are the leading neonatology research organization in the U.S. with the largest neonatal database anywhere.

With this in mind, we urge the Departments to reconsider several critical policy choices. We offer specific recommendations below.

Needless to say, we at Mednax are available to discuss any aspect of these concerns and our comments. If you have any questions, please contact me at any time.

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Sincerely,

/s/ Mark Ordan

Chief Executive Officer Mednax Services, Inc,

Cc: David Kanter, MD, MBA, CPC

SVP, Medical Administrative Services, Mednax

Member, American Academy of Pediatrics Committee on Coding and Nomenclature

Member, American Academy of Pediatrics Editorial Advisory Board

Member, American Medical Association CPT Editorial Panel

Member, American Medical Association Digital Medicine Payment Advisory Group

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Urgent Areas for Consideration

- Fixing the QPA Methodology
- II. Independent Dispute Resolution Factors
- III. Batching Neonatology Claims to Support the IDR Process
- IV. Clarifying Application of the Cooling Off Period
- V. Good Faith Estimates
- VI. All-Payer Claims Databases

I. Fixing the QPA Methodology

We are already seeing payers engage in bad behaviors in anticipation of the No Surprises Act's (the "Act") January 1st effective date. For example, one payer with an existing, multi-year contract contacted us – outside the course of regular negotiations – to renegotiate their contract in light of the Act. We have been unable to resolve these discussions, to date. We have experienced an increasing number of contracts being terminated, with payers explicitly citing the Act as the reason for initiating terminations and pausing negotiations until January 2022. It is clear that payers have become emboldened by the Act and are increasingly displaying an unwillingness to negotiate.

i. The Departments should fix the QPA methodology. The methodology for calculating the QPA is built on broad generalizations that fail to account for the market dynamics that dictate rates. For example, the QPA does not use a weighted median nor does it incorporate critical differences between sub-specialties. Most of our physicians are board certified in Pediatrics, but are also board certified in at least one sub-specialty, like Neonatology, Cardiology or Neurology, among others. The median contracted rates for a pediatric cardiologist or neonatologist can vary significantly compared to a traditional primary care pediatrician. The training, experience, and settings in which these professionals practice can also be quite different. For example, while the majority of pediatricians primarily furnish services in an office setting, our specialists primarily furnish services in facility settings, like hospital emergency departments, NICUs and PICUs. Combining all sub-specialties into one median amount at the specialty level dilutes the weight of a specialist's experience (i.e., because there are considerably more contracted rates for payment for pediatric services than there are for neonatal intensive care services, for example).

The Departments begin with a faulty assumption: that the QPA "represents a reasonable market-based payment for relevant items and services." This assumption is not accurate. By definition, the QPA is *not* a market-based rate because it excludes all out-of-network payments, alternative payment arrangements, single case agreements, and more. It reflects only contracted rates as recognized by one payer, thereby discounting and underrepresenting a significant portion of the market. Moreover, the Departments acknowledge the market dynamic that occurs in payer-provider contracts: "Joining a plan's … network assures providers of patient

¹ 86 Fed. Reg. 55980, 55,996.

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volume in exchange for lower reimbursements."² That is the arm's length transaction that underlies payer-provider contracts. If an out-of-network provider is more or less made to accept the QPA – which is the median rate under plan-provider contracts – as payment in full for out-of-network services, the provider is taking the discounted rate for nothing in exchange, e.g., patient volume. As such, the QPA as written, cannot be a credible proxy for out-of-network payments. By nature, an out-of-network payment indicates a failure or breakdown of in-network status, generally because the proposed rates are financially unsustainable or there is an inability to reach agreement on other considerations. Therefore, simply assigning a payer-recognized amount to a provider disparages the contracting process.

For these reasons and more, the QPA does *not* represent a market-based rate. Rather, the Departments have selected a subset of the market and applied it to the industry as a whole, often with the effect of artificially deflating rates. We urge the Departments to fix the QPA methodology so that it more accurately reflects what payers have been willing to offer and providers willing to accept. Accordingly, we urge the Departments to base the QPA on actual payments issued to individually contracted physicians.

ii. The Departments should base the median contracted rate on service codes that a provider has actually billed. The median contracted rate for an item or service is calculated based on care rendered by a provider in the same or similar specialty or facility in the same or similar facility type provided in a particular geographic region. This median includes rates that a provider may have accepted as part of a broader network agreement, even though the provider itself may not render or bill for select services. Such agreements may include rates that are folded into a larger contract without negotiation or discussion and are, therefore, lower than the true cost of providing care. For example, a provider may contract for hundreds of services, even though it does not offer and does not plan to offer a subset of those services. It has no incentive to fight for a fair payment rate on the subset and will generally accept the amounts the payer establishes, even if the rates are inadequate to cover the cost of care. Yet, under the Departments' methodology, rates established via this "ghost contracting" approach would be incorporated in the median, thereby devaluing the rates for services actually delivered.

Given the significant role the median rate plays in establishing the QPA and, evidently, in directing the final payment amount, the median rate should not be influenced by rates that a provider has accepted but not used. Instead, the Departments should base the median on codes that providers bill. If the Departments do not modify this methodology, the independent dispute resolution (IDR) entity should, at a minimum, be informed that the median is based on amounts that were not thoroughly negotiated and the entity should be required to consider this discrepancy as one factor in its consideration.

II. Independent Dispute Resolution Factors

The Act requires arbiters to consider a number of factors in selecting the final payment amount in IDR, including the QPA, the provider's level of training and experience, the parties' market shares, patient's level of acuity, and

² 86 Fed. Reg. 55980, 56,046.

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more. The Act deliberately and clearly specified that the arbiter shall consider all factors equally. Specifically, the statute noted that the IDR entity "shall consider" the QPA and "information on any circumstance" described in the statute as requested by the IDR entity or submitted by a party.³ However, the Departments add new restrictions in the IFR, which require arbiters to "select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate [.]" This approach is inconsistent with the process Congress designed and could have the unintended consequence of diminishing the value of this dispute resolution process, and worse, disrupting existing payer-provider contracts and future negotiations.

i. The Departments should allow arbiters to freely assess information submitted to IDR. In designing the dispute resolution process, Congress sought to create a fair and efficient process that would incentivize providers and payers to resolve payment disputes or otherwise accept the selection of a reasonable offer. Congress outlined the elements it believed to be critical in reaching this final amount and then it provided a catchall for parties to submit additional information relevant to the unique circumstances of the dispute. In this way, Congress acknowledged the complexities often involved in reaching a final payment and created the opportunity for payers and providers alike to make their case to an independent dispute resolution body.

Instead of implementing Congress's vision, the Departments have redesigned the IDR process to, in most cases, reach a predetermined outcome solely recognized by the payer. Rather than considering all of the factors and information submitted, the IFR requires arbiters to select the offer closest to the QPA, unless a party can overcome the high bar of demonstrating that the QPA is materially different from the out-of-network rate. This requires parties to expend additional effort and incur additional costs in gathering materials and building their argument before they even get in the door. Only once parties' successfully demonstrate that the out-of-network rate *is* materially different from the QPA, may they then engage in the full IDR process where the IDR entity will weigh that "credible information." The Departments have, therefore, created an additional step (i.e., requiring parties to prove their information is credible) that Congress did not call for when it established a two-part resolution (i.e., negotiation and IDR).

The requirement that arbiters place primary weight on the QPA also ignores Congress's directive for multiple factors to be considered. By favoring the QPA and making it difficult to introduce other evidence, the Departments have essentially discarded the factors Congress intended to be part of the consideration, and changed the nature of IDR. Instead of being an independent, deliberative process where a trained entity must wrestle with the evidence and reach a balanced decision, the Departments seek to implement a process where the QPA is dispositive in most instances. Before parties even initiate IDR, they now know that the outcome will most likely reflect the QPA, and they face an uphill battle of convincing the arbiter to rule otherwise.

This approach is inconsistent with aspects of the IFR itself. For example, the IFR establishes extensive requirements related to IDR entity selection and certification, yet, under the Departments' proposal, these

³ Pub. L. No. 116-260, tit. I, div. BB.

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standards are largely unnecessary if the IDR entity's only function in the vast majority of instances is to select the amount that most resembles the QPA. If IDR entities are not going to engage in traditional dispute resolution procedures, it is not clear why parties must pay IDR fees or why the Departments would spend resources vetting applicants.

If Congress had wanted to resolve payer-provider disputes based on one factor, it would not have gone through the trouble of creating an IDR process and could have simply mandated that all payment disputes end with the QPA. Congress did not take that approach. It designed a comprehensive process to remove patients from disputes and to provide an avenue for swift resolution taking into account a variety of factors. The Departments have dramatically strayed from this framework. The Departments' qualifying terms (i.e., "credible information" and "materially different") were not included in the statute and diminish the role of the other factors that Congress clearly viewed as relevant in the payment determination. The Departments should revise this approach and allow arbiters to freely assess the evidence submitted.

ii. Providers should have a better understanding of how the QPA is derived and greater scrutiny of the QPA is required. The IFRs provide little oversight of the QPA, including how it is derived, reported, and efforts to safeguard against manipulation. This is a departure from regulators' generally careful approach to rate review. When a payer establishes its annual premium rates for the commercial market, those rates are closely scrutinized by State Departments of Insurance, including robust documentation justifying the amounts and any meaningful year-over-year increases. Similarly, Medicare Advantage plans must submit annual bids that estimate the cost of providing Parts A and B benefits, which are then compared to a benchmark established by the Centers for Medicare and Medicaid Services. Determining what Medicare Advantage plans will be paid involves a complex methodology, close analysis of the bids submitted, and back-and-forth communication with the agency. Yet, under the IFRs, the Departments have established a reimbursement methodology that payers alone calculate and apply, with little independent scrutiny or transparency. Like premium rates in the commercial and Medicare Advantage markets, QPAs should be submitted for review and approval before they are eligible for use and the Departments should play a role in overseeing how these amounts are reached.

The Departments have encouraged providers to monitor for and report instances of payers' bad behaviors related to the QPA, but this responsibility should not fall on providers alone. Documenting payers' bad behaviors requires additional time and resources and it is not clear how providers will be able to identify these accounts when hardly any information on the QPA is made available. Payers should be required to disclose considerably more information about the QPA methodology, including the number of contracts that contributed to the median, the specialty and subspecialties included, and the states in which the contracted rates are derived. At present, providers have no access to this data or the ability to confirm that calculations were performed accurately. To ensure that providers have confidence in the QPA and to ensure fairness, the methodology the payer used should be transparent and disclosed in the communication of the initial payment or notice of denial of payment. The Departments should not allow QPAs to be used until they are certified as accurate.

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iii. Assigning the QPA primary weight in IDR determinations will disrupt payer-provider contract negotiations and create an unleveled playing field, which will negatively impact patient access to specialized care. In redesigning the IDR process, the Departments have not only tilted the scale in favor of payers, but have actually made it more difficult for providers to maintain and form fair in-network agreements with payers. Payers hold all the information because the QPA is based on their own contracted rates. If payers believe that the maximum they will ever have to pay in a dispute is the QPA, they have every incentive to only contract with providers who are willing to accept less than the QPA. Over time, this will drive down median contracted rates and compromise fair negotiations. The Departments have effectively eliminated providers' ability to engage in payment discussions: providers will, most often, have to accept QPA-like rates – which will deteriorate over time – or will likely be placed out-of-network; and any payment dispute providers pursue will likely settle near the QPA. Thus, it will be difficult for providers to ever move beyond the QPA.

We believe the IFR's structure harms the ability to form new agreements and also threatens the contracts that payers and providers have worked hard to secure, by incentivizing payers to abandon these existing agreements and seek artificially lower rates. As discussed earlier, patients will ultimately suffer through diminished access. If provider payments decline, subsidized outreach arrangements, like staffing rural facilities with specialized care, will be difficult to sustain. Patients may find it harder to find specialized neonatology services anywhere but large urban medical centers. The Departments should clarify that while the QPA is one data point for determining payment, it is not the overriding factor and should not be viewed as a benchmark for setting future rates. The Departments should also clarify that where parties had a prior contractual relationship, the arbiter should give deference to the parties' prior negotiated rates in IDR. If the QPA for the item or service does not align with the parties' prior contracted rates, then it should not be used as the determining factor in a dispute.

iv. Arbiters should not be biased or pressured to select one party over the other. The Act directed the Departments to create an unbiased process for settling disputes and it established certain guardrails to achieve this, including standards related to conflicts of interest and IDR certification. However, the Departments have now created a process where arbiters may only deviate from the QPA in rare instances and must explain any deviation from that amount. Whereas certified IDR entities must submit their decisions and underlying rationale through the Federal IDR portal in a form and manner specified by the Departments, the IFR suggests that an IDR entity that strays from the QPA must go a step further. The IFR states that "[i]f a certified IDR entity does not choose the offer closest to the QPA, the written decision's rationale must include a detailed explanation of the additional conditions relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate."⁴

The IDR entity must, therefore, do considerably more work to select a final amount that differs from the QPA. This approach is not practical. When an arbiter is managing hundreds of disputes and has been directed to presume that the QPA is accurate, we believe the vast majority of arbiters will do as directed and select the

⁴ 86 Fed. Reg. 55,980, 56,000.

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offer closest to the QPA, with no further consideration. Even if they are willing to undertake the work, an IDR entity may hesitate to stray from the QPA out of concern that its decision may be challenged or subject to scrutiny. Entities that select the offer closest to the QPA are less likely to be reviewed, to have their decision overturned, or to be cast out of the Federal IDR system. This creates a disincentive for arbiters to consider evidence submitted by providers and pressures arbiters to default to the payer-driven QPA.

Arbiters should not be biased and pressured to select one party over the other. The Departments should allow arbiters greater flexibility to consider the information submitted and reduce any barriers that might prevent an arbiter from selecting a party.

III. Batching Neonatology Claims to Support the IDR Process

Claims should be eligible for batching based on an episode of care and at the sub-specialty level. The Act provides that multiple qualified IDR items or services may be considered jointly as part of a single determination when certain criteria are met. Such "batching" of services will only be permitted if such items or services are: (i) furnished by the same provider or facility; (ii) paid by the same group health plan or health insurance issuer; (iii) related to the treatment of a similar condition; and (iv) furnished within the 30-day period following the date on which the first item or service was furnished "or an alternative period as determined by the Secretary [.]" The IFR adds that if items or services are billed by a provider as part of a bundled arrangement, or where a payer makes an initial payment as a bundled payment, those qualified items or services may be submitted and considered as part of one payment determination.

We appreciate the Departments' thoughtful consideration of the batching process and the flexibility provided in IFR Part II related to bundled arrangements. We endorse the opportunity to batch multiple claims in a single determination and agree, as the IFR recognizes, that there are instances where items or services should be considered at the same time as part of a bundled arrangement. We believe the Departments should expand this approach to allow for claims to be batched based on an episode of care at the sub-specialty level. An episode of care should include any claims incurred during the period of time the patient is under care (e.g., an entire stay in a NICU, or at least a continuous 30-day period of care within the NICU stay inclusive of all services rendered by the same group of subspecialists). NICU care often involves continuous, consecutive days of service within and beyond 30 days, with treatment sometimes continuing for two or three months for preterm newborns and complex cases. To better support the IDR process, neonatologists should be able to batch all of the services performed during these consecutive days, at least for the full 30-day period, if not also extending through the entire hospital course. Neonatology is unique in this sense, because care involves consistent treatment over the course of days and weeks to manage the hospitalization of preterm babies. During this time, the number of CPT codes relevant to neonatology is not extensive, but the assignment of those codes can vary from day to day or week to week depending on the patient's status. The ability to batch the full hospitalization (or at least, the full 30-day period) in one determination at the specialty and subspecialty level across multiple service types (as reflected by different CPT codes) will reduce the administrative burden for the physician and IDR entity. It will also allow the IDR entity to better assess variations in the cost of care based on the relative differences in Secretaries Becerra, Walsh and Yellen November 19, 2021 Page 10 of 12

reported codes, which reflect clinical condition. Therefore, the Secretaries should use their authority to allow for claims to be batched where care is delivered in a coordinated fashion; the batching of multiple items or services should not be limited by the reimbursement structure.

IV. Clarifying Application of the Cooling Off Period

The Departments should clarify that the "cooling off" period applies at the plan level. Once the IDR entity renders a final determination, the law requires a 90-day "cooling off" period for the party that submitted the initial IDR request. During this time, the party may not submit a subsequent request involving the same opposing party and same item or service. While the IFR clarifies some aspects of the IDR process, it still does not answer whether the cooling off period applies at the payer or plan level. We believe the Departments intend to apply this standard at the plan level, since pending all disputes against a payer would significantly slow the resolution process and require both parties to undertake the burdensome task of tracking all disputes. Mednax requests clarification on the meaning of "opposing party," as well as what providers will be paid during the 90-day period and what procedural rules apply. We recommend that the Departments consider flexibilities to implementing this 90-day period and request that all eligible disputes have timely access to the IDR process.

V. Good Faith Estimates

The Departments should delay implementation of the good faith estimate requirement to give providers more time to identify and prepare resources on the estimates. The IFR requires providers to inquire about an individual's insurance status and provide a notification that the individual may receive a good faith estimate of the expected charges, including the expected billing and diagnostic codes for any such item or service. On August 20, 2021, the Departments released an FAQ deferring enforcement of this requirement on behalf of insured individuals until rulemaking is adopted and applicable. The Departments noted that "given the complexities of developing the technical infrastructure for transmission of the necessary data from providers and facilities to plans and issuers, [the Department of Health and Human Services] recognizes that compliance with this section related to individuals who are enrolled in a health plan or coverage and are seeking to have a claim from the scheduled items and services submitted to the plan or coverage is likely not possible by January 1, 2022." The Departments did not defer enforcement of the requirement for uninsured individuals.

While Mednax appreciates the Departments' commitment to greater transparency and patient education, the IFR contains complex requirements that will take time for providers to understand and implement. For example, it is not clear how providers are to exchange this information and coordinate to reach a reasonable estimate. Does the convening entity need to provide an individual's entire medical record to all providers involved? How are providers to calculate the estimate if an individual has multiple co-morbidities or co-morbidities are not yet known? Do providers have only one day to evaluate the patient's record and model and report an estimated

⁵ FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021). Accessible at: https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

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amount? One approach would be for providers to calculate an average cost based on the average patient's profile. This would likely require a disclaimer that the good faith estimate is based on a patient with low or high needs. Will this approach satisfy the good faith standard?

If the charged amount ultimately exceeds the estimate by \$400 or more, patients may bring a claim through the patient-provider dispute resolution process. In the context of highly specialized services, like neonatology, \$400 is a very small margin in which to get the estimate correct. Despite providers' best efforts, there are many circumstances in which the billed amount may exceed this threshold. For instance, a patient may schedule services for a standard procedure, like a mole removal, but it will be difficult to predict up-front whether a specialist may need to be involved or if further testing will be required. Given the number of outstanding questions and the need for more guidance on how these estimates should be calculated and issued, we recommend that the Departments delay implementation of this requirement, similar to the delay of good faith estimates for insured individuals. A delay would give providers more time to identify and prepare resources on the estimates and train staff on how to comply with the requirements. This time may allow providers to give consumers better estimates that are well-aligned with the expected charges, based on data modeling and collaboration with our downstream providers.

Congress intended for consumers to have insight into the costs of care and we believe that with more time we can achieve this goal by providing estimates that are data-driven and thoughtful, rather than compiled on a compressed timeline, as the Departments themselves have acknowledged.

VI. All-Payer Claims Databases (APCDs)

APCDs should not be relied on until the Departments have established minimum standards for use and have verified that the databases are reliable for QPA calculations. The IFR places significant reliance on APCDs. When there is insufficient information to calculate the median contracted rate, payers must determine the QPA by using an eligible database. APCDs are considered "categorically eligible" to serve in this role because they are identified as not having any conflicts of interest and as having sufficient information reflecting the allowed amounts. This is not an accurate assumption.

HHS's Agency for Healthcare Research and Quality (AHRQ) has noted that APCDs tend to omit a large number of claims and populations, including uninsured patients and some substance abuse, mental health, and HIV populations. States may not compel data collection from non-governmental self-insured health plans, which represent approximately one-third of all insured people, leaving a large gap in the data APCDs can collect. States then apply different rules regarding which patients to include in the databases, making it difficult to

⁶ See Agency for Healthcare Research and Quality, *All-Payer Claims Databases* (Feb. 2018). Accessible at: https://www.ahrq.gov/data/apcd/index.html.

⁷ See M. Fiedler and C. Linke Young, Federal Policy Options to Realize the Potential of APCDs, USC-Brookings Schaeffer Initiative for Health Policy (Oct. 2020). Accessible at: https://www.brookings.edu/wp-content/uploads/2020/10/APCD-Final-1.pdf/

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compare data state-to-state.⁸ There are also several concerns with data quality, including that claims data does not consistently contain information on patient outcomes, bundled payments, or details from electronic health record data.⁹ AHRQ reports that data submitters do not always provide complete or clean data in a timely manner, which results in additional claims being omitted.¹⁰ And, where quality measures *are* included, these measures have not been thoroughly tested for validity.¹¹ As RAND most recently reported to HHS, "APCDs cannot be assumed to be representative of state populations or health care."¹²

Given this evidence, we urge the Departments to consider the existing research on APCDs and adjust the presumption that they are "categorically eligible" for QPA calculations. Once an APCD has demonstrated the minimum requirements and the Departments have found it to be a reliable source, there should be transparency regarding the underlying data, including but not limited to, who submits to a state's APCD, how many allowable amounts are included, whether workers' compensation is included, what constitutes a "product," and what percentage of the market is reflected in the data. In addition to promoting transparency, the Departments should engage in ongoing validation and verification of the data.

⁸ Agency for Healthcare Research and Quality, All-Payer Claims Databases (Feb. 2018).

⁹ *Id*.

¹⁰ *Id*.

¹¹Id.

¹² See K. Grace Carman, M. Dworsky, S. Heins, D. Schwam, S. Shelton, and C. Whaley, *The History, Promise and Challenges of State All Payer Claims Databases* (June 2021), prepared for the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. Accessible at: https://aspe.hhs.gov/sites/default/files/private/pdf/265666/apcd-background-report.pdf.

EXHIBIT 3

PCP Contracting Practices and Qualified Payment Amount Calculation Under the No Surprises Act





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Funding for this research was provided by American Society of Anesthesiologists(ASA), American College of Radiology (ACR), and The American College of Emergency Physicians (ACEP). Avalere Health retained full editorial control.



Executive Summary

The qualifying payment amount (QPA) is a calculation used to determine individual cost sharing for items and services covered by balance-billing protections under the No Surprises Act (NSA). The QPA is defined as the median in-network contracted rate recognized by a plan for the same or similar service that is furnished by a provider in the same or similar specialty, and in the same geographic region. The QPA is impacted by all contracts, regardless of how frequently a service is rendered. However, public plans such as Medicare Advantage or Medicaid managed care plans, are not included in any insurance market for purposes of determining the QPA.

To assess the extent to which a QPA may be impacted by including rates from low or no volume contracts in the calculation, Avalere Health surveyed individuals involved in contracting at primary care practices to solicit information on whether they contract with insurers for specialized services they rarely or never provide, whether those services include anesthesia, emergency services, or advanced imaging, and if they actively negotiate the rates for such services they rarely or never provide.

Key Findings

- Many primary care providers (PCPs), who significantly outnumber other specialties, are contracting with insurers for services the providers rarely or never provide.
- Most PCPs who rarely or never provide certain services do not actively negotiate payment rates for those services.
- The existence of PCP contracted rates for services rarely or never provided could cause the QPA to provide an inaccurate representation of the rates commonly paid for services rendered.

Background and Objective

QPA Background

A surprise medical bill occurs when insured patients are issued unexpected medical invoices after receiving medical care from out-of-network (OON) providers. In December 2020, Congress sought to address the issue of surprise medical bills by passing the NSA. The NSA was included in the Consolidated Appropriations Act of 2021 and went into effect on January 1, 2022. The law defines surprise bills as bills patients receive from providers who are outside of their health plan's network after receiving emergency care or when seeking services at an innetwork facility.1

¹ Centers for Medicare & Medicaid Services. "No Surprises Act: Overview of rules & fact sheets." https://www.cms.gov/nosurprises/policies-andresources/overview-of-rules-fact-sheets (accessed June 1, 2022).

The NSA protects insured patients from receiving surprise bills for most emergency services. regardless of whether those services were rendered by an OON provider. The law includes provisions to determine the amount the health plan will pay the provider when the plan and provider do not agree on the payment amount. The same requirements apply when a patient schedules care at an in-network facility and is treated by an OON provider, unless the OON provider obtains the patient's consent to waive the requirement.² The law establishes the basis for patient cost-sharing liability, provider payment, and an independent dispute resolution (IDR) process for determining OON provider payment in instances where a rate is not agreed upon.

Congress debated including a benchmark or standard for determining payment rates to OON providers or facilities during the drafting of the legislation. However, a benchmark was ultimately not included in the law, and the resolution of a final payment rate was left to arbitration.³ Determining patient cost sharing often requires knowledge of the underlying payments from insurers to providers, for example, when a plan includes coinsurance.4 In the absence of a mandated payment rate, a methodology is customarily needed to calculate patient cost sharing in the scenarios impacted by the law.

To determine patient cost-sharing amounts in the scenarios protected under the law, the NSA introduced a new term, Qualifying Payment Amount (QPA). The law specifies that the QPA will be used to determine patient cost sharing in many scenarios.⁵ Interim final regulations implementing the NSA have defined QPA as a health plan's median contracted payment rate to providers in a given region. The NSA requires the QPA to be calculated based on rates for providers with the "same or similar specialty" and facility type; however, the interim final regulations provide health plans with the flexibility to define specialties based on their own contracting practices and to calculate separate QPAs per specialty "where the plan or issuer otherwise varies its contracted rates based on provider specialty ⁶. While the interim final rule aims for an "apples-to-apples" comparison of rates, stakeholders have expressed concerns that the administration did not clearly define what may be considered the "same or similar specialty" or articulate enforcement mechanisms for that nuance of the calculation. 7

The interim final rules stated that the QPA must be a factor considered by an arbitrator during the IDR process for determining payment, and directed the arbitrator to choose the offer closest

² Department of Health & Human Services. "HHS Announces Rule to Protect Consumers from Surprise Medical Bills." https://www.hhs.gov/about/news/2021/07/01/hhs-announces-rule-to-protect-consumers-from-surprise-medical-bills.html (accessed June 1, 2022).

³ Commonwealth Fund. "Summary of the No Surprises Act." https://www.commonwealthfund. org/sites/default/files/202101/Surprise_Billing_Law_Summary_ v2_UPDATED_01-1920 21.pdf (accessed June 1, 2022).

⁴ Coinsurance definition: Cost sharing that is a percentage of the total amount the provider will be paid by beneficiaries.

^{5 &}quot;In cases where a specified state law applies, the recognized amount (the amount upon which cost sharing is based) and out-of-network rate for emergency and non-emergency services subject to the surprise billing protections is calculated based on such specified state law." Where there is no specified state law, the "QPA would apply to determine the recognized amount, and either an amount determined through agreement between the provider and issuer, or an amount determined by an IDR entity would apply to determine the out-of-network rate."

⁶ Requirements Related to Surprise Billing; Part I, 86 FR 36872, (July 13, 2021)

Regulations.gov "Requirements Related to Surprise Billing; Part I CMS-9909-IFC Display." https://www.regulations.gov/docket/CMS-2021-0117/comments. (accessed June 1, 2022).

to the QPA unless significant evidence is provided to indicate another amount is appropriate.8 Currently, regulatory provisions related to the QPA are being challenged in court in six different lawsuits across several states. Due to the suits, certain provisions, including the requirement that the IDR entity select the offer closest to the QPA, are currently vacated. 10 The lawsuits are on hold pending updates to the rule, which are expected to be released in 2022.11

Objectives

Avalere conducted a study to assess the impact of physician contracting practices for services rarely or never provided, and how contracted rates for services rarely or never provided may influence the QPA calculation.¹²

Survey Methodology

1. Approach

Avalere surveyed 75 primary care practice employees who have a role in contracting with insurers to capture key insights related to payer contracting practices. These surveys solicited information on whether those surveyed contract with insurers for services they rarely or never provide, as well as their negotiation practices related to these services. In the survey, the term "rarely" was defined as a service that is provided fewer than 2 times per year. Participants were asked if their primary practice negotiated reimbursement rates with commercial payers for anesthesia services, emergency services, and advanced imaging services.

2. Rationale

Primary care providers were selected for this survey because they outnumber other specific specialties when comparing total number of providers (Figure 2), and do not typically provide the specialized services of focus: anesthesiology, emergency medicine, and advanced imaging. As such, contracting practices within primary care offices may impact the QPA in ways not anticipated by policymakers when the QPA was defined. The survey questions were intended to provide insight into whether QPA for services that are rarely provided are influenced by such contracts and the degree of that impact.

^{8 &}quot;If a certified IDR entity does not choose the offer closest to the QPA, the written decision's rationale must include a detailed explanation of the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-

⁹ Keith, Katie. "The Six Provider Lawsuits Over The No Surprises Act: Latest Developments." Health Affairs. February 16, 2022. https://www.healthaffairs.org/do/10.1377/forefront. 20220216.824139/

¹⁰ Vacated definition: to annul, set aside, or render void.

¹¹ Keith, Katie. "Court Sets Aside Key Parts of No Surprises Act Rule." Health Affairs. February 24, 2022. https://www.healthaffairs.org/do/10.1377/forefront.20220224.298748/

¹² The survey of primary care providers focused on scenarios impacted by the NSA.

3. Survey Questions

A list of 5 screening questions and 5 key survey questions was provided to guide survey participants and ensure response consistency. Questions articulated specific areas of rationale and targeted the collection of specific data/information related to:

- The type of organization to which a provider belongs (multi-practice provider group. independent practice, etc.), their position within the organization, and their role in negotiating reimbursement rates with commercial payers.
- Whether respondents generally contract for services they rarely or never provide.
- Whether PCPs' rate schedules include services likely to be provided in the scenarios covered by the NSA: anesthesiology, emergency medicine, and advanced imaging.
- Whether PCPs who contract for services they rarely or never provide negotiate those rates with insurers and if negotiation practices have shifted since 2019.

Key Findings

The majority (72%) of the 75 primary care professionals surveyed represented independent practices. Most of the survey respondents reported having a high level of authority in contracting decisions, with 37% of respondents identifying as independent decision makers. The second largest category of decision makers (33%) included respondents who make the final decision with input from staff.

According to survey results, most respondents do contract for services they rarely or never provide:

- 68% of respondents contract for services they rarely provide (i.e., services that are provided fewer than 2 times per year)
- 57% of respondents contract for services they never provide

Many PCPs contract for services typically provided by anesthesiologists, emergency physicians, or radiologists:

- 23% contract for anesthesiology services
- 59% contract for emergency services
- 56% contract for advanced imaging

Most survey respondents (41%) who contract for services they rarely or never provide do not actively negotiate the rates for those services, implying they accept the rates offered by insurers.

Discussion

PCPs outnumber anesthesiologists, emergency physicians, and radiologists (Figure 1). The existence of PCP contract rates for services rarely or never provided may cause the QPA to reflect an inaccurate view of the rates commonly paid for in-network services. The inclusion of rates that are not actively negotiated may cause the QPA to be lower than the rates for some services in the market today.

Figure 1 — Total Number of Providers by Type¹³

Provider Type	Total Number of Providers
Primary Care Physicians	496,065
Anesthesiologists	51,282
Emergency Physicians	60,204
Radiologists	48,823

The illustration below (Figure 2) depicts a hypothetical example of a large number of nonnegotiated rates for no/low volume procedures, (e.g., PCP rates) in the calculation of a QPA for an NSA-impacted service. In this example, there are a total of 11 rates included in the determination of the median for a QPA. The total is comprised of 8 rates that are not negotiated (e.g., from contracts with providers in other specialties who rarely or never provide the service) and 3 are negotiated rates from providers who regularly provide the service. The QPA changes depending on which providers are included in the calculation. If all providers are included, the QPA for the service would be \$175. When providers who rarely or never provide the service, and who therefore may not negotiate payment and accept a lower rate, are excluded, the QPA for the service would be \$275.

Figure 2 — Hypothetical Example of Contracted Service Rates¹⁴



¹³ Kaiser Family Foundation. "Professionally Active Physicians" and "Professionally Active Specialist Physicians by Field" QPA: Qualifying Payment Amount; IDR: Independent Dispute Resolution

¹⁴ The hypothetical illustration includes fictitious contracted service rates but serves to reflect where real data would be placed. The illustration depicts actual projections of the potential impact of contracted service rates on the QPA.

Consistent with this example, PCP rates could directly impact payments to anesthesiologists, radiologists, and emergency medicine physicians. While this study was limited to specific specialties, it may suggest larger implications. Furthermore, the effects of other recent policy initiatives that focus on contracted rates, such as the Transparency in Coverage rule, may also be affected by the contracting practices explored in this research.

Conclusion

This analysis suggests that for QPA calculations, including rates for providers who rarely or never provide a service may lead to QPA values that do not reflect payments typically accepted by in-network providers. Using the example of anesthesiology, emergency medicine, and advanced imaging services, the majority of primary care practices have contracted rates for these services that they never or rarely provide and that they do not negotiate with payers.

When policymakers consider methodologies to approximate market rates, approaches that include contracted rates for providers who rarely or never provide a service may result in estimated values that are not reliable estimates of real-world payment rates. If policymakers aim to approximate market rates, approaches that incorporate utilization rates could mitigate unintended consequences of the contracting practices identified in this research.

About Us

A healthcare consulting firm for more than 20 years, Avalere Health partners with leading life sciences companies, health plans, providers, and investors to bring innovative, data-driven solutions to today's most complex healthcare challenges. For more information, please contact info@avalere.com. You can also visit us at avalere.com.

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EXHIBIT G

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

TEXAS MEDICAL ASSOCIATION, et al.,)
Plaintiffs,)) Case No.: 6:22-cv-00372-JDK
v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,) Lead Consolidated Case)
Defendants.)))

DECLARATION OF JAMES L. GAINES

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.

I. LifeNet's Operations

- 2. LifeNet provides air ambulance services in Texas, Arkansas, Louisiana, and Oklahoma. LifeNet's headquarters are in Texarkana, Texas.
- 3. Many of the emergency air ambulance services that LifeNet provides are subject to the No Surprises Act's (NSA's) balance-billing prohibition and to that Act's Independent Dispute Resolution (IDR) process.
- 4. As of the date of this Declaration, LifeNet has performed dozens of emergency air transports, in 2022, for which the right to reimbursement may be governed by the No Surprises Act and its implementing regulations.

II. LifeNet's Contractual Arrangement With Air Methods Corporation

- 5. LifeNet is compensated for its emergency air transport services by Air Methods Corporation ("Air Methods") pursuant to a contract between the two companies. That contract also provides that Air Methods has responsibility for pursuing the collection of bills for LifeNet's services.
- 6. LifeNet's contract with Air Methods Corporation was executed on August 24, 2021, more than a month before IFR Part II, containing the QPA Presumption, was published.
- 7. Section 2.3 of the contract is entitled "Termination for Decline in Revenue." It reads, in full: In the event that the revenue producing flight volume or payor mix for one or more Base Sites drops to a financially unviable situation that is beyond the reasonable expectations of either Party, then either Party may terminate all or part of this Agreement (including the closure of one or more Base Sites) upon at least 180 days prior written notice to the other Party. AMC [Air Methods Corporation] and LifeNet will meet to discuss potential adjustments to the Clinical Crew services prior to either Party exercising its rights under this Section 2.3."

III. LifeNet's Contract Should Be Sealed Because It Contains Commercially Sensitive Information

- 8. 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.
- 9. The unredacted 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; 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. *See* Ex. 1, Aug. 24, 2021 Contract, § 27.0, p. 19.

IV. LifeNet Will Be Harmed by Reimbursement for Its Services at the Level of the QPA

- 10. I expect that open negotiation with insurance companies and health plans, over out-of-network air ambulance services provided by LifeNet, will not always successfully resolve disagreements over an appropriate reimbursement rate. In these circumstances, a certified IDR entity will then determine the reimbursement rate, according to processes set forth in the NSA and the Departments' regulations.
- 11. I believe that the offers submitted to the IDR entity, for air ambulance services provided by LifeNet, will in many and perhaps all cases be above the QPA. That is because, among other reasons, LifeNet has for years attempted to become an "in network" provider for many ERISA health plans, but those plans have refused to agree to pay reasonable rates for LifeNet's services. The QPA is supposedly calculated based on the same in-network rates that LifeNet reviewed during contract negotiations, and rejected as being too low. Therefore, based on LifeNet's experience in the market, I expect that the QPAs will in many cases be significantly below the amounts that LifeNet has been paid for its out-of-network emergency transports prior to the enactment of the No Surprises Act.
- 12. There is a significant risk that reimbursement rates at the level of the QPA will create a "financially unviable situation that [was] beyond the reasonable expectations" of Air Methods and that will therefore risk the early termination of the contract. Ex. 1, Aug. 24, 2021 Contract, § 2.3.

V. LifeNet Is Harmed by the New QPA Presumption

- ambulance services provided by LifeNet, will in many if not all cases will be close to the QPA. Indeed, health insurance companies have indicated they plan to submit bids equal to the QPA. See, e.g., Br. of America's Health Insurance Plans, Texas Medical Association, et al. v. U.S. Dep't Health & Hum. Serv'cs, et al., 21-cv-00425, Dkt. 75, at 3 (insurers' brief, describing the Departments' "QPA-centric" approach to the IDR process and praising it for making out-of-network rates "more predictable," because "most cases can be resolved by reference to the QPA alone").
- 14. I am familiar with the regulatory provisions enacted in the Departments' Final Rule, entitled *Requirements Related to Surprise Billing*, 87 Fed. Reg. 52,618 (August 26, 2022), which LifeNet's Motion for Summary Judgment refers to as the New QPA Presumption:

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

Regulatory Text (bold language contains the New QPA Presumption)	Citation	Reason Why This Language Creates a New QPA Presumption
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 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.	text, applicable to air ambulance IDRs)	(i) the factor "relates to the offer" and (ii) is not "already 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 <i>forbidden</i> 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	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
certified IDR Entity concluded that this information was not already reflected in the qualifying payment amount		

- 15. The New QPA Presumption will make it more difficult for Air Method's offers (of an appropriate amount of reimbursement for LifeNet's services) to win the IDR proceeding, compared to a process in which the IDR entity was free to consider all the statutory factors without the New QPA Presumption. Thus, the New QPA Presumption will thus result in lower IDR determinations of reimbursement rates for the services provided by LifeNet.
- 16. The application of the New QPA Presumption in IDR proceedings will drive outof-network reimbursement rates to the QPA as a benchmark.
- 17. The lower reimbursement rates, determined by IDRs applying the New QPA Presumption, will immediately cause an injury to LifeNet because these lower rates will constitute a lower dollar valuation for LifeNet's services. These determinations will instantly devalue LifeNet's services in a critically important market, namely, the market of reimbursement paid by commercial payors. This lower reimbursement rate will cause the value of LifeNet's services, in this market, to correspondingly decrease.
- 18. For the foregoing reasons, the New QPA Presumption directly harms LifeNet's procedural, financial, and reputational interests.

I declare under penalty of perjury that the foregoing is true and correct. Executed on October 11,

2022.

Signature:

James L. Gaines, Esq.

EXHIBIT 1 to the Gaines Declaration

FILED UNDER SEAL

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

TEXAS MEDICAL ASSOCIATION, et al.,)
Plaintiffs,)) Case No.: 6:22-cv-00372-JDK
v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,) Lead Consolidated Case)
Defendants.)))

[PROPOSED] ORDER GRANTING LIFENET'S MOTION FOR SUMMARY JUDGMENT

For the reasons stated in the Memorandum accompanying LifeNet's motion for summary judgment, and the reasons stated in TMA's Memorandum, LifeNet's Motion for Summary Judgment is GRANTED.

The Court has already vacated the portions of the New QPA Presumption that were challenged in TMA's motion for summary judgment. Those provisions are set forth in the Final Rule, 87 Fed. Reg. 52,618 (Aug. 26, 2022), where they are identified by their forthcoming C.F.R. codifications as follows:

- (1) The word "then" in 45 C.F.R. § 149.510(c)(4)(iii)(B); the entirety of 45 C.F.R. § 149.510(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 45 C.F.R. § 149.510(c)(4)(vi)(B).
- (2) The word "then" in 26 C.F.R. § 54.9816-8(c)(4)(iii)(B); the entirety of 26 C.F.R. § 54.9816-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 26 C.F.R. § 54.9816-8(c)(4)(vi)(B).

(3) The word "then" in 29 C.F.R. § 2590-716-8(c)(4)(iii)(B); the entirety of 29 C.F.R. § 2590-716-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 29 C.F.R. § 2590-716-8(c)(4)(vi)(B).

In addition, and for the same reasons, the Court also vacates the portion of the New QPA Presumption that appears in the regulations governing the air-ambulance IDR process specifically. The following provisions in the Final Rule, 87 Fed. Reg. 52,618 (Aug. 26, 2022), identified by their forthcoming codifications in the C.F.R., are hereby VACATED:

- (1) The entirety of 45 C.F.R. § 149.520(b)(3);
- (2) The entirety of 26 C.F.R. § 54.9817-2(b)(3); and
- (3) The entirety of 29 C.F.R. § 2590-717-2(b)(3).

All of the foregoing vacated provisions, cited above, are DECLARED to have been promulgated by Defendants in violation of the Administrative Procedures Act (APA) because they are "arbitrary, capricious, [and] an abuse of discretion" and are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

The Defendants are ENJOINED from enforcing the foregoing vacated provisions, cited above.

This matter is REMANDED to Defendants with the following specific instructions: In any future rulemaking giving guidance to arbitrators on how to make IDR determinations, the Departments may not (i) instruct arbitrators to place any greater weight on the QPA than on the other statutory factors, (ii) condition arbitrators' consideration or weighing of the other factors upon any additional findings relating to the QPA, or (iii) impose on arbitrators any administrative burdens that are conditioned upon arbitrators' relying on factors other than the QPA or selecting the offer farther from the QPA.