

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

LIFENET, INC.

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

U.S. DEPARTMENT OF LABOR,

U.S. DEPARTMENT OF THE TREASURY,

OFFICE OF PERSONNEL MANAGEMENT,

and the

CURRENT HEADS OF THOSE
AGENCIES IN THEIR OFFICIAL
CAPACITIES,

Defendants.

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

**PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT
AND MEMORANDUM IN SUPPORT THEREOF**

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Plaintiff respectfully moves for summary judgment on Counts I and II of Plaintiff's Complaint, which are essentially the same as Counts I and II of the complaint filed by the plaintiffs in *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, No. 6:21-CV-425-JDK, 2022 WL 542879, at *1 (E.D. Tex. Feb. 23, 2022) ("*TMA*").

INTRODUCTION

This case is about a single sentence in the implementing regulations of the No Surprises Act. This Court's *TMA* decision already vacated *an identical sentence*:

45 C.F.R. § 149.510(c)(4)(iii)(C) (bold language, <u>vacated</u> by the <i>TMA</i> Decision, applies to <i>non-air ambulance</i> IDRs)	45 C.F.R. § 149.520(b)(2) (bold language is <u>still being applied by the Defendants</u> to require the QPA Presumption in <i>air-ambulance</i> IDRs)
Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.	Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

This single sentence should be vacated (again) for the reasons given in *TMA*: *first*, the QPA Presumption conflicts with the unambiguous provisions of the text of the No Surprises Act; *second*, the Defendants failed to provide the required notice-and-comment.

In addition, this sentence should also be vacated for another reason: enforcing the QPA Presumption against *solely* air ambulance providers would arbitrarily and irrationally discriminate against them, with no basis in the statutory text for that differential treatment.

Plaintiff LifeNet has standing to bring this challenge. LifeNet, like the individual doctor plaintiff in *TMA* (Dr. Adam Corley), does not itself submit claims to the IDR process. Instead, LifeNet is compensated by non-party Air Methods Corporation—just as Dr. Corley received an hourly salary from non-party Precision Emergency Physicians, PLLC. LifeNet, like Dr. Corley, nevertheless has standing because LifeNet is a regulated party, i.e., is the “object of” the relevant regulations. The QPA Presumption effects both a procedural injury-in-fact and an economic injury-in-fact on LifeNet, just as it did on Dr. Corley. Furthermore, a lower-than-appropriate IDR determination is itself an immediate intangible harm to LifeNet because it assigns a low dollar value to LifeNet’s services in a critically important market.

STATEMENT OF THE ISSUES

The first two issues presented are identical to those presented in the *TMA* plaintiffs’ motion for summary judgment:

1. Did the Departments act contrary to law and/or exceed their statutory authority when, without any basis in the statutory text, they [enacted the QPA Presumption] . . . ?

2. Did the Departments have good cause for issuing the [QPA Presumption] without providing notice and comment as required by the APA . . . ?

TMA, Plaintiffs’ Mot. Summary Judgment, ECF 25, at 3.

The other issues presented are:

3. Are the Departments acting arbitrarily and capriciously by continuing to apply the QPA Presumption solely in air ambulance IDRs, without any statutory or rational basis for discriminating in this way against air ambulance providers?

4. Does Plaintiff have standing?

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. The No Surprises Act

The No Surprises Act (“NSA”) was enacted on December 27, 2020, as part of the Consolidated Appropriations Act of 2021 to address “surprise medical bills.” *TMA*, 2022 WL 542879, at *1 (citing Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758–2890 (2020)).

The NSA made parallel amendments to provisions of the Public Health Service (“PHS”) Act, which is enforced by the Department of Health and Human Services (“HHS”); the Employee Retirement Income Security Act (“ERISA”), which is enforced by the Department of Labor; and the Internal Revenue Code (“IRC”), which is enforced by the Department of the Treasury. These Departments, along with the Office of Personnel Management (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the implementing regulations challenged here, and are referred to collectively as “the Departments.”

The relevant statutory and regulatory provisions at issue generally appear in triplicate. The NSA’s IDR provisions are codified at 42 U.S.C. §§ 300gg-111(c) & 300gg-112(b) (PHS Act), 29 U.S.C. §§ 1185e(c) & 1185f(b) (ERISA), and 26 U.S.C. §§ 9816(c) & 9817(b) (IRC). For ease of reference, this brief—like *TMA*—cites the PHS Act provisions and implementing regulations.

II. There Is *No* Relevant Difference Between the Statutory Provision Regarding *Non-Air Ambulance* IDRs (Section 300gg-111) and the Statutory Provision Regarding *Air Ambulance* IDRs (Section 300gg-112)

This Court in *TMA* considered Section 300gg-111 of the NSA, which sets forth the procedures to be followed in *non-air-ambulance* IDRs. *TMA*, 2022 WL 542879, at *1-*3 (describing the relevant provisions of 42 U.S.C. § 300gg-111). This Section also defines the statutory term “qualifying payment amount” (QPA) and provides instructions for calculating the QPA. “The QPA is generally ‘the median of the contracted rates recognized by the plan or issuer ... under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item

or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item[s] or service is furnished,’ with annual increases based on the consumer price index.” *TMA*, 2022 WL 542879, at *2 (quoting 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I)-(II)).

The very next provision of the statute—Section 300gg-112—sets forth the procedures to be followed in *air ambulance* IDRs. *See* 42 U.S.C. § 300gg-112(b)(1)(A) (“In general—With respect to air ambulance services furnished . . . by a nonparticipating provider”). Section 300gg-112 was not cited in the *TMA* decision, likely because no air ambulance provider was a plaintiff in *TMA*.

There is *no* relevant difference between Section 300gg-112 and Section 300gg-111 for purposes of the QPA Presumption challenged by the *TMA* plaintiffs and by Plaintiff LifeNet here. Section 300gg-112, like Section 300gg-111, provides that an air ambulance IDR is a “baseball-style” arbitration in which the IDR entity chooses between the two competing offers submitted by the provider and by the health plan or insurer. The relevant statutory text is exactly the same. *See* 42 U.S.C. § 300gg-112(b)(5)(A)(i) (“the certified IDR entity shall--(i) taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such services”).

Section 300gg-112 adopts by reference the definition of the QPA, and the calculation method for the QPA, that are set forth in Section 300gg-111(a)(3). *See* 42 U.S.C. § 300gg-112(b)(5)(C)(i) (using QPA “as defined in section 300gg-111(a)(3)”).

Most important, the relevant statutory text—regarding what weight to give to the QPA—is identical in both sections. *Compare* 42 U.S.C. § 300gg-112(b)(5)(C)(i) (“In determining which offer” to select, the “the certified IDR entity . . . shall consider . . . the qualifying payment

amounts . . . and . . . information on any circumstance described in clause (ii)); *with id.* § 300gg-111(c)(5)(C)(i) (identical); *see TMA*, 2022 WL 542879, at *7 (this text is “unambiguous”).

Section 300gg-112(b)(5)(C) sets forth the “additional circumstances” that the IDR entity “shall consider” when deciding which of the two offers to select in an air ambulance IDR. There are a small number of differences between the “additional circumstances” applicable to air ambulance IDRs and the “additional circumstances” applicable to all other IDRs. However, the crucial statutory language mandating that the IDR entity “shall consider” these additional circumstances is identical for both types of IDRs. *Compare* 42 U.S.C. § 300gg-111(c)(5)(C)(i), *with id.* § 300gg-112(b)(5)(C)(i).

The complete list of statutory “considerations,” including the “additional circumstances,” are as follows:

“Considerations in determination” for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5)(C).	“Considerations in determination” for <i>air ambulance</i> IDRs. 42 U.S.C. § 300gg-112(b)(5)(C).
“[T]he qualifying payment amounts [QPAs] . . . for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region . . . as such qualified IDR item or service.”	<i>Substantially the same.</i>
“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.”	<i>Substantially the same.</i>
Any information the IDR entity requests from the parties.	<i>Same.</i>

“Considerations in determination” for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5)(C).	“Considerations in determination” for <i>air ambulance</i> IDRs. 42 U.S.C. § 300gg-112(b)(5)(C).
Any additional information submitted by a party relating to an offer.	<i>Same.</i>
“The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.”	<i>Substantially the same.</i>
“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).”

III. There Is *No* Relevant Difference Between the Implementing Regulation Regarding *Non-Air Ambulance* IDRs (45 C.F.R. § 149.510) and the Implementing Regulation Regarding *Air Ambulance* IDRs (45 C.F.R. § 149.520)

The full certified administrative record, relevant to this matter, is already before the Court on the *TMA* docket: No. 6:21-CV-425-JDK, at ECF 66.

The NSA directed the Departments, not later than December 27, 2021, to promulgate rules implementing the IDR process. Congress gave *identical directives* in both Section 300gg-111 and Section 300gg-112. *See* 42 U.S.C. § 300gg-111(c)(2)(A); *id.* § 300gg-112(b)(2)(A) (same language, adding only “air ambulance” in a few places).

On September 30, 2021, the Departments publicly released IFR Part II, which contains regulations implementing the IDR process. *Requirements Related to Surprise Billing; Part II*, 86

Fed. Reg. 55,980 (Oct. 7, 2021) (“IFR Part II”). IFR Part II was published in the Federal Register on October 7, 2021, and became effective on that date. *Id.* at 55,980.

As relevant here, IFR Part II requires IDR entities—in *both* kinds of IDRs—to apply the QPA Presumption, that is, a “rebuttable presumption that the QPA is the appropriate payment amount.” *Id.* at 56,060. In other words, the IDR entity—in *both* kinds of IDRs—is to “begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate.” *Id.* at 55,999. The QPA is to be the “presumptive factor.” *Id.* at 55,996-97. IFR Part II did not distinguish between air ambulance IDRs and other IDRs in any way that is relevant to the QPA Presumption.

The principal provisions of IFR Part II, relating to the IDR Process, are codified in 45 C.F.R. § 149.510.¹ Section 149.510 applies, in full, to any IDR that is *not* an air ambulance IDR.

The very next section—Section 149.520—applies to air ambulance IDRs. This section is much shorter. It simply incorporates, by reference, nearly all of Section 149.510. *See* 45 C.F.R. § 149.520(b)(1).²

Section 149.520(b)(2) directs the IDR entity to consider the different “additional circumstances” that the statute (Section 300gg-112) provides for air ambulance IDRs. Aside from that one difference, air ambulance IDRs are to follow the same procedures that are set forth in Section 149.510, and that apply to all other IDRs. *See* 45 C.F.R. § 149.520(b)(1).

¹ The Departments also codified these regulations under titles 26 and 29 of the Code of Federal Regulations, which concern ERISA and the Internal Revenue Service. These other codifications are the same, in all material respects, as the codifications in the PHS Act regulations that are found in 45 C.F.R. Part 149. For ease of reference, this brief—like *TMA*—cites the PHS Act regulations.

² 45 C.F.R. § 149.520(b)(1) states: “Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.”

The Departments’ QPA Presumption is codified in five parts of 45 C.F.R § 149.510 and in one sentence of 45 C.F.R. § 149.520, as shown in the chart below. The five parts of Section 149.510 (shown in the first five rows) were expressly vacated by *TMA*. The one sentence from Section 149.520 (shown in the sixth and final row of the chart) was not expressly vacated by *TMA*, but is word-for-word identical to a provision in Section 149.510 that was vacated (these identical provisions are indicated by highlighting):

Regulatory Text (bold language contains the QPA Presumption)	Citation
<p>“(viii) Material difference means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.”</p>	<p>45 C.F.R. § 149.510(a)(2)(viii)</p>
<p>ii) Payment determination and notification. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:</p> <p>(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions.</p>	<p>45 C.F.R. § 149.510(c)(4)(ii)(A)</p>

Regulatory Text (bold language contains the QPA Presumption)	Citation
<p>(iii) Considerations in determination. In determining which offer to select, the certified IDR entity must consider:</p> <p>...</p> <p>(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.</p>	<p>45 C.F.R. § 149.510(c)(4)(iii)(C)</p>
<p>(iv) Examples. The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples: ... [four examples illustrating the QPA Presumption].</p>	<p>45 C.F.R. § 149.510(c)(4)(iv)</p>
<p>(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.</p>	<p>45 C.F.R. § 149.510(c)(4)(vi)(B)</p>
<p>(b) Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process—</p> <p>....</p> <p>(2) Additional information. Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.</p>	<p>45 C.F.R. § 149.520(b)(2)</p>

IV. The Departments Continue to Require the QPA Presumption in Air Ambulance IDRs

On April 12, 2022, the Departments issued “guidance” to IDR entities that requires the IDR Entities to continue applying the QPA Presumption in air ambulance IDRs, as follows:

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

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

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

Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities, at 22 (Apr. 12, 2022), *available at* <https://www.cms.gov/sites/default/files/2022-04/Revised-IDR-Process-Guidance-Certified-IDREs.pdf>. This Guidance is attached as Exhibit 1 hereto, and the just-quoted language appears on page 22.

The Guidance states that the QPA Presumption should *not* be applied in non-air-ambulance IDRs. Specifically, Section 6.3 of the Guidance—a section entitled “Payment Determinations Involving Non-Air Ambulance Qualified IDR Items and Services”—states that IDR entities must consider *all* credible information submitted relating to the relevant “additional circumstances.” Ex. 1, at 19-20. This Section does *not* contain the limitation, quoted above in Section 6.4.1, that additional information should only be considered “to the extent that the information **clearly demonstrates** that the QPA is **materially different** from the appropriate” rate. *See id.*

The Guidance does not provide any explanation for this difference between air ambulance IDRs and all other IDRs.

V. Undisputed Material Facts Relevant to Plaintiff's Standing

The first Gaines Declaration, re-attached hereto as Exhibit 2, establishes that LifeNet is regulated by the NSA and its implementing regulations. Specifically, LifeNet is a “nonparticipating provider” (i.e., out-of-network provider) of air ambulance services for emergency patients with commercial health plans or commercial health insurance. *See* Ex. 2 (Gaines Decl.), ¶ 3. Indeed, LifeNet has *already provided* air ambulance transports, in 2022, that may soon be subjected to the IDR process. *Id.* ¶ 4. The QPA Presumption will result in lower dollar valuations for LifeNet’s services in these IDRs than would have been awarded without the presumption. *Id.* ¶ 9. The QPA Presumption will “drive out-of-network reimbursement rates” for LifeNet’s services “to the QPA as a benchmark.” *Id.* ¶ 10. This systematic reduction of out-of-network reimbursement rates, to the QPA amount, is the *intended effect* of the QPA Presumption—as Defendants acknowledged in *TMA*. *See* Defendants’ Cross-Motion for Summary Judgment, *TMA*, No. 6:21-CV-425-JDK, ECF 62, at 10–11, 22, 32, 37 (filed Jan. 10, 2022).

In response to Plaintiff’s motion seeking expedited briefing, Defendants asserted that they intend to challenge Plaintiff’s standing based on the fact that Plaintiff is directly compensated for its emergency air transports by non-party Air Methods Corporation (“Air Methods”), pursuant to a contract between those two companies. This contract sets an agreed amount of compensation for LifeNet’s emergency air transport services, which amount is to be paid to LifeNet by Air Methods. According to the contract, Air Methods is responsible for collecting reimbursement from other payors (e.g., patients, health plans, health insurers) for LifeNet’s services. But Air Methods owes the agreed amount to LifeNet, for a given transport, even if Air Methods is unsuccessful at collecting reimbursement for that transport from other payors. The contract entered into force in October 2021. Ex. 2 (Gaines Decl.), ¶ 5. It is of “limited duration.” *Id.*

The second Gaines declaration, attached hereto as Exhibit 3, provides more information about this contract. Although the contract entered into force in October 2021, it was *executed* more than a month earlier, on August 24, 2021—well before IFR Part II, containing the QPA Presumption, was published. Ex. 3 (Second Gaines Decl.), ¶ 2. The contract can be terminated early, by Air Methods, in the event of a “decline in revenue.” *Id.* ¶ 3. Specifically, the contract states that if Air Methods’ reimbursement from other payors “drops to a financially unviable situation that is beyond the reasonable expectations” of the parties on August 24, 2021, when they signed the contract, then Air Methods “may terminate all or part of” the contract. *Id.*

The QPA Presumption—and the decline in reimbursement rates that it will cause—was not within “the reasonable expectations” of LifeNet and Air Methods on August 24, 2021, since at that point in time the Defendants had not yet published their contrary-to-statute QPA Presumption. *See id.* ¶ 4. There is a “significant risk” that the decline in revenue, caused by the QPA Presumption, will create a “financially unviable situation.” *Id.* There is a “significant risk” that LifeNet’s contractual rights to compensation, from Air Methods, will be terminated or reduced because of the decline in revenues caused by the QPA Presumption. *Id.*

ARGUMENT

I. The QPA Presumption Conflicts with the Statutory Text of the NSA

The NSA “unambiguously establishes the framework for deciding payment disputes” between air ambulance providers and commercial payors. *TMA*, 2022 WL 542879, at *7. The QPA Presumption, as enacted in Section 149.520(b)(2), “conflicts with the statutory text.” *Id.*

Section 300gg-112, like Section 300gg-111, is “unambiguous.” *Id.* Section 300gg-112 provides that in an air ambulance IDR, the IDR entity “shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii).” 42 U.S.C. § 300gg-

112(b)(5)(C). This Court, in *TMA*, found identical language in Section 300gg-111 to be “unambiguous.” *TMA*, 2022 WL 542879, at *7 (quoting Section 300gg-111(c)(5)(C)(i)).

A few of the “additional circumstances” to be considered by the IDR entity in an air ambulance IDR differ from the “additional circumstances” to be considered in a *non*-air-ambulance IDR. However, the instruction to the IDR entity—that it “shall” consider these circumstances—is the same for all IDRs and identical in both statutory provisions.

“Because the word ‘shall’ usually connotes a requirement, the Act plainly requires arbitrators to consider all the specified information in determining which offer to select.” *TMA*, 2022 WL 542879, at *7 (quoting *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016)).

Nothing in the Act instructs arbitrators, in an air ambulance IDR, to “weigh any one factor or circumstance more heavily than the others.” *TMA*, 2022 WL 542879, at *8. That “lack of text” is “more telling” than the text itself. *Id.* (quoting *Gulf Fishermens Ass'n v. Nat'l Marine Fisheries Serv.*, 968 F.3d 454, 460 (5th Cir. 2020)). Congress knows how to create a rebuttable assumption when it wishes to do so. *See id.* (citing examples of other provisions of the U.S. Code that create rebuttable presumptions). Congress did not do so here.

“Because Congress spoke clearly on the issue relevant here, the Departments’ interpretation of the statute is owed no *Chevron* deference.” *Id.*

“Because the Rule rewrites clear statutory terms, it must be held unlawful and set aside on this basis alone.” *Id.* at *9 (cleaned up) (citing *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 328 (2014) and 5 U.S.C. § 706(2)(A)).

II. The QPA Presumption Should Be Set Aside Because the Departments Failed to Provide for Public Notice and Comment

The APA requires federal agencies to publish a “notice of proposed rule making” and to “give interested persons an opportunity to participate ... through submission of written data, views, or arguments.” 5 U.S.C. § 553(b), (c). The purpose of the “notice-and-comment” requirement is to “assure fairness and mature consideration of rules having a substantial impact on those regulated” and for the agency to “disclose its thinking on matters that will affect regulated parties.” *TMA*, 2022 WL 542879, at *10 (quoting *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011)). Unless an agency can show an exception to the APA’s notice-and-comment requirement, the regulation is “contrary to law” and must be “set aside.” *Id.* (quoting 5 U.S.C. § 706(2)(A)).

A. There Is No Exception to Notice-and-Comment for Regulations Concerning Air Ambulance IDRs

The APA allows a statute to modify or supersede the APA’s procedural requirements “to the extent [the statute] does so expressly.” 5 U.S.C. § 559. The NSA did not “expressly” provide for any exception to the APA’s notice-and-comment requirement. This Court already conducted this analysis with respect to Section 300gg-92, which authorizes the Departments to “promulgate any interim final rules as the Secretary determinates are appropriate.” *See TMA*, 2022 WL 542879, at *10. The *TMA* analysis also controls the outcome here. Section 300gg-92 applies to “this subchapter,” which includes both Section 300gg-111 and Section 300gg-112 and thus applies to all types of IDRs.

B. There Was No “Good Cause” For Not Providing Notice and Comment

In *TMA*, the Departments offered various reasons why they contended that “good cause” existed for not allowing notice-and-comment. *See TMA*, 2022 WL 542879, at *11-*12 (rejecting the Departments’ “good cause” contentions). Since the sole provision relevant here—the sixth

provision, contained in Section 149.520(b)(2)—was enacted together with the other five provisions in IFR Part II, the “good cause” analysis in *TMA* applies in full to this case.

The Departments cannot show that the failure to provide for notice-and-comment was “harmless.” *TMA*, 2022 WL 542879, at *13-*14. “If the Departments had provided notice and comment,” then Plaintiff LifeNet, and other air ambulance providers, and other emergency medical providers affected by the QPA Presumption, “could have submitted the specific reasons and authorities for why they believed the Rule [i.e., the QPA Presumption] is inconsistent with the Act, how the Rule would impact them as providers, and how the Rule could be drafted to track the statutory text more closely. On the record before the Court, the Departments cannot demonstrate that they considered and fully addressed these issues.” *TMA*, 2022 WL 542879, at *13.

III. The Departments’ Application of the QPA Presumption *Solely* In Air Ambulance IDRs, And *Not* In Other IDRs, Conflicts with the Statute and Is Arbitrary and Capricious

The two bases for vacating the final sentence of Section 149.520(b)(2), which were described above and applied in *TMA*, are each a complete and independent basis for granting this relief.

Solely as an alternative, however, this sentence should also be vacated for an additional reason, namely: the current differential treatment of air ambulance providers is arbitrary and capricious. 5 U.S.C. § 706(2)(A).

As the attached April 12 “guidance” indicates, the Departments are currently applying the QPA Presumption solely in air ambulance IDRs, and *not* in any other kinds of IDRs. *Supra*, at 10 (describing Exhibit 1). This “guidance” provides no explanation of why the Departments believe it is appropriate for air ambulance IDRs to be treated any differently from all other IDRs for purposes of the QPA Presumption. The “guidance” is mere *fiat*—it asserts, without any reasoned

basis, that the QPA Presumption must remain in effect in air ambulance IDRs. There is no statutory or rational basis for this discriminatory treatment.

The statute does not provide for any different use of the QPA, in air ambulance IDRs, from all other IDRs. On the contrary, the relevant statutory text regarding the use of the QPA is identical in both Section 300gg-111 and Section 300gg-112: the IDR entity “*shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii).*” 42 U.S.C. § 300gg-112(b)(5)(C) (emphasis added); *id.* § 300gg-111(c)(5)(C)(i). Because the statutory text is so clear—and is so clearly *the same*—the Departments should not receive any *Chevron* deference for their current decision to apply the QPA Presumption *solely* in air ambulance IDRs and not in any other IDRs.

The Departments’ formal rulemaking (IFR Part II) provides no explanation or justification for according the QPA any greater weight, in air ambulance IDRs, than in other IDRs. On the contrary, that rulemaking described the QPA Presumption as applying equally to all IDRs. *See generally* IFR Part II. Because the newly announced differential treatment, for air ambulance IDRs, is not enacted in any formal rulemaking, this differential treatment is not entitled to deference under the *Chevron* doctrine. *See Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 740–41 (1996) (explaining that *Chevron* deference is appropriately applied to “a full-dress regulation” but *not* to “agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice”).

The April 12 “guidance” (and the Departments’ forthcoming opposition brief to this Motion) are not entitled to deference under the *Auer* doctrine, since the differential treatment of air ambulance IDRs is contrary to the formal rulemaking of the Departments that was published in IFR Part II. That rulemaking treated all IDRs the same for purposes of the QPA. *Auer* deference

does not apply to an agency’s litigation position that is wholly at odds with the agency’s published regulation. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-156 (2012) (*Auer* deference, to an agency’s interpretation of “its own ambiguous regulation,” is “undoubtedly inappropriate” where the interpretation is plainly erroneous or inconsistent with the promulgated regulation or is “nothing more than a *post hoc* rationalization advanced by an agency seeking to defend past agency action against attack”) (cleaned up)).

The Department’s recent decision to treat air ambulance IDRs differently, for purposes of the QPA Presumption, is arbitrary and capricious for at least the following four reasons: (1) the differential treatment has no statutory basis, *see Judulang v. Holder*, 565 U.S. 42, 55 (2011); (2) there is no “rational connection” between a provider’s status (as an air ambulance provider or as some other kind of provider) and the applicability of the QPA Presumption, *see Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); (3) the differential treatment of air ambulance providers is illogical, *see Venetian Casino Resort, L.L.C. v. EEOC*, 530 F.3d 925, 934 (D.C. Cir. 2008); and (4) the Departments failed to provide any coherent explanation for why they are now treating air ambulance IDRs differently from all other IDRs, *see Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012).

IV. LifeNet Has Standing

A. Article III Standing

1. LifeNet Is An “Object Of” of the Challenged Regulations

Standing is generally “self-evident” where, as here, the challenge is brought by a regulated party. *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.”); *see also Markle Interests, LLC v. U.S. Fish & Wildlife Serv.*, 40 F. Supp. 3d 744, 756 (E.D. La. 2014). That is because when a party is an “object of” government action, there is “ordinarily little question that the [government]

action” concretely affects the party, causing an injury in fact that supports standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). So the law, in this Circuit as elsewhere, is that the “object of a government” rule “ordinarily has standing to challenge” that rule. *Duarte v. City of Lewisville*, 759 F.3d 514, 518 (5th Cir. 2014).

The First Gaines Declaration, re-attached hereto as Exhibit 2, establishes that Plaintiff LifeNet is a regulated party who is an “object of” the challenged regulations. LifeNet is a “nonparticipating provider” (i.e., out-of-network provider) of air ambulance services for which compensation is governed by the NSA and its implementing regulations. *See* Ex. 2 (First Gaines Decl.), ¶ 3. Indeed, LifeNet has *already provided* air ambulance transports, in 2022, that may soon be subjected to the IDR process. *Id.* ¶ 4. LifeNet’s services will be analyzed by the IDR entities, and LifeNet’s services will be valued by the IDR entities’ determinations, which will assign a dollar value to LifeNet’s services after considering all the other “additional circumstances” that pertain to LifeNet and to LifeNet’s specific services at issue. *See* 42 U.S.C. § 300gg-112(b)(5)(C) (IDR entity “shall consider” LifeNet’s personnel’s “training, experience, and quality” and LifeNet’s “quality and outcomes measurements”).

LifeNet remains a regulated party, with standing to challenge these regulations, even though LifeNet’s compensation is (for the moment at least) paid by non-party Air Methods pursuant to the contract between those two companies. *Supra*, at 10-11. Regardless of that contractual arrangement, LifeNet remains an “object of” the challenged rule because it is LifeNet’s services that are valued in the IDR proceeding. *See, 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).

Because LifeNet and LifeNet’s services are analyzed and valued in the IDR proceedings, LifeNet suffers three distinct kinds of “injury in fact” as a result of the challenged QPA Presumption, even though LifeNet’s compensation for these services is (for the moment) paid by Air Methods pursuant to the contract.

2. Procedural Injury to 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).

There is procedural injury here, just as there was in *TMA*. In the NSA, Congress carefully designed an IDR procedure—one in which an independent arbitrator would resolve reimbursement disputes based on all relevant factors—to protect the economic interests of air ambulance providers like LifeNet. The QPA Presumption strips away that protection by replacing Congress’s balanced scheme with the unlawful presumption that IDR entities must select the offer closest to the QPA. LifeNet has standing to vindicate this procedural right because LifeNet provides air ambulance transport services that are subject to the IDR Process, Ex. 2 (Gaines First Decl.), ¶ 3, and because “in many and perhaps all cases” the offer submitted to the IDR entity, for LifeNet’s services, will “be above the QPA.” *Id.* ¶ 7.

3. Economic Injury to LifeNet

LifeNet is in a similar economic position as Dr. Adam Corley, the individual plaintiff in *TMA*. Dr. Corley did not himself seek reimbursement from the health plans and insurers; nor did he personally participate in the IDR process. Instead, Dr. Corley was paid an hourly salary by non-party Precision Emergency Physicians, PLLC, which company was responsible for collecting reimbursement from the plans and insurers and, in the event of a dispute, was responsible for engaging in the IDR process. *TMA*, Corley Supp. Decl., Dkt. 98-4, ¶ 3. Dr. Corley nevertheless had standing because, as his declaration attested, the QPA Presumption will “result in lower reimbursement rates for my services ... and, correspondingly, will cause my hourly compensation ... to decrease.” *Id.* ¶ 8. The Court correctly held that this economic injury is “a quintessential injury upon which to base standing.” *TMA*, 2022 WL 542879, at *5 (citing Dr. Corley’s Supplemental Declaration, among others).

In similar fashion, LifeNet is directly reimbursed for its services by Air Methods. Nevertheless, the QPA Presumption “will drive out-of-network reimbursement rates to the QPA as a benchmark. That in turn will cause LifeNet’s compensation to decrease significantly.” Ex. 2 (Gaines Decl.), ¶ 11.

This economic injury may not occur right away. For the moment, at least, Air Methods is honoring its contractual obligation to pay LifeNet the agreed-upon amount for LifeNet’s services. But there is a “significant risk” that this contract will be terminated (and the payments to LifeNet reduced or ceased entirely) if QPA Presumption’s systematic reduction of IDR payments to the QPA benchmark makes the agreed-upon contractual amounts “financially unviable.” Ex. 3 (Second Gaines Decl.), ¶ 4. A “substantial risk that the harm will occur” in the future qualifies as an injury-in-fact for purposes of Article III. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (substantial risk of future enforcement conferred standing). A substantial risk of future

economic harm “immediately and directly affects the borrowing power, financial strength, and fiscal planning” of the party that must plan for that future economic harm. *Clinton v. City of New York*, 524 U.S. 417, 431 (1998). In *City of New York*, the Court held that New York City had standing to challenge the constitutionality of President Clinton’s line-item veto, of an item that had eliminated a potential “contingent liability” of the city. *Id.* at 423. The city had standing even though its potential future “liability” would only come due if the Department of Health & Human Services denied a “waiver request” that had been submitted to it. *See id.* at 422 (“Because HHS had not taken any action on the waiver requests, New York turned to Congress for relief.”); *id.* at 426 (“If HHS ultimately denies the State's waiver requests, New York law will automatically require [the city corporation] to make retroactive tax payments to the State.”); *see also Ass’n of Data Processing Serv. Organizations, Inc. v. Camp*, 397 U.S. 150, 152 (1970) (plaintiff had Article III standing to challenge ruling by Comptroller of the Currency, which exposed plaintiff to increased competition, because the increased competition “might entail some future loss of profits” to plaintiff).

4. Injury to LifeNet from Lower Dollar Valuations, by IDR Entities, for LifeNet’s Services

In addition to the procedural and economic injuries-in-fact already discussed, LifeNet also suffers an immediate injury-in-fact from IDR entities low dollar valuations of LifeNet’s services. *See* Gaines First Decl. ¶ 10. Low dollar valuations, by these federally certified arbitrators, cause immediate concrete harm regardless of the fact that LifeNet may be paid some different dollar amount, for the specific services in question, as a result of LifeNet’s contract with Air Methods.

To be sure, the harm from a low dollar valuation is intangible. But a harm does not need to be “tangible” to provide Article III standing. *Cranor v. 5 Star Nutrition, L.L.C.*, 998 F.3d 686, 689-90 (5th Cir. 2021). 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).

A low dollar valuation, determined in an IDR proceeding, is an immediate concrete harm to LifeNet despite being “intangible.” The NSA has drastically restricted the relevant market for LifeNet’s emergency air transport services. By their very nature, emergency transport services are unplanned, unscheduled, and payment for them cannot be negotiated with the patient in advance. The NSA forbids LifeNet from seeking compensation from the emergency patient after the transport has occurred, for any amount in excess of the patient’s “cost sharing.” *See* 42 U.S.C. § 300gg-135. Thus, the market for LifeNet’s emergency transport services is now limited, by the NSA, to reimbursement from the commercial health plans and insurers that cover LifeNet’s emergency patients. And the valuation that matters most, in that market, is the valuation determined by the IDR entities. Commercial health plans and insurers are sophisticated economic actors that will not agree to pay LifeNet any more than what they believe LifeNet can obtain through the IDR process. The imminent IDR determinations will (as a result of the QPA Presumption) assign lower-than-appropriate dollar values to LifeNet’s services. Those lower dollar valuations will be reported immediately to each counter-party (i.e., each payor). Therefore, the dollar value of LifeNet’s services, in this “critically important market,” will be directly and (and negatively) affected by the QPA Presumption. Ex. 2 (Gaines Decl.), ¶ 10.

These lower dollar valuations, resulting from imminent IDR determinations, are far more consequential than other intangible harms that have been held to be sufficiently “concrete”

purposes of Article III. *See Cranor*, 998 F.3d at 689 (a “single unwelcome text message” was a sufficiently “concrete” injury-in-fact); *Robins*, 867 F.3d at 1115 (website’s inaccurate reporting of plaintiff’s age, marital status, and similar information was a sufficiently “concrete” injury-in-fact).

Moreover, lower-than-appropriate 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).

B. LifeNet Has “Prudential” Standing

LifeNet has “prudential” or “statutory” standing because, as a “nonparticipating provider” of covered out-of-network services under the NSA, LifeNet is within the “zone of interests” of the NSA’s IDR provisions. *See, e.g., Match-E-Be-Nash-She-Wish Band of Pottawatomí Indians v. Patchak*, 567 U.S. 209, 224–25 (2012).

CONCLUSION

For the foregoing reasons, Plaintiff LifeNet respectfully requests an order vacating the final sentence of 45 C.F.R. § 149.520(b)(2), the final sentence of 26 C.F.R. § 54.9817-2T(b)(2), and the final sentence of 29 C.F.R. § 2590.717-2(b)(2).

Dated: May 18, 2022

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CERTIFICATE OF SERVICE

I certify that I caused the foregoing document to be filed on the CM/ECF system on May 18, 2022, which will effect service on call counsel of record.

Steven M. Shepard
Steven M. Shepard

EXHIBIT 1

Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities

April 2022

Disclaimer Language

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

This document is up-to-date as of April 12, 2022; please visit www.cms.hhs.gov/nosurprises for the most current guidance documents related to the Federal IDR Process.

This communication was printed, published, or produced and disseminated at U.S. taxpayer expense.



IDR Guidance for Certified IDR Entities

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1. General Information and Background

1.1 Background

Effective January 1, 2022, the No Surprises Act (NSA)¹ prohibits surprise billing in certain circumstances in which surprise billing is common (see Section 1.2 for which items and services are covered). Surprise billing occurs when an individual receives an unexpected bill after obtaining items or services from an out-of-network (OON)² provider, facility, or provider of air ambulance services where the individual did not have the opportunity to select a provider, facility, or provider of air ambulance services covered by their health insurance network (in-network), such as during a medical emergency. In such cases, the individual's health plan often does not cover the full amount of the OON charges, and the OON provider, facility or provider of air ambulance services then bills the patient for the outstanding amount (also known as balance billing). Prior to the NSA, the patient would often be responsible for paying these balance bills.

The NSA provides Federal protection for patients against surprise bills. In situations covered by the NSA, patients will be required to pay no more than in-network cost-sharing amounts for these services. Health plans, issuers, and Federal Employees Health Benefits (FEHB) Program Carriers³ must pay the OON provider, facility, or provider of air ambulance services an amount in accordance with a state All-Payer Model Agreement or specified state law, if applicable. In the absence of an applicable All-Payer Model Agreement or specified state law, the plan must make an initial payment or a denial of payment⁴ within 30 calendar days. If either party believes that the payment amount is not appropriate (it is either too high or too low), it has 30 business days from the date of initial payment or denial of payment to notify the other party that it would like to negotiate. Once notified, the parties may enter into a 30-business-day open negotiation period to determine an alternate payment amount. If that open negotiation is unsuccessful, the NSA also provides for a Federal independent dispute resolution process (Federal IDR Process) whereby a certified independent dispute resolution entity (certified IDR entity) will review the specifics of the case and the items or services received and determine the final payment amount. The parties must exhaust the 30-business-day open negotiation period before requesting payment determination through the Federal IDR Process.

On October 7, 2021, the Departments of the Treasury, Labor, and Health and Human Services (collectively, the Departments) and the Office of Personnel Management (OPM) published interim final rules titled [*Requirements Related to Surprise Billing; Part II*](#),⁵ (October 2021 interim

¹ Enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260).

² A provider network is a collection of the doctors, other health care providers, hospitals, and facilities that a plan contracts with to provide medical care to its members. These providers are called "network providers" or "in-network providers." A provider or facility that hasn't contracted with the plan is called an "OON provider" or "OON facility." An OON provider or facility or provider of air ambulance services is also referred to as a nonparticipating provider or facility or provider of air ambulance services.

³ The FEHB Program contracts only with health benefits carriers that offer a complete line of medical services, such as doctor's office visits, hospitalization, emergency care, prescription drug coverage, and treatment of mental conditions and substance abuse. <https://www.opm.gov/healthcare-insurance/healthcare/carriers/>.

⁴ Note that a denial of payment is not the same as a denial of coverage as the result of an adverse benefit determination. An adverse benefit determination must be disputed through a plan's or issuer's claims and appeals process, not through the Federal IDR Process. See 86 FR at 36901-02.

⁵ Requirements Related to Surprise Billing; Part II, 86 FR 55980 (October 7, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf>.

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final rules) implementing various provisions of the NSA, including the Federal IDR Process for payment determinations. The October 2021 interim final rules are applicable for plan and policy years beginning on or after January 1, 2022, except for the provisions related to IDR entity certification, which are applicable as of October 7, 2021. These interim final rules build on the interim final rules issued on July 13, 2021, [*Requirements Related to Surprise Billing; Part I*](#)⁶ (July 2021 interim final rules), which were issued to restrict surprise billing for participants, beneficiaries, and enrollees of group health plans, group and individual health insurance issuers, and FEHB carriers who receive emergency care, non-emergency care from OON providers at in-network facilities, and air ambulance services from OON providers.

1.2 Applicability

The October 2021 interim final rules establish a Federal IDR Process that OON providers, facilities, and providers of air ambulance services and group health plans and health insurance issuers in the group and individual market, as well as FEHB Carriers, may use following the end of an unsuccessful open negotiation period to determine the OON rate for certain services. More specifically, in situations where an All-Payer Model Agreement or specified state law does not apply, the Federal IDR Process may be used to determine the OON rate for “qualified IDR items or services,” which include:

- Emergency services;
- Certain nonemergency items and services furnished by OON providers at in-network health care facilities; and
- Air ambulance services furnished by OON providers of air ambulance services.

The October 2021 interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans), and FEHB Carriers offering a health benefits plan under 5 U.S.C. § 8902, with respect to plan years (in the individual market, policy years) and contract years beginning on or after January 1, 2022. In this document, unless otherwise specified, the generic terms “plan” or “health plan” are used to refer to all such plans, issuers, and FEHB Carriers.

The interim final rules do not apply to items and services furnished by the provider, facility or provider of air ambulance services for services payable by Medicare, Medicaid, the Children’s Health Insurance Program, or TRICARE, as each of these programs already has other protections in place against unanticipated medical bills.

The Federal IDR Process also does not apply in cases where a state law or All-Payer Model Agreement establishes a method for determining the final OON payment amount. Specifically, some state laws provide a method for determining the total amount payable by a plan for an item or service furnished by an OON provider or facility or provider of air ambulance services to a participant, beneficiary, or enrollee, in circumstances covered by the NSA. The NSA refers to such laws as “specified state laws.” The NSA also recognizes that All-Payer Model Agreements under Section 1115A of the Social Security Act may provide state-approved amounts for OON items and services as well. Where an All-Payer Model Agreement or specified state law provides a method for determining the total amount payable for OON items and services, the state process will govern, rather than the Federal IDR Process for determining the OON rate

⁶ Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36872 (July 13, 2021), <https://www.federalregister.gov/documents/2021/07/13/2021-14379/requirements-related-to-surprise-billing-part-i>.

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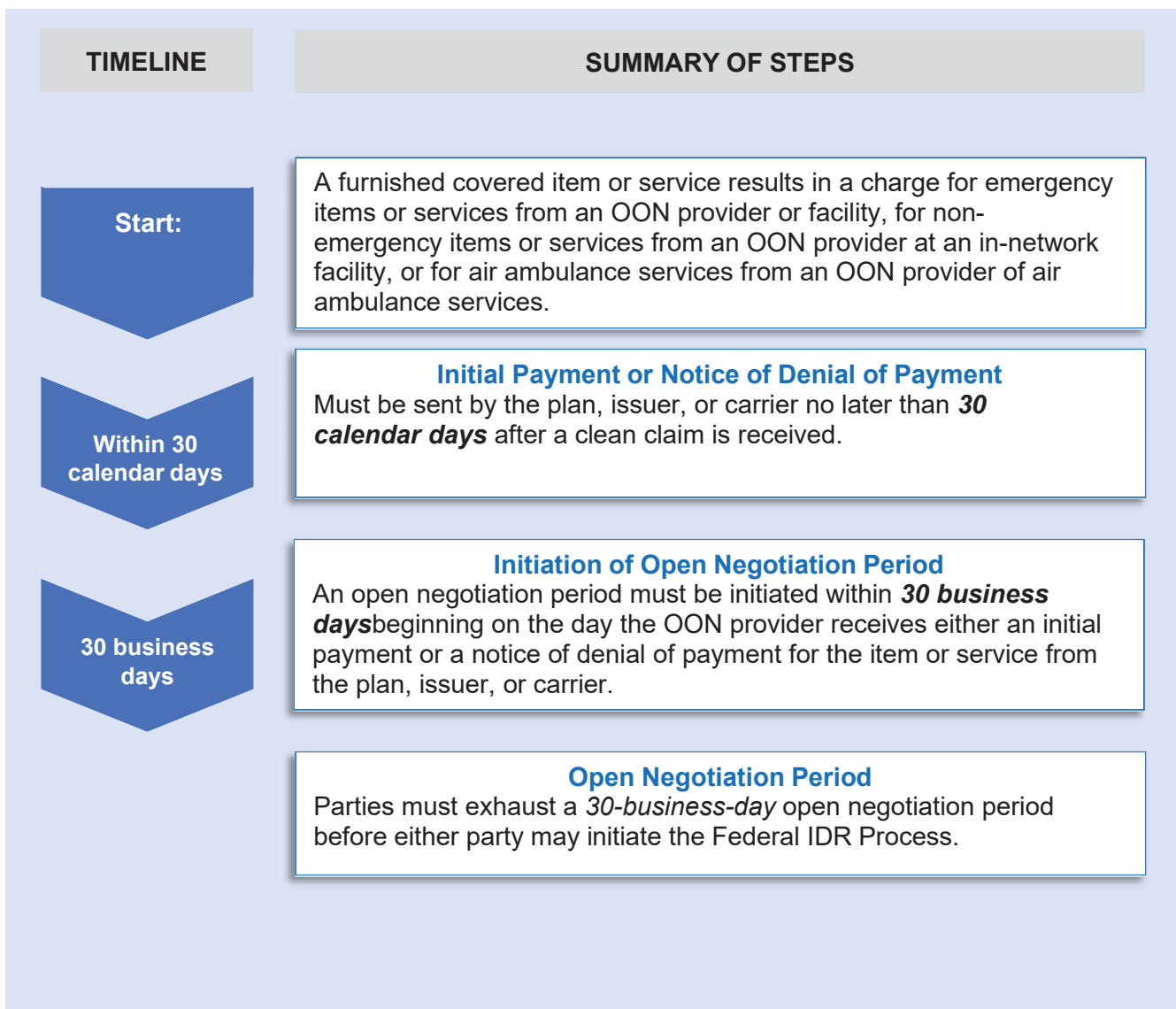
under the NSA.

To learn more about what items and services fall under the Federal IDR Process for each state see the CAA Enforcement Letters that are posted here: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/CAA>.

1.3 Purpose

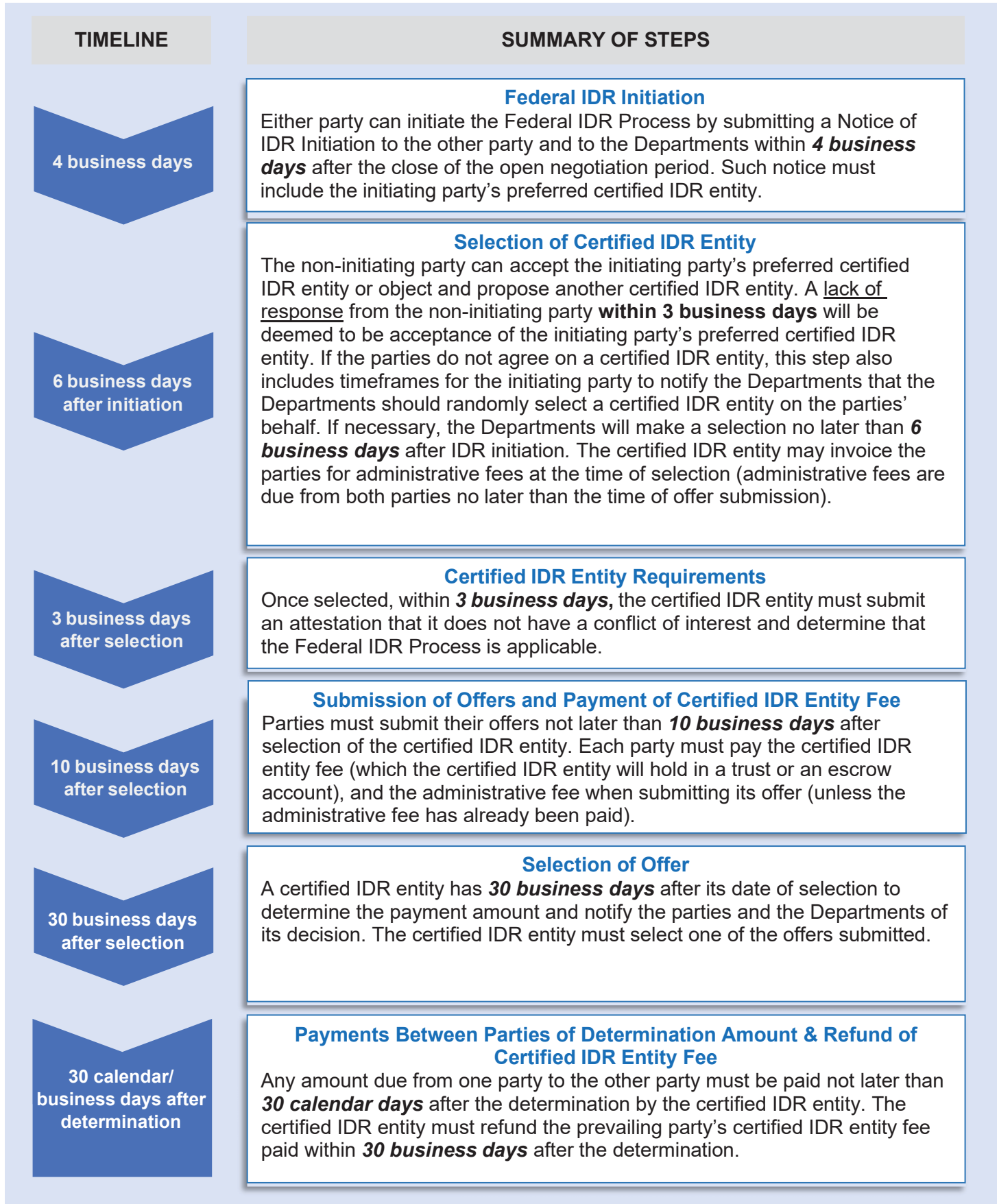
The purpose of this document is to provide guidance to certified IDR entities on various aspects of the Federal IDR Process. This document includes information on how the parties to a payment dispute may initiate the Federal IDR Process and describes the requirements of the Federal IDR Process, including the requirements that certified IDR entities must follow in making a payment determination. This document also includes information related to other aspects of the Federal IDR Process that certified IDR entities must follow, including guidance on confidentiality standards, record-keeping requirements, and the process for revocation of IDR certification, as well as how parties may request an extension of certain time periods for extenuating circumstances. For a detailed overview of the Federal IDR Process, see the visual below, "Federal IDR Process Overview." Additional guidance may be developed in the future to address specific questions or scenarios submitted by certified IDR entities. See Appendix A for the definitions of defined terms used in this document.

Steps Preceding the Federal IDR Process



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Federal IDR Process Overview



2. Open Negotiations

The parties must undertake an open negotiation period prior to initiating the Federal IDR Process to determine the OON rate if the items or services are:

- Emergency services furnished by an OON provider or facility subject to the NSA, air ambulance services furnished by an OON provider of air ambulance services, or non-emergency services furnished by an OON provider at an in-network facility; and
- Furnished to a covered participant, beneficiary, or enrollee who did not receive notice or did not provide adequate consent to waive the balance billing protections with regard to such items and services, pursuant to regulations at 45 CFR 149.410(b) or 149.420(c)-(i), as applicable; and
- Items or services for which the OON rate is not determined by reference to an All-Payer Model Agreement under Section 1115A of the Social Security Act or a specified state law.

2.1 Initiation of Open Negotiations

Either party may initiate the open negotiation process **within 30 business days** (Monday through Friday, not including Federal holidays), beginning on the day the OON provider, facility, or provider of air ambulance services receives either an initial payment or a notice of denial of payment for the item or service from the plan.

The plan must include with its initial payment or denial of payment certain information, including the appropriate person or office to contact if the provider, facility, or provider of air ambulance services wishes to initiate open negotiations; a statement that, if the open negotiation period does not result in an agreement on the OON rate, either party to the open negotiation may initiate the Federal IDR Process; and the applicable qualifying payment amount (QPA) for each item or service involved (see the definition of QPA in Section 6.2.1).

The party initiating the open negotiation must provide **written notice** to the other party of its intent to negotiate, referred to as an **open negotiation notice**, and must include information sufficient to identify the items or services subject to negotiation, including:

- The date(s) the item(s) or service(s) was/were furnished;
- Corresponding service code(s) for the item(s) or service(s);
- The initial payment amount or notice of denial of payment, as applicable;
- Any offer for the OON rate; and
- Contact information of the party sending the open negotiation notice.

To facilitate communication between parties and compliance with this notice requirement, the Departments issued [a standard notice](#) that the parties must use to satisfy the open negotiation notice requirement.⁷

The **open negotiation notice** may be sent electronically (such as by email) if:

⁷ See “Open Negotiation Period Notice” at: <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/no-surprises-act>.

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- The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and
- Upon request, the notice is provided in paper form and free of charge.

2.2 Commencement of Open Negotiations

The **30-business-day open negotiation** period begins on the day on which the open negotiation notice is first sent by a party.

The requirement for a 30-business-day open negotiation period prior to initiating the Federal IDR Process does not preclude the parties from reaching an agreement in fewer than 30 business days or from continuing to negotiate after 30 business days. However, in the event the parties do not reach an agreement, the parties must still exhaust the 30-business-day open negotiation period before either party may initiate the Federal IDR Process. Parties may continue to negotiate after the open negotiation period has concluded, but if they do, it does not change the timeline for the Federal IDR Process. For example, the Federal IDR Process would still need to be initiated during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period, even if the parties continue to negotiate.

If the open negotiation notice is not properly provided to the non-initiating party (and no reasonable measures have been taken to ensure that actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such a case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement, and the certified IDR entity would retain the certified IDR entity fee of the initiating party. Therefore, the Departments encourage parties submitting open negotiation notices to take steps to confirm that the other party's contact information is correct and confirm receipt by the other party, through approaches such as read receipts, especially where a party does not initially respond to an open negotiation notice. If either party has a concern that the open negotiation process did not occur or that the party was not notified of the open negotiation period, the party will be able to request an extension due to extenuating circumstances from the Departments by emailing the Federal IDR mailbox at FederalIDRQuestions@cms.hhs.gov. While a request for an extension due to extenuating circumstances is under review by the Departments, the Federal IDR Process and all of its timelines continue to apply, so the parties should continue to meet deadlines to the extent possible, as described in Section 8.

As part of open negotiations, the non-initiating party may request that the initiating party provide additional information identifying the claim in dispute (such as a claim reference number and location of service).

If either party believes that the other party is not in compliance with the balance billing protections it may file a complaint with the No Surprises Help Desk at 1-800-985-3059.

3. Initiating the Federal IDR Process

3.1 Timeframe

If the parties do not reach an agreement on the OON rate by the end of the 30-business-day open negotiation period, either party can initiate the Federal IDR Process by submitting a **Notice of IDR Initiation**⁸ to the other party and to the Departments **within 4 business days after the close of the open negotiation period** (in other words, 4 business days beginning on the 31st business day after the start of the open negotiation period). The initiating party must furnish the Notice of IDR Initiation to the Departments by submitting the notice through the Federal IDR portal at <https://www.nsa-idr.cms.gov>.⁹ A party may not initiate the Federal IDR Process if, with respect to an item or service, the party knows or reasonably should have known that the provider or facility provided notice and obtained consent from a participant, beneficiary, or enrollee to waive surprise billing protections.¹⁰ The notice must be furnished to the Departments on the same day it is furnished to the non-initiating party.

The initiation date of the Federal IDR Process is the date that the Departments receive the **Notice of IDR Initiation**. The Federal IDR portal will display the date on which the Notice of IDR Initiation has been received by the Departments.

3.2 Delivery of the Notice of IDR Initiation

The **Notice of IDR Initiation form** to be sent by the initiating party to the non-initiating party may be filled out and saved through the Federal IDR portal at <https://www.nsa-idr.cms.gov> and may be sent electronically to the non-initiating party (such as by email) if:

- The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and
- The notice is provided in paper form free of charge upon request.

The **Notice of IDR Initiation** sent to the Departments must be submitted through the Federal IDR portal.

3.3 Notice Content

The **Notice of IDR Initiation** must include:

- Initiating party type (i.e., provider, facility, provider of air ambulance services, issuer,

⁸ Notice of IDR Initiation. <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-3.pdf>.

⁹ The Departments established the Federal IDR portal to administer the Federal IDR Process. The Departments' Federal IDR portal will be available at <https://www.nsa-idr.cms.gov> and will be used throughout the Federal IDR Process to maximize efficiency and reduce burden. The Federal IDR portal may be used to satisfy various functions including provision of notices, Federal IDR initiation, submission of an application to be a certified IDR entity, as well as satisfying reporting requirements.

¹⁰ This is consistent with PHS Act sections 2799B-1(a) and 2799B-2(a), and the implementing regulations at 45 CFR 149.410(b) and 149.420(c)-(i). These sections and regulations state that an OON provider or facility satisfies the notice and consent criteria with respect to items or services furnished by the provider or facility to a participant, beneficiary, or enrollee if the provider or facility fulfills the listed requirements. The OON provider or facility must provide to the participant, beneficiary, or enrollee a written notice in paper or, as practicable, electronic form, as selected by the individual. The written notice will be deemed to contain the information required, provided such written notice is in accordance with guidance issued by HHS, and in the form and manner specified in such guidance.

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plan, or FEHB Carrier);

- Information sufficient to identify the qualified IDR items or services under dispute, including:
 - A description of qualified item(s) or service(s);
 - Whether item(s) and/or service(s) are batched;
 - The date(s) the item(s) was/were provided or the date of the service(s);
 - The location where the item(s) or service(s) was/were furnished (including the state or territory);
 - Any corresponding service and place-of-service codes;
 - The type of qualified IDR item(s) or service(s) (e.g., emergency, post-stabilization; professional);
 - The amount of cost sharing allowed; and
 - The amount of initial payment by the plan, where payment was made on the claim(s), if applicable;
- The QPA for each of the item(s) or service(s) involved;
- The following information from the plan about the QPA(s) that was provided to the provider, facility, or provider of air ambulance services with the initial payment or notice of denial of payment:
 - The statement that the QPA applies for purposes of the recognized amount for the item(s) or service(s) in question (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing);
 - Any related service codes used to determine the QPA for new services;
 - Where requested by the provider, facility, or provider of air ambulance services, any information given by the plan about:
 - Whether the QPA was calculated using non-fee-for-service rates and/or underlying fee schedules;
 - Any databases used by the plan to determine the QPA; and
 - Any statements noting that the plan's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments;
- The names and contact information of the parties involved, including:
 - Email addresses;
 - Phone numbers; and
 - Mailing addresses;
- The start date of the open negotiation period;
- The initiating party's preferred certified IDR entity;
- An attestation that the item(s) or service(s) under dispute is/are qualified IDR item(s) or service(s) within the scope of the Federal IDR Process; and
- General information describing the Federal IDR Process as specified by the Departments.
 - This general information will help ensure that the non-initiating party is informed about the process and is familiar with the next steps. Such general information should include a description of the scope of the Federal IDR Process and key deadlines in the Federal IDR Process, including the dates to initiate the Federal

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IDR Process, how to select a certified IDR entity, and the process for selecting an offer.

4. Federal IDR Process Following Initiation: Selection of the Certified IDR Entity

4.1 Timeframe

The disputing parties in the Federal IDR Process may jointly select the certified IDR entity. The parties must select the certified IDR entity no later than **3 business days** following the date of the IDR initiation. The Departments will provide a list of certified IDR entities on the Federal IDR portal.

In the **Notice of IDR Initiation**, the initiating party will identify its preferred certified IDR entity. The other party, once in receipt of the **Notice of IDR Initiation**, may agree or object to the selection of the preferred certified IDR entity. Any objection must be raised within the **3-business-day period** for the selection of the certified IDR entity. Otherwise, absent any conflicts of interest, the initiating party's preferred certified IDR entity will be selected.

4.2 Objection to the Initiating Party's Selection of the Certified IDR Entity

If the party in receipt of the **Notice of IDR Initiation** objects to the initiating party's preferred certified IDR entity, that party must notify the initiating party of the objection. The notice provided to the initiating party must propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity within the same initial **3-business-day period** for the selection of the certified IDR entity.

4.3 Notice of Agreement or Failure to Agree on Selection of Certified IDR Entity

The initiating party must notify the Departments by submitting **the Notice of Certified IDR Entity Selection (or failure to select)** through the Federal IDR portal that both parties agree on a certified IDR entity, or, in the alternative, that the parties have not agreed on a certified IDR entity. A notice must be submitted by the initiating party not later than 1 business day after the end of the 3-business-day period for certified IDR entity selection (or in other words, 4 business days after the date of initiation of the Federal IDR Process) through the Federal IDR portal.

The **Notice of the Certified IDR Entity Selection** must include:

- The name of the certified IDR entity;
- The certified IDR entity number (unique number assigned to the entity through the Federal IDR portal); and
- An attestation by both parties (or by the initiating party if the other party has not responded) that the selected certified IDR entity does not have a conflict of interest with the parties (or party, as applicable), as described in Section 4.6.1. This attestation must be submitted based on a conflicts-of-interest check using information available (or accessible using reasonable means) to the parties (or the initiating party if the other party has not responded) at the time of the selection.

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The **notice of failure to select a certified IDR entity** must include:

- Indication that the parties have failed to select a certified IDR entity;
- Information regarding the lack of applicability of the Federal IDR Process (if applicable); and
- Signature of a representative of the initiating party, full name, and date.

4.4 Instances When the Non-Initiating Party Believes That the Federal IDR Process Does Not Apply

If the non-initiating party believes that the Federal IDR Process is not applicable, the non-initiating party must notify the Departments by submitting the relevant information through the Federal IDR portal as a part of the certified IDR entity selection process. This information must be provided not later than **1 business day** after the end of the 3-business-day period for certified IDR entity selection, (the same date that the notice of selection or failure to select a certified IDR entity must be submitted). This notification must include information regarding the Federal IDR Process' inapplicability. The Departments will supply this information to the selected certified IDR entity, who may ask for additional information pursuant to this notification.

The certified IDR entity must determine whether the Federal IDR Process is applicable. The certified IDR entity must review the information submitted in the **Notice of IDR Initiation** and the notification from the non-initiating party claiming the Federal IDR Process is inapplicable, if one has been submitted, to determine whether the Federal IDR Process applies. If the Federal IDR Process does not apply, the certified IDR entity must notify the Departments and the parties within 3 business days of making that determination, as described in Section 4.6.2. While the matter is under review by the certified IDR entity, the timelines of the Federal IDR Process continue to apply, so the parties should continue to meet deadlines to the extent possible, as described in Section 8. Further, the Departments will maintain oversight of the applicability of the Federal IDR Process through their audit authority.

4.5 Failure to Select a Certified IDR Entity: Random Selection by the Departments

When the parties cannot agree on the selection of a certified IDR entity, the Departments will randomly select a certified IDR entity **no later than 6 business days** after the date of initiation of the Federal IDR Process and will notify the parties of the selection.¹¹ The certified IDR entity selected by the Departments will be one that charges a fee within the allowed range (as provided for in the [Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act](#) or later guidance). If there is an insufficient number of certified IDR entities available that charge a fee within the allowed range, the Departments will randomly select a certified IDR entity that has approval to charge a fee outside of that range.

4.6 Certified IDR Entity Responsibilities After Selection

¹¹ A situation in which the non-initiating party does not object to the preferred certified IDR entity included in the initiating party's Notice of IDR Initiation, and the initiating party submits its preferred certified IDR entity on the Notice of Certified IDR Entity Selection, is not considered a failure to select a certified IDR entity.

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After a certified IDR entity is selected, either by the parties or by the Departments, it must attest to meeting the conflicts of interest requirements as described in Section 4.6.1. The certified IDR entity must also determine whether the Federal IDR Process applies as described in Section 4.6.2.

A certified IDR entity:

- 1) Must attest to being free of conflicts of interest, and
- 2) Must determine whether the Federal IDR Process applies to the dispute.

See Sections 4.6.1 and 4.6.2 for more details.

4.6.1 Conflicts of Interest

If the selected certified IDR entity cannot attest to meeting the conflicts of interest requirements, it may not participate in the dispute between the parties. In that case, the certified IDR entity must notify the Departments of its inability to attest via the Federal IDR portal. This notification to the Departments must occur within **3 business days** after the selection of the certified IDR entity. Upon receiving notice of the certified IDR entity's inability to attest (or in the event the certified IDR entity fails to attest to meeting the conflicts-of-interest requirements within the 3-business-day period), the Departments will notify the parties that their selected certified IDR entity will not be able to participate in their dispute. Once the parties are notified, they will have **3 business days** to select another certified IDR entity, or, when the parties have indicated that they cannot agree on a certified IDR entity, the Departments will randomly select another certified IDR entity, pursuant to Section 4.5.

A certified IDR entity **must not have any conflicts of interest** with respect to either party to a payment determination. Specifically, neither the selected certified IDR entity nor a party to the payment determination can have a material relationship, status, or condition that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. Among other things, the **certified IDR entity must not**:

- Have, or have personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed. This extends to material relationships with any plan, officer, director, management employee, administrator, fiduciaries, or employees; the health care provider or the health care provider's group or practice association; the provider of air ambulance services or the provider of air ambulance services' group or practice association; or the facility that is a party to the dispute.

In addition, *the certified IDR entity must also ensure that any personnel decisions, such as hiring, compensation, or promotion, are not based on personnel supporting one party or a particular type of party.* Finally, personnel of the certified IDR entity must not have been party to the payment determination being disputed, or an employee or agent of such a party within the one-year period immediately preceding an assignment to a payment determination, similar to

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the requirements described in 18 U.S.C. §§ 207(b), (c), and (e).¹²

4.6.2 Determining Whether the Federal IDR Process Applies to the Dispute

In addition to checking for and submitting an attestation regarding conflicts of interest, the **certified IDR entity must determine whether the Federal IDR Process applies** by reviewing whether any specified state laws or All-Payer Model Agreements are applicable to the dispute in question. The Federal IDR Process will apply to self-insured plans sponsored by private employers, private employee organizations, or both, except in cases where a self-insured plan has opted into a state process that constitutes a specified state law or into an All-Payer Model Agreement under Section 1115A of the Social Security Act, in a state that permits an opt-in. Similarly, the Federal IDR Process will apply to health benefits plans offered under 5 U.S.C. § 8902, except in cases where an OPM contract with an FEHB Carrier includes terms that adopt the state process. If the certified IDR entity concludes that the Federal IDR Process does not apply (including to any particular claim under dispute in the case of batched claims), it must notify both the Departments and the parties within **3 business days** of making this determination.

4.7 Treatment of Batched Items and Services

The NSA allows for multiple qualified claims to be considered as part of a single IDR determination (batching). Batching the same or similar qualified IDR items and services decreases the number of IDR proceedings, avoids unnecessary complications from single disputes from plans and providers, and streamlines certified IDR entity decision-making.

A certified IDR entity may consider multiple qualified IDR items and services jointly as a part of one IDR payment determination when:

- The qualified IDR items or services are billed by the same provider, group of providers, facility, or provider of air ambulance services, under the same National Provider Identifier (NPI) or Taxpayer Identification Number (TIN);
- The payment for the items and services is made by the same plan;
- The qualified IDR items and services are the same or similar items or services, meaning they are items and services that are billed under the same service code, or a comparable code under a different procedural code system. The Departments have defined the service codes as the code that describes a qualified IDR item or service using Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG); and
- All the qualified IDR items and services were furnished within the same 30-business-day period (or had a 30-business-day open negotiation period that ended during the same 90-calendar-day cooling off period), as described in Section 7.1.

4.8 Payment of Administrative Fees

¹² 18 U.S.C. § 207 imposes restrictions on former officers, employees, and elected officials of the executive and legislative branches of the government. Specifically, Section 207(b) provides a one-year restriction on aiding and advising, Section 207(c) provides a one-year restriction on certain senior personnel of the executive branch and independent agencies, and Section 207(e) provides restrictions on Members of Congress and officers and employees of the legislative branch.

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If the certified IDR entity attests to no conflicts of interest and concludes that the Federal IDR Process applies, the **certified IDR entity must collect the administrative fee** from both parties and remit the fee to the Departments. Parties are required to pay the administrative fee when the certified IDR entity is selected. As an operational matter, administrative fees may be invoiced by the certified IDR entity at the time of selection and must be collected by the time of offer submission (see Section 5.4). So long as administrative fees are collected by the time the offers are submitted (which is also when the certified IDR entity fees must be paid), the certified IDR entity has discretion on when to collect the administrative fee.

See Section 10 for additional information on the administrative fee.

5. Payment Determination: Submission of Offers

5.1 Content Offers

No later than 10 business days after the selection of the certified IDR entity, each party must submit **to the certified IDR entity**:

- An offer for the OON rate expressed both as a dollar amount and as a percentage of the QPA (see Section 6.2.1) represented by that dollar amount;
- For batched qualified IDR items or services, where batched items or services have different QPAs, parties should provide these different QPAs and may provide different offers for these items and services, provided that the same offer should apply for all items and services with the same QPA;
- Information requested by the certified IDR entity relating to the offer; and
- Additional information, as applicable:
 - Providers and facilities must specify whether the provider practice or organization has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;
 - Providers and facilities must also provide information on their practice specialty or type, respectively;
 - Plans must provide the coverage area of the plan, the relevant geographic region for purposes of the QPA, and, for group health plans, whether they are fully-insured, or partially or fully self-insured;
 - Plans must provide the QPA for the applicable year for the same or similar item or service as the qualified IDR item or service; and
 - Parties may submit any additional information relating to the offer that does not include information on prohibited factors described in Section 6.5 and must do so no later than 10 business days after the selection of the certified IDR entity.

5.2 Submission of Offers to the Certified IDR Entity

Final offers of payment and information related to the offer must be submitted through the Federal IDR portal at <https://www.nsa-idr.cms.gov> or directly to the selected certified IDR entity. After selection, the certified IDR entity must provide instructions to both parties for how to submit offers and any other requested information, as outlined in sections 6.3.2 and 6.4.2 and Tables 1 and 2.

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5.3 Consequences of Failure to Submit an Offer

If, by the deadline for the parties to submit offers, one party has not submitted an offer, the certified IDR entity will select the other party's offer as the final payment amount.

5.4 Payment of Certified IDR Entity Fees and Administrative Fees and Consequences of a Failure to Pay the Fees

Each party **must pay the certified IDR entity fee** to the certified IDR entity with the submission of its offer and **must pay the administrative fee** by the time it submits its offer. **Therefore, an offer will not be considered received by the certified IDR entity until the certified IDR entity fee and the administrative fee have been paid. As described in 5.3, if an offer is not considered received from one party, the certified IDR entity will select the other party's offer as the final payment amount. See Section 10 for additional information on the certified IDR entity fee and the administrative fee.**

6. Payment Determination: Selection of Offer

6.1 Timeframe

Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the disputing parties to be the OON rate for the qualified IDR item or service.

Selection of Offer – Baseball Style Arbitration:

The certified IDR entity must select one of the offers submitted by the disputing parties. The certified IDR entity's determination is legally binding unless there is fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim.

6.2 Factors and Information Certified IDR Entities Must Consider

In determining which offer to select, the certified IDR entity must consider:

- ✓ **The QPA(s)** for the applicable year for the qualified IDR item or service; and
- ✓ **Additional credible information relating to the offers submitted by the parties that relates to the circumstances** as described in sections 6.3.2 and 6.4.2, which does not include information on the prohibited factors described in Section 6.5 This information includes additional information requested by the certified IDR entity from the parties, and all of the credible information that the parties submit that is consistent with the requirements for non-air ambulance qualified IDR items and services in 26 CFR 54.9816-8T(c)(4)(iii)(C), 29 CFR 2590.716-8(c)(4)(iii)(C), or 45 CFR 149.510(c)(4)(iii)(C) (See Table

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1); and the requirements for air ambulance qualified items and service in 54.9817-2T(b)(2), 29 CFR 2590.717-2(b)(2) and 45 CFR 149.520(b)(2) (See Table 2).

It is **not** the role of the certified IDR entity to determine whether the QPA has been calculated correctly by the plan, make determinations of medical necessity, or to review denials of coverage. **NOTE:** If the certified IDR entity or a party believes that the QPA has not been calculated correctly, the certified IDR entity or party is encouraged to notify the Departments through the Federal IDR portal, and the Departments may take action regarding the QPA's calculation.

For batched or bundled items and services, the certified IDR entity may select different offers, from either or both parties, when the QPAs for the qualified IDR items or services within the batch or bundle are different. For example, if a dispute batched multiple claims for Service A furnished by Provider B to individuals covered by Issuer C, with some individuals covered by plans in the individual market and others covered by plans in the large group market, there likely would be two different QPAs for the certified IDR entity to consider – one QPA for the services furnished to individuals enrolled in individual market coverage, and one QPA for individuals with large group market coverage. In these instances, the parties must provide the relevant information for each QPA, and the certified IDR entity must consider each QPA for each qualified IDR item or service separately. Note that items and services paid for by different self-insured group health plans are not allowed to be batched.

6.2.1 Definition of QPA

Generally, the QPA is the **median of the contracted rates** recognized by the plan for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in the same geographic region in which the item or service under dispute was furnished, increased by inflation. The plan calculates the QPA using a methodology established in the July 2021 interim final rules.¹³

6.2.2 Standards for Determining Credible Information

Information is considered **credible** if, upon critical analysis, the information is worthy of belief and is trustworthy.

Certified IDR Entities Must Consider:

1. QPA(s) for the applicable year for the qualified IDR item or service; and
 2. **Other information submitted by a party** as long as it does not contain prohibited factors and is credible.
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6.3 Payment Determinations Involving Non-Air Ambulance Qualified IDR Items and Services

¹³ 86 FR 36872 (July 13, 2021).

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For **non-air ambulance qualified items and services**, after determining that the Federal IDR Process applies, the certified IDR entity is responsible for determining the appropriate OON rate.

In determining which offer to select, the certified IDR entity must consider:

1. The QPA(s) for the applicable year for the qualified IDR item or services; and
2. Additional credible information relating to the offer submitted by the parties, including information that was requested by the certified IDR entity, information submitted by the parties that does not include the prohibited information described in Section 6.5, and information submitted by the parties that relates to the circumstances described in Section 6.3.2 (see Table 1).

6.3.1 Consideration of Information Requested by the Certified IDR Entity or Provided by Either Party Related to Either Offer for Non-Air Ambulance Qualified IDR Items and Services

The certified IDR entity must consider credible information submitted by the parties. Three general rules govern the consideration of additional information:

- **First**, the certified IDR entity must consider only information that it considers credible.
- **Second**, the certified IDR entity must consider only information that relates to an offer of either party.
- **Third**, the certified IDR entity must not consider information on prohibited factors, described further in Section 6.5.

6.3.2 Additional Information Submitted by a Party that Relates to Certain Circumstances

For non-air ambulance qualified IDR items and services, parties may submit additional information regarding any of the five circumstances discussed in **Table 1** and any information that relates to the offer of either party or that is requested by the certified IDR entity (that is not otherwise prohibited). The certified IDR entity must consider credible information submitted to determine the appropriate OON rate (unless the information relates to a factor that the certified IDR entity is prohibited from considering as described in Section 6.5).

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Table 1: Non-Air Ambulance Items and Services – Additional Circumstances

Circumstance/Factor
<p>1. The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service.</p> <ul style="list-style-type: none"> • Credible information should demonstrate the experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient, or that their experience or training made an impact on the care that was provided.
<p>2. The market share held by the provider or facility or that of the plan in the geographic region in which the qualified IDR item or service was provided.</p> <ul style="list-style-type: none"> • Credible information should demonstrate how the market share affects the appropriate OON rate.
<p>3. The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.</p> <ul style="list-style-type: none"> • Credible information should demonstrate how patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee affects the appropriate OON rate for the qualified IDR item or service.
<p>4. The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable:</p> <ul style="list-style-type: none"> • Credible information should demonstrate that the teaching status, case mix, or scope of services of the OON facility in some way affects the appropriate OON rate.
<p>5. Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan during the previous 4 plan years. For example, a certified IDR entity should consider what the contracted rate might have been had the good faith negotiations resulted in the OON provider or facility being in-network, if a party is able to provide related credible information of good faith efforts or the lack thereof.</p>

6.4 Payment Determinations Involving Air Ambulance Qualified IDR Services

For **air ambulance qualified IDR services**, after determining that the Federal IDR Process applies, the certified IDR entity is responsible for considering whether the information presented by the parties is credible, and, if credible (and not related to prohibited factors, as described in Section 6.5), whether the information submitted demonstrates that the QPA is materially different from the appropriate OON rate based on that information.

In determining which offer to select, the certified IDR entity must consider:

1. The QPA(s) for the applicable year for the qualified IDR services; and
2. Additional credible information relating to the offer submitted by the parties, including information that was requested by the certified IDR entity, information submitted by the parties that does not include the prohibited information described in Section 6.5, and

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information submitted by the parties that relates to the circumstances specified in Section 6.4.2.

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

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

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

6.4.2. Additional Circumstances Submitted by a Party for Air Ambulance Services

For air ambulance services, parties may submit additional information regarding any of the six circumstances discussed in **Table 2** and any information that relates to the offer of either party or that is requested by the certified IDR entity (that is not otherwise prohibited). The certified IDR entity should consider credible information submitted by the parties that clearly demonstrates that the QPA is materially different from the appropriate OON rate.

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Table 2: Air Ambulance Services – Additional Circumstances

Circumstance/Factor
<p>1. The quality and outcomes measurements of the provider of air ambulance services that furnished the services.</p> <ul style="list-style-type: none"> • Credible information about the quality and outcomes measurements of the provider of air ambulance services that furnished the services should clearly demonstrate that the QPA is materially different from the appropriate OON rate.
<p>2. The acuity of the condition of the participant, beneficiary, or enrollee receiving the services, or the complexity of providing services to the participant, beneficiary, or enrollee.</p> <ul style="list-style-type: none"> • Credible information about the acuity of the condition of the participant, beneficiary, or enrollee receiving the services, or the complexity of providing the services to the participant, beneficiary, or enrollee, should clearly demonstrate that the QPA is materially different from the appropriate OON rate.
<p>3. The level of training, experience, and quality of medical personnel that furnished the air ambulance services.</p> <ul style="list-style-type: none"> • Credible information about the level of training, experience, and quality of medical personnel that furnished the air ambulance services should clearly demonstrate the QPA is materially different from the appropriate OON rate.
<p>4. The air ambulance vehicle type, including the clinical capability level of such vehicle.</p> <ul style="list-style-type: none"> • Certified IDR entities should consider whether credible information about the ambulance vehicle type, including the clinical capability level of the vehicle, clearly demonstrates that the QPA is materially different from the appropriate OON rate. • Certified IDR entities should consider whether the air ambulance is fixed wing or rotary wing only to the extent that the information is not already taken into account by the QPA. • Certified IDR entities should consider credible information on the air ambulance vehicle type and the vehicle's level of clinical capability only to the extent not already taken into account by the QPA.
<p>5. The population density of the point of pick-up for the air ambulance of the participant, beneficiary, or enrollee (such as urban, suburban, rural, or frontier).</p> <ul style="list-style-type: none"> • The QPA for the geographic regions used to calculate the QPA may already reflect the population density of the pick-up location. Nevertheless, in certain circumstances, the QPA for air ambulance services may not adequately capture the population density, due to additional distinctions, such as between metropolitan areas within a state, or between rural and frontier areas. • Credible information about additional circumstances should clearly demonstrate that the QPA is materially different from the appropriate OON rate for a particular air ambulance service.
<p>6. Demonstrations of good faith efforts (or lack of thereof) made by the OON provider of air ambulance services or the plan to enter into network agreements, as well as contracted rates between the provider and the plan during the previous 4 plan years.</p> <ul style="list-style-type: none"> • Credible information about demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan to enter into network agreements, as well as contracted rates between the provider and the plan, as applicable, during the previous 4 plan years, should clearly demonstrate that the QPA is materially different from the appropriate OON rate for such air ambulance services.

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6.5 Prohibited Factors

When making a payment determination, the certified IDR entity *must not* consider the following factors:

- Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);
- The amount that would have been billed by the provider, facility, or provider of air ambulance services with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410, 149.420, and 149.440 (as applicable) not applied; or
- The payment or reimbursement rate for items and services furnished by the provider, facility, or provider of air ambulance services payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under Section 1115 of the Social Security Act. This provision also prohibits consideration of payment or reimbursement rates expressed as a proportion of rates payable by public payors.

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7. Written Payment Determination

Certified IDR entities have **30 business days** from their date of selection to select one of the offers submitted and notify the plan, and the provider, facility, or provider of air ambulance services, as well as the Departments, of the certified IDR entity’s payment determination.

The certified IDR entity must notify the parties and the Departments and must explain its payment determination by submitting a written decision through the Federal IDR portal. Details on the form and manner for submitting the written decision will be provided in future guidance.

The written payment determination must contain the certified IDR entity’s determination of the payment amount and the underlying rationale for its determination.

Payment Determination:

Certified IDR entities must select a payment offer **within 30 business days** and notify the plan, and the provider, facility, or provider of air ambulance services, as well as the Departments.

The determination is legally binding unless there is fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim.

7.1 Effect of Determination

After a certified IDR entity makes a payment determination, the following requirements apply:

- **Payment:** The amount due to the prevailing party, which is the party whose offer is selected, must be paid not later than **30 calendar days** after the determination by the certified IDR entity, as follows:

<i>If payment is owed by a plan to the provider, facility, or provider of air ambulance services...</i>	<i>If the plan is owed a refund...</i>
The plan will be liable for additional payments when the amount of the offer selected exceeds the sum of any initial payment the plan has paid to the provider, facility, or provider of air ambulance services and any cost sharing paid or owed by the participant, beneficiary, or enrollee.	The provider, facility, or provider of air ambulance services will be liable to the plan when the offer selected by the certified IDR entity is less than the sum of the plan’s initial payment and any cost sharing paid by the participant, beneficiary, or enrollee.

NOTE: This determination of the OON rate does not change the participant’s, beneficiary’s, or enrollee’s cost sharing, which is based on the recognized amount, or, in the case of air ambulance services, the lower of the QPA or billed charges.

Also note that the non-prevailing party is ultimately responsible for the certified IDR entity fee, which is retained by the certified IDR entity for the services it performed. The certified IDR entity fee that was paid by the prevailing party will be returned to the prevailing party by the certified IDR entity within 30 business days of the certified IDR

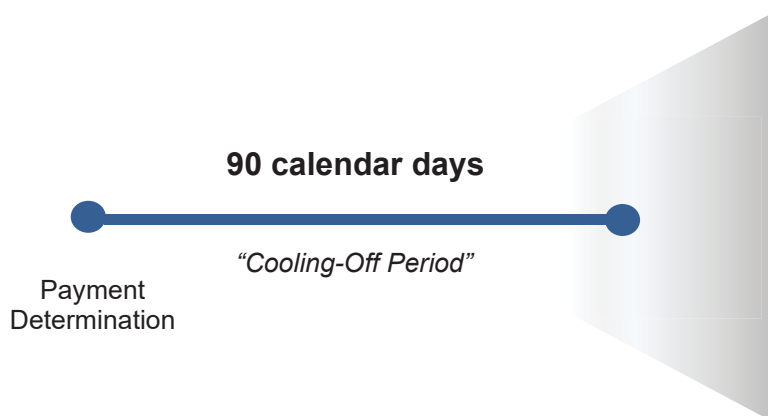
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entity's determination. In the event a resolution is reached outside of the Federal IDR Process, the certified IDR entity must refund each party half of the certified IDR entity fee unless the parties agree otherwise on a method for allocating the applicable fee.

The certified IDR entity must refund the prevailing party the IDR entity fee within 30-business days. In the event neither party is the prevailing party or a resolution is reached outside of the IDR Process, the IDR entity must refund each party half of the certified IDR entity fee unless the parties agree otherwise.

- **Binding Determination:** The certified IDR entity's determination is binding upon the disputing parties unless there is fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim.
- **Subsequent IDR Requests:** The party that initiated the Federal IDR Process may not submit a subsequent Notice of IDR Initiation involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial Notice of IDR Initiation during the 90-calendar-day suspension period following the determination, also referred to as a "cooling off" period.

"Cooling Off Period": The 90-calendar-day period following a payment determination when the initiating party cannot submit a subsequent Notice of IDR Initiation involving the same party with respect to a claim for the same or similar item or service that was the subject of the initial Notice of IDR Initiation.



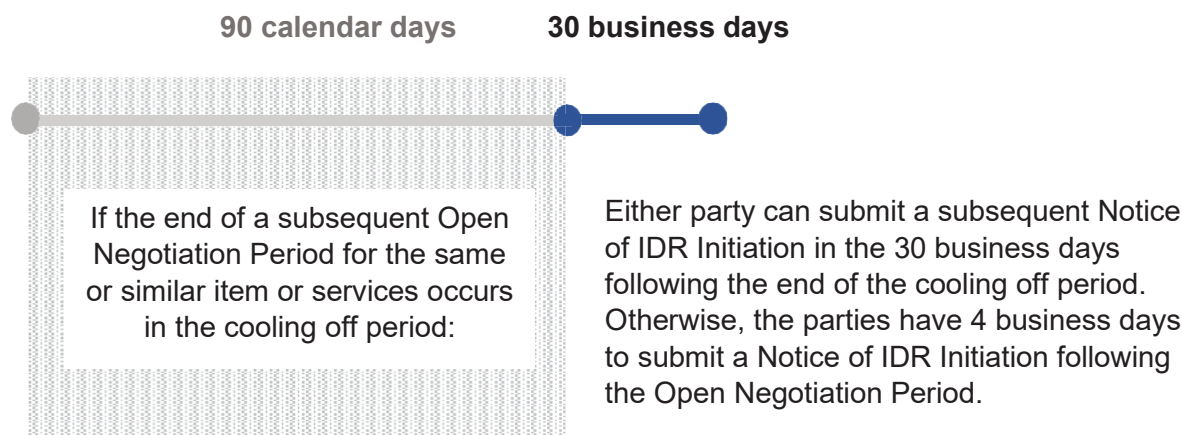
When does the "cooling off period" apply to subsequent IDR initiations? Must meet three criteria:

- ✓ Same parties;
- ✓ Same or similar items or services subject to initial Notice of IDR Initiation; and
- ✓ Payment determination made on the initial Notice of IDR Initiation.

NOTE: A subsequent submission is permitted for the same or similar items or services if the end of the open negotiation period occurs during the 90-calendar-day cooling off period. For these items or services, either party must submit the Notice of IDR Initiation within 30 business days following the end of the cooling off period, as opposed to the standard 4-business-day period following the end of the open negotiation period. The 30-business-day period begins on the day after the last day of the cooling off period.

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Subsequent Submissions if the End of the Open Negotiation Period Occurs During the “Cooling Off Period”



8. Extension of Time Periods for Extenuating Circumstances

Certain time periods in the Federal IDR Process may be extended in the case of extenuating circumstances at the Departments’ discretion.

- **Time periods for payments CANNOT be extended:** The timing of the payments to the provider, facility, provider of air ambulance services, or plan, as a result of a payment determination or settlement cannot be extended. All other time periods are eligible for an extension at the Departments’ discretion.
- **What qualifies as “extenuating circumstances” for an extension:** The Departments may extend time periods if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such an extension may be necessary if, for example, a natural disaster impedes efforts by the disputing parties to comply with time-period requirements.
- **How to request an extension:** For extensions on a case-by-case basis, parties may request an extension, and provide applicable attestations, by emailing a **Request for Extension Due to Extenuating Circumstances** to FederalIDRQuestions@cms.hhs.gov, including an explanation about the extenuating circumstances that require an extension and why the extension is needed. The requesting party is required to attest that prompt action will be taken to ensure that the determination delayed under the extension will be made as soon as administratively practicable.
- **When to request an extension:** A request for an extension must be filed as soon as administratively practicable following the event that has resulted in the need for the applicable extension. The request for an extension can be filed at any time, either before or after a deadline, and the Departments will consider the request and may grant the extension. However, requesting an extension does not pause or stop the Federal IDR Process, and all of its timelines continue to apply unless and until an extension is

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granted, so the parties should continue to meet deadlines to the extent possible.

- **Extensions for IDR Entities:** If a certified IDR entity is unable to satisfy certain timing requirements under the Federal IDR Process due to an extenuating circumstance, the certified IDR entity should submit such information to the Departments by emailing the Federal IDR mailbox at FederalIDRQuestions@cms.hhs.gov.
- The Departments may also provide for extensions in guidance, due to extenuating circumstances. Information on these extensions may be found at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/no-surprises-act> and <https://www.cms.gov/nosurprises>.

9. Recordkeeping and Reporting Requirements

6-year recordkeeping requirement: *Certified IDR entities must maintain records of all claims and notices associated with the Federal IDR Process with respect to any payment determination for 6 years.* These records must be available upon request by the parties to the dispute or a state or Federal agency with oversight authority over a disputing party, except when disclosure is not permitted under state or Federal privacy law.

Mandatory monthly reporting by certified IDR entities: *Certified IDR entities are required to submit data to the Departments on the Federal IDR Process as an ongoing condition of certification.* The Departments will use this information to publish certain aggregated information on a public website as required by the NSA.

Each certified IDR entity will be required to report the data in Table 3 within 30 business days of the close of each month through the Federal IDR portal.

The Departments expect that many of these reporting requirements will be captured through the Federal IDR portal, and the Departments do not intend for certified IDR entities to report duplicative information. The Departments will provide additional guidance to certified IDR entities on their specific reporting obligations.

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Table 3: Information to be Reported by Certified IDR Entities on a Monthly Basis

Category of Information	Reporting for Qualified IDR Items and Services That Are <u>Not</u> Air Ambulance Services:	Reporting for Air Ambulance Qualified IDR Services:
QPA versus OON Rate	For each determination issued during the immediately preceding month, the number of times the OON rate payment amount determined or agreed to was higher than the QPA, as specified by items or services.	Same.
Notices of IDR Initiation	<p>Number of Notices submitted to the certified IDR entity during the immediately preceding month.</p> <p>The number of these Notices with respect to which a final determination was made in the immediately preceding month.</p>	Same.
Offers	The amount of the offers submitted by each party expressed as both a dollar amount and as a percentage of the QPA, and whether the offer selected was submitted by the plan, issuer, or FEHB carrier, or provider or facility.	Whether the offer selected by the certified IDR entity to be the out-of-network rate was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services.
Size of the Provider Practices and/or Facilities; Vehicle Type	In instances where the provider or facility submits the initial Notice of IDR Initiation, specify whether each provider's practice subject to a dispute indicated fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For each facility subject to disputes, indicate whether the facility has 50 or fewer employees, 51 to 100 employees, 101-500 employees, or more than 500 employees.	Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent the parties have provided such information).

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Category of Information	Reporting for Qualified IDR Items and Services That Are <u>Not</u> Air Ambulance Services:	Reporting for Air Ambulance Qualified IDR Services:
Items or Services Subject to Determinations	A description of each of the items or services included in the notices of IDR initiation received, including the relevant billing codes (such as Current Procedural Terminology (CPT, Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG), or National Drug (NDC) Codes) furnished to the patient subject to dispute.	A description of each air ambulance service, including the relevant billing and service codes.
Relevant Geographic Region	For the immediately preceding month, the relevant geographic region for purposes of the QPA for the items and services with respect to the notices of IDR initiation received.	The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification.
Offers Submitted by Each Party	For each determination issued during the immediately preceding month, the amount of the offers submitted by each party expressed as both a dollar amount and as a percentage of the QPA, and whether the offer selected was submitted by the plan, issuer, or FEHB carrier, or provider or facility.	Same.
Rationale for Choosing the Selected Offer	For each determination issued during the immediately preceding month, the rationale for the certified IDR entity's selection of offer, including the extent to which a decision relied on criteria other than the QPA.	Same.
Additional Information on the Parties Involved	For each determination issued during the immediately preceding month, the practice specialty and type of each provider or facility, as well as identifying information for each plan, FEHB carrier, or issuer, or provider or facility, such as each party's name and address, as applicable.	Same.

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Category of Information	Reporting for Qualified IDR Items and Services That Are <u>Not</u> Air Ambulance Services:	Reporting for Air Ambulance Qualified IDR Services:
Number of Days Elapsed Between Selection of the Certified IDR Entity and the Selection of the Payment Amount by the Certified IDR Entity	For each determination issued during the immediately preceding month, the number of business days taken between the selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.	Same.
Number of times During the Month That the Payment Amount Determined Exceeded the QPA Specified by Items or Services	For each determination issued during the immediately preceding month, the number of times the payment amount determined or agreed to was higher than the QPA, as specified by items or services.	Same.
Administrative Fees Collected on Behalf of the Departments	Number of determinations for which the certified IDR entity collected administrative fees from parties during the immediately preceding month.	Same.
Certified IDR Entity Fees	Total amount of fees paid to the certified IDR entity during the immediately preceding month, not including amounts refunded by the certified IDR entity to the prevailing party (or both parties, such as in the case of settlements) or the administrative fees that are collected on behalf of the Departments.	Same.

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10. Federal IDR Process Fees**10.1 Administrative Fee**

- The administrative fee is based on an estimate of the cost to the Departments to carry out the Federal IDR Process;
- Each party is required to pay an administrative fee;
- Each party pays one administrative fee per single or per batched determination;
- Administrative fees may be invoiced by the certified IDR **entity at the time of selection and must be paid by the time of offer submission**, but the certified IDR entity has discretion on when to collect the administrative fee (as long as it is collected by the time the offers are submitted, which is when the certified IDR entity fees must be paid); and
- The administrative **fees will not be refunded** even if the parties reach an agreement before the certified IDR entity makes a determination.

10.2 Certified IDR Entity Fee

Each party must pay the entire certified IDR entity fee. **The certified IDR entity fee is due when the party submits its offer.**

- As a condition of certification, each certified IDR entity is **required** to indicate to the Departments the certified IDR entity fees it intends to charge;
- The fee must be within a pre-determined range specified by the Departments, unless otherwise approved by the Departments in writing. The Departments will review and update the allowable fee range annually, and a certified IDR entity may seek approval from the Departments to update its fees annually; and
- A **certified IDR entity must submit a written proposal** to charge a fee beyond the upper or lower limit of the pre-determined range. The Federal IDR portal will provide the functionality for certified IDR entities and entities applying to become certified IDR entities to request an alternative fixed fee. The written proposal must include:
 - The alternative fixed fee the IDR entity seeking certification or certified IDR entity believes is appropriate;
 - A description of the circumstances that require an alternative fixed fee; and
 - A description of how the alternative fixed fee will be used to mitigate the effects of these circumstances. Note that the certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity receives written approval from the Departments to charge a fixed rate beyond the upper or lower limits determined in the annual fee guidance.

The **certified IDR entity must hold the certified IDR entity fees in a trust or escrow account** until the certified IDR entity determines the OON rate, after which point the certified IDR entity must refund to the prevailing party the amount submitted for the certified IDR entity fee **within 30 business days**.

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The certified IDR entity **retains the non-prevailing party's certified IDR entity fee** as compensation for the certified IDR entity's services. If the parties negotiate an OON rate before a determination is made, the certified IDR entity will return half of each party's payment for the certified IDR entity fee within 30 business days, unless directed otherwise by both parties to distribute the total amount of the refund in different shares.

Collection of Certified IDR Entity Fees:

The certified IDR entity **fee** must be paid by both parties by the time of offer submission.

The certified IDR entity retains the non-prevailing party's certified IDR entity fee as compensation unless the parties settle on an OON rate before a determination.

If the parties settle, the certified IDR entity will return half of each party's fee payment, unless directed otherwise by the parties.

10.2.1 Batched Claims, Certified IDR Entity Fee, and Administrative Fee

The certified IDR entities may make different payment determinations for each qualified IDR item or service in a batched claim dispute. In such cases, the party with the fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties.

The certified IDR entity will collect a single administrative fee from each of the parties for batched claims.

10.2.2 Bundled Payments

Bundled payment arrangements are when a plan pays a provider one payment amount for multiple items and services. Bundled payment arrangements are subject to the rules for batched determinations allowing items and services to be considered jointly, but the certified IDR entity fee and administrative fee will be the same as for single determinations.

11. Confidentiality Requirements

While conducting the Federal IDR Process, a certified IDR entity will be entrusted with individually identifiable health information (IIHI). The certified IDR entity must comply with the confidentiality requirements applicable to certified IDR entities, including provisions regarding privacy, security, and breach notification under 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v), and the Independent Dispute Resolution Entity Certification Agreement (the "Agreement"). Failure to comply with these privacy and security measures may result in immediate revocation of an IDR entity's certification and may prevent the IDR entity from future certification and participation in the program, subject to the appeals process.

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11.1 Privacy

The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI to perform its required duties, when required to do so.

11.2 Security

Certified IDR entities are required to maintain the security of the IIHI they obtain by: ensuring the confidentiality of all IIHI they create, obtain, maintain, store, and transmit; protecting against any reasonably anticipated threats or hazards to the security of this information; protecting against any reasonably anticipated unauthorized uses or disclosures of this information; and ensuring compliance by any of their personnel who have access to IIHI, including their contractors and subcontractors (as applicable).

Certified IDR entities are required to have policies and procedures in place to properly use and disclose IIHI, identify when IIHI should be destroyed or disposed of, properly store and maintain confidentiality of IIHI that is accessed or stored electronically, and identify the steps the certified IDR entities will take in the event of a breach regarding IIHI.

Certified IDR entities must securely destroy or dispose of IIHI in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier. In determining what is appropriate and reasonable, certified IDR entities should assess potential risks to participant, beneficiary, or enrollee privacy, as well as consider such issues as the form, type, and amount of IIHI to be disposed of. In general, shredding, burning, pulping, or pulverizing paper records so that IIHI is rendered unreadable, indecipherable, and otherwise cannot be reconstructed; and, for IIHI contained on electronic media, clearing (using software or hardware products to overwrite media with non-sensitive data), purging (degaussing or exposing the media to a strong magnetic field in order to disrupt the recorded magnetic domains), or destroying the media (disintegration, pulverization, melting, incinerating, or shredding) may be reasonable methods of disposal.

When IIHI is stored by the certified IDR entity, it must periodically review, assess, and modify the security controls implemented to ensure the continued effectiveness of those controls and the protection of IIHI.

Certified IDR entities must develop and utilize secure electronic interfaces when transmitting IIHI electronically, including through data transmission through the Federal IDR portal, and between disputing parties and the certified IDR entity during the Federal IDR Process.

The certified IDR entity must implement and follow policies and procedures for guarding against, detecting, and reporting malicious software; monitoring log-in attempts and reporting discrepancies; creating, changing, and safeguarding passwords; and protecting IIHI from improper alteration or destruction. The certified IDR entity must also implement policies and procedures for the administrative, technical, and physical safeguards for electronic information systems that maintain IIHI to allow access only to those persons or software programs that have been granted access rights.

All confidentiality requirements applicable to certified IDR entities also apply to certified IDR

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entities' contractors and subcontractors performing any duties related to the Federal IDR Process with access to IIHI. For example, if a breach rises to the level of requiring notification (as described in Section 11.3), the contractor or subcontractor must notify the certified IDR entity, at the time they determine there is a potential breach, to inform it of the risk assessment results (as described in Section 11.3), and the certified IDR entity must notify the Departments, or OPM if an FEHB Carrier is involved.

The Departments reserve the right to audit certified IDR entity privacy and security protocols to ensure they are operating in compliance with regulatory and contractual requirements.

11.3 Breach Notification

Please refer to the Agreement for detailed instructions, definitions, and legal requirements regarding breaches.

Certified IDR entities must report any actual or suspected breach of unsecured IIHI to the CMS IT Service Desk by telephone (1-800-562-1963 or 410-786-2580) or email at cms_it_service_desk@cms.hhs.gov and must also contact the Information Security and Privacy Group by emailing ACASecurityandPrivacy@cms.hhs.gov within 24 hours of discovery of an actual or suspected breach. Incidents must be reported to the CMS IT Service Desk and the Information Security and Privacy Group by the same means as breaches within 72 hours of from discovery of the actual or suspected incident.¹⁴

Within five business days of discovery of an actual or suspected breach, the certified IDR entity must conduct a risk assessment to determine whether it is likely or unlikely that the IIHI was compromised based on the nature of the IIHI, the unauthorized person who received (or may have received) it, the acquisition or use of the IIHI, and any steps taken to mitigate the effects of the breach; it must also prepare and submit a written document describing all information relevant to the risk assessment, including a description of the breach, a description of the risk assessment conducted by the certified IDR entity, and the results of the risk assessment. The written risk assessment must be submitted to the Departments (and OPM, if applicable), through the Federal IDR portal; to the CMS IT Service Desk at cms_it_service_desk@cms.hhs.gov; and to the Information Security and Privacy Group at ACASecurityandPrivacy@cms.hhs.gov. If necessary, certified IDR entities may also make a verbal report of the results of its risk assessment to the CMS IT Service Desk by telephone (1-800-562-1963 or 410-786-2580).

If the risk assessment results in a determination that the risk that the IIHI was compromised is greater than 'low,' the certified IDR entity must provide notification of the breach without unreasonable delay, and in no case later than 60 calendar days after the discovery of the breach, to the Departments (and OPM, if applicable); the plan, as applicable; the provider, facility, or provider of air ambulance services, as applicable; and each individual whose

¹⁴ "Breach" of IIHI is defined in 26 CFR 54.9816-8T(a)(2)(ii), 29 CFR 2590.716-8(a)(2)(ii), and 45 CFR 149.510(a)(2)(ii). "Security incident" or "incident" has the meaning contained in OMB Memoranda M 17-12 (January 3, 2017) and means an occurrence that, in relation to a certified IDR Entity's information technology system that stores and maintains unsecured IIHI: (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or the information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.

IDR Guidance for Certified IDR Entities

unsecured IIHI has been, or is reasonably believed to have been, subject to the breach.

12. Revocation of Certification

The Departments may revoke certification if it is determined that the certified IDR entity:

1. Has a pattern or practice of noncompliance with the requirements applicable to certified IDR entities under the Federal IDR Process;
2. Is operating in a manner that hinders the efficient and effective administration of the Federal IDR Process;
3. No longer meets the applicable standards for certification, including having violated the confidentiality provisions set forth in Section 11;
4. Has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Departments;
5. Lacks the financial viability to provide arbitration under the Federal IDR Process;
6. Has failed to comply with requests from the Departments made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR Process; and
7. Is otherwise no longer fit or qualified to make determinations.

The Departments will issue a written notice of revocation to the certified IDR entity within **10 business days** of the Departments' decision. To appeal the notice of revocation, the certified IDR entity must submit a request for appeal to the Departments within **30 business days** of the date of the notice. During this time period, the Departments will not issue a final notice of revocation, and a certified IDR entity may continue to work on previously assigned determinations but will not be permitted to accept new determinations.

12.1 Procedures after Final Revocation for Incomplete Determinations

Upon notice of final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR Process. Moreover, the IDR entity must cease conducting any ongoing payment determinations (if applicable), which will be reassigned to an appropriate certified IDR entity by the Departments. The IDR entity must agree to these terms as part of entering into the Agreement.

12.2 Certified IDR Entity Administrative Fees for Incomplete Determinations

In the event the previously certified IDR entity has any remaining ongoing payment determinations at the time of revocation of its certification, the IDR entity must also refund all previously paid certified IDR entity fees and any administrative fees related to ongoing payment determinations to the parties, who shall pay the certified IDR entity and administrative fees to the appropriate reassigned certified IDR entity selected by the Departments.

Appendix A – Definitions

- (1) “**Batched items and services**” means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR Process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in 26 CFR 54.9816-8T(c)(3), 29 CFR 2590.716-8(c)(3), and 45 CFR 149.510(c)(3).
- (2) “**Certified IDR entity**” means an entity responsible for conducting determinations under 26 CFR 54.9816-8T(c), 29 CFR 2590.716-8(c), and 45 CFR 149.510(c) that meets the certification criteria specified in 26 CFR 54.9816-8T(e), 29 CFR 2590.716-8(e), and 45 CFR 149.510(e) and that has been certified by the Departments.
- (3) “**Clean claim**” generally means a claim that has no defect, impropriety, or special circumstance, including incomplete documentation that delays timely payment.
- (4) “**Conflict of interest**” means, with respect to either party to a payment determination or a certified IDR entity, a material relationship, status, or condition of the party or certified IDR entity that impacts the ability of a certified IDR entity to make an unbiased and impartial payment determination. For purposes of this definition, a conflict of interest exists when a certified IDR entity is:
 - (A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility or a provider of air ambulance services;
 - (B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. § 8902; or a provider, a facility, or a provider of air ambulance services;
 - (C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; FEHB Carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.
 - (D) A certified IDR entity that has or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan (or coverage) administrator, plan (or coverage) fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

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- (5) “**Health care facility (facility)**” means, in the context of non-emergency services, each of the following: (1) a hospital (as defined in Section 1861(e) of the Social Security Act); (2) a hospital outpatient department; (3) a critical access hospital (as defined in Section 1861(mm)(1) of the Social Security Act); or (4) an ambulatory surgical center described in Section 1833(i)(1)(A) of the Social Security Act.
- (6) “**Individually identifiable health information (IIHI)**” means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- (7) “**Material familial relationship**” means any relationship as a spouse, domestic partner, child, parent, sibling, spouse’s or domestic partner’s parent, spouse’s or domestic partner’s sibling, spouse’s or domestic partner’s child, child’s parent, child’s spouse or domestic partner, or sibling’s spouse or domestic partner.
- (8) “**Material financial relationship**” means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR Process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.
- (9) “**Material professional relationship**” means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.
- (10) “**Physician or health care provider (provider)**” means a physician or other health care provider who is acting within the scope of practice of that provider’s license or certification under applicable State law, but does not include a provider of air ambulance services.
- (11) “**Qualified IDR item or service**” means an item or service that is either an emergency service from an OON provider or facility, an item or service furnished by an OON provider at an in-network health care facility subject to the requirements of the NSA, or air ambulance services furnished by a provider of air ambulance services, for which the provider or facility (as applicable) or provider of air ambulance services or plan, issuer, or FEHB carrier submits a valid Notice of IDR Initiation. For the notification to be valid, the open negotiation period must have lapsed without agreement on the payment amount.

IDR Guidance for Certified IDR Entities

- (12) “**Qualifying Payment Amount (QPA)**” generally means the median of the contracted rates recognized by the plan for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in the same geographic region in which the item or service under dispute was furnished, increased by inflation.
- (13) “**Recognized amount**” means: (1) an amount determined by reference to an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, an amount determined by reference to a specified state law; or (3) if there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the QPA.
- (14) “**Service code**” means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

IDR Guidance for Certified IDR Entities

Appendix B – Process Steps Summary and Associated Notices

All standard notice templates related to surprise billing can be found on the [Department of Labor website](#).

PROCESS STEPS SUMMARY	STANDARD FEDERAL IDR NOTICE
Before the Federal IDR Process:	
<p>1. Covered item or service results in: an OON charge for furnishing emergency items or services from an OON provider or facility, an OON provider charge for items/services at an in-network facility (without notice and consent), or an OON charge for air ambulance services.</p>	None
<p>2. Initial payment or notice of denial of payment: Must be sent by the plan to the provider, facility, or provider of air ambulance services not later than <i>30 calendar days</i> after a clean claim is submitted. This notice must include information on the QPA, certification that the QPA applies and was determined in compliance with the relevant rules, a statement the provider or facility may contact the appropriate person or office to initiate open negotiation, and contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations.</p>	None
<p>3. Open negotiation period: Parties must exhaust a <i>30-business-day</i> open negotiation period before either party may initiate the Federal IDR Process. This period must be initiated within <i>30 business days</i> beginning on the day the OON provider receives either an initial payment or a notice of denial of payment for the item or service from the plan. The open negotiation period begins on the day on which the open negotiation notice is first sent by a party.</p>	Open Negotiation Notice
Federal IDR Process:	
<p>4. IDR initiation: Either party can initiate the Federal IDR Process by submitting a Notice of IDR Initiation to the other party and to the Departments within <i>4 business days</i> after the close of the open negotiation period (or within <i>30 business days</i> after a cooling off period, if applicable). Such notice includes the initiating party's preferred certified IDR entity.</p>	Notice of IDR Initiation

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PROCESS STEPS SUMMARY	STANDARD FEDERAL IDR NOTICE
<p style="text-align: center;">Before the Federal IDR Process:</p> <p>5. Selection of certified IDR entity: Once the Federal IDR Process is initiated:</p> <ul style="list-style-type: none"> - <i>Within 3 business days:</i> If the non-initiating party does not object to the initiating party's preferred certified IDR entity (included in the Notice of IDR initiation), selection defaults to the initiating party's preferred certified IDR entity unless there is a conflict of interest. If non-initiating party objects, it must provide an alternative certified IDR entity to the initiating party. - <i>Within the next business day following the 3-business-day selection period:</i> The initiating party must submit a Notice of Certified IDR Entity Selection indicating agreement (or failure to select a certified IDR entity). Also, if the non-initiating party believes that the Federal IDR Process is not applicable, it must notify the Departments via the Federal IDR portal in the same timeframe. - <i>Within 6 business days from IDR initiation:</i> If the parties cannot agree on selection of a certified IDR entity, the Departments will randomly select a certified IDR entity. <p>Administrative fees may be invoiced by the certified IDR entity at the time the parties to a payment determination select the certified IDR entity and must be collected by the certified IDR entity from the parties by the time the parties submit their offers. The administrative fee amount will be established in guidance published annually by the Departments (available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf). The certified IDR entity must follow the process for remitting the administrative fees to HHS each month according to HHS guidance.</p>	<p style="text-align: center;">Notice of Certified IDR Entity Selection (or Failure to Select)*</p>
<p>6. Certified IDR Entity requirements: Following selection, the certified IDR entity must:</p> <ul style="list-style-type: none"> - <i>Attest on conflicts of interest:</i> The certified IDR entity must attest to meeting the requirements of the conflicts of interest rules or notify the Departments of an inability to meet those requirements within <i>3 business days</i>. - <i>Determine whether the Federal IDR Process applies:</i> The certified IDR entity must notify both the Departments and the parties within <i>3 business days</i> if it determines the Federal IDR Process does not apply. 	<p style="text-align: center;">None</p>
<p>7. Submission of offers: Parties must submit their offers not later than <i>10 business days</i> after certified IDR entity selection.</p>	<p style="text-align: center;">Federal Independent Dispute Resolution (IDR) Process Notice of Offer Data Elements</p>
<p>8. Payment of Certified IDR Entity fees: Certified IDR entity fees are collected by the certified IDR entity upon submission of the offers.</p>	<p style="text-align: center;">None</p>

IDR Guidance for Certified IDR Entities

PROCESS STEPS SUMMARY Before the Federal IDR Process:	STANDARD FEDERAL IDR NOTICE
9. Continuing negotiations: The parties may continue to negotiate after initiation of the Federal IDR Process and may reach an agreement before a certified IDR entity makes a determination. If the parties agree to a payment amount after providing the Notice of IDR Initiation, the initiating party must submit a notification to the Departments and the certified IDR entity through the Federal IDR portal or by contacting the selected certified IDR entity, as soon as possible, but not later than <i>3 business days</i> after the date of the agreement.	Federal Independent Dispute Resolution (IDR) Process: Notice of Agreement Data Elements
10. Selection of offer: A certified IDR entity has <i>30 business days</i> from its date of selection to select one of the offers submitted and notify the parties, as well as the Departments, of its decision.	Certified IDR Entity's Written Decision of Payment Determination Data Elements
11. Extenuating circumstances: The parties may request extensions, granted at the Departments' discretion, to the time periods above (except timelines related to payments) in cases of extenuating circumstances such as matters beyond the control of the parties or for good cause.	Request for Extension due to Extenuating Circumstances
12. Payment: Any amount due from one party to the other party must be paid not later than <i>30 calendar days</i> after the determination by the certified IDR entity. The certified IDR entity must refund the certified IDR entity fee to the applicable party(ies) within <i>30 business days</i> after the determination.	None

*Indicates that a standard Federal notice has not been developed for this step, however, required communication is expected to take place through the Federal IDR portal or directly with the selected certified IDR Entity.

Appendix C– Resources

Notices:

- Paperwork Reduction Act (PRA) notices and information collection requirements for the Federal Independent Dispute Resolution Process ([Download Notices and Information Requirements](#))
- Standard notice & consent forms for nonparticipating providers & emergency facilities regarding consumer consent on balance billing protections ([Download Surprise Billing Protection Form](#)) (PDF)
- Model disclosure notice on patient protections against surprise billing for providers, facilities, health plans and insurers ([Download Patient Rights & Protections Against Surprise Medical Bills](#)) (PDF)

Federal [IDR Portal](#)

Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under No Surprises ([Download Fee Information](#)) (PDF)

[Where to go for help](#)

[CMS.Gov/NoSurprises](#)

No Surprises Help Desk: 1-800-985-3059.

IDR Guidance for Certified IDR Entities



Department of Health & Human Services
200 Independence Avenue, S.W. Washington,
D.C. 20201
Toll Free Call Center: 1-877-696-6775
www.hhs.gov



Department of Labor
200 Constitution Ave NW
Washington, DC 20210
1-866-4-USA-DOL / 1-866-487-2365
www.dol.gov



Department of the Treasury
1500 Pennsylvania Ave., N.W.
Washington, D.C. 20220
General Information: (202) 622-2000
www.treasury.gov

Federal Independent Dispute Resolution (IDR) Process
Guidance for Certified IDR Entities

April 2022

EXHIBIT 2

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

LIFENET, INC.

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

U.S. DEPARTMENT OF LABOR,

U.S. DEPARTMENT OF THE TREASURY,

OFFICE OF PERSONNEL MANAGEMENT,

and the

CURRENT HEADS OF THOSE
AGENCIES IN THEIR OFFICIAL
CAPACITIES,

Defendants.

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

DECLARATION OF LIFENET, INC.

1. My name is James L. Gaines. I am over the age of eighteen. I am employed by LifeNet, Inc. (“LifeNet”). My job title is General Counsel. I have personal knowledge of the matters contained herein.

2. 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 approximately 21 emergency air transports, in 2022, for which the right to reimbursement may be governed by the No Surprises Act and its implementing regulations.

5. LifeNet is compensated for these services by Air Methods Corporation (“Air Methods”) pursuant to a contract between the two companies, which was first entered into in October 2021, and which is of limited duration. That contract also provides that Air Methods has responsibility for pursuing the collection of bills for LifeNet’s services.

6. 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.

7. 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. Based on LifeNet’s experience in the market, I expect the QPA will in many cases be significantly below the amounts that LifeNet has been paid for its out-of-network emergency transports. Additionally, at least in some cases, the QPA will not reflect the acuity of the patient who received the air transport or the population density at the point of pickup, both of which are factors that the No Surprises Act requires an IDR entity to consider, but which the QPA Presumption will overwhelm.

8. I believe that the offers submitted to the IDR entity by *payors*, for the air ambulance services provided by LifeNet, will in many if not all cases will be close to the QPA. Indeed, health insurance companies have already 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 (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").

9. The QPA Presumption adopted in the Department's regulations will therefore make it more challenging 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 QPA Presumption. Thus, the QPA Presumption will thus result in lower IDR determinations of reimbursement rates for the services provided by LifeNet.

10. The lower reimbursement rates, determined by IDRs applying the 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.

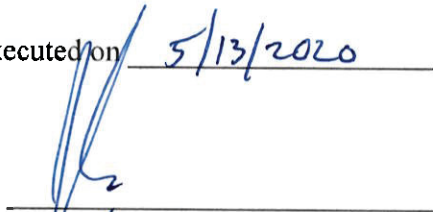
11. This lower reimbursement rate will cause LifeNet's compensation to decrease. The application of the QPA Presumption in IDR proceedings will drive out-of-network reimbursement rates to the QPA as a benchmark. That in turn will cause LifeNet's compensation to decrease significantly.

12. For the foregoing reasons, the QPA Presumption directly harms LifeNet's financial interests.

13. LifeNet is not a member of the Association of Air Medical Services (AAMS).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on 5/13/2020. (date).

Signature:



Printed Name:

JAMES L. GAINES

EXHIBIT 3

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

LIFENET, INC.

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

U.S. DEPARTMENT OF LABOR,

U.S. DEPARTMENT OF THE TREASURY,

OFFICE OF PERSONNEL MANAGEMENT,

and the

CURRENT HEADS OF THOSE
AGENCIES IN THEIR OFFICIAL
CAPACITIES,

Defendants.

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

SECOND DECLARATION OF LIFENET, INC.

1. My name is James L. Gaines. I am over the age of eighteen. I am employed by LifeNet, Inc. (“LifeNet”). My job title is General Counsel. I have personal knowledge of the matters contained herein.

2. 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.

3. 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

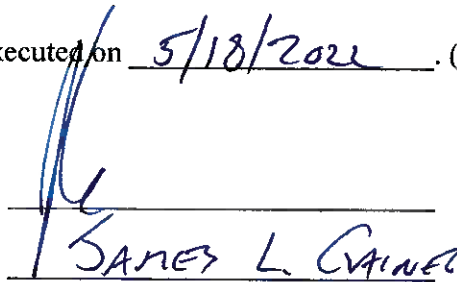
either Party, then either Party may terminate all or part of this Agreement (including the closure of one or more Base Sites) upon at least 180 days prior written notice to the other Party. AMC [Air Methods Corporation] and LIFENET will meet to discuss potential adjustments to the Clinical Crew services prior to either Party exercising its rights under this Section 2.3.

4. As I attested in my First Declaration, the QPA Presumption “will drive out-of-network reimbursement rates” for LifeNet’s services “to the QPA as a benchmark.” 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 LifeNet and Air Methods Corporation at the time the parties entered into their contract.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on 5/18/2022. (date).

Signature:

Printed Name:



JAMES L. CAINES

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

LIFENET, INC.

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

U.S. DEPARTMENT OF LABOR,

U.S. DEPARTMENT OF THE TREASURY,

OFFICE OF PERSONNEL MANAGEMENT,

and the

CURRENT HEADS OF THOSE
AGENCIES IN THEIR OFFICIAL
CAPACITIES,

Defendants.

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

**[PROPOSED] ORDER GRANTING PLAINTIFFS'
MOTION FOR SUMMARY JUDGMENT**

Before the Court is Plaintiff's motion for summary judgment. Being fully advised in the premises, the Court finds that the motion should be GRANTED as to Count I [and/or Count II].

It is, therefore, ORDERED that the motion is hereby GRANTED as to Count I [and/or Count II], and the following provisions are hereby VACATED: (i) The final sentence of 45 C.F.R. § 149.520(b)(2), (ii) the final sentence of 26 C.F.R. § 54.9817-2T(b)(2), and (iii) the final sentence of 29 C.F.R. § 2590.717-2(b)(2).

IT IS SO ORDERED.