UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AIR MEDICAL SERVICES, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Civ. Action No. 1:21-cv-3031-RJL

COMBINED REPLY OF PLAINTIFFS AMERICAN MEDICAL ASSOCIATION AND AMERICAN HOSPITAL ASSOCIATION, ET AL., IN SUPPORT OF THEIR MOTION FOR STAY PENDING JUDICIAL REVIEW, OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT, AND MEMORANDUM IN OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Departments spend pages of their response describing the negative consequences of surprise billing and the need for a solution. Plaintiffs have no quarrel with the Departments on that point. The American Medical Association and the American Hospital Association have long advocated for patient protection from surprise billing and welcomed Congress's solution. The issue here is not whether patients will be protected from surprise bills—they are, in provisions not challenged—but whether the compromise solution adopted by Congress, or the one-sided, atextual policy preferred by the Departments, will govern arbitrations under the Act.

After extensive debate, Congress rejected the Departments' preference for a presumptive benchmark payment amount in favor of a balanced baseball-style arbitration process. By requiring each party to submit a single, final offer, and the arbitrator to select between the two, the No Surprises Act incentivizes each side to submit reasonable offers. To further this balanced approach, Congress directed an independent expert arbitrator to evaluate these offers in light of a series of specified factors (the "Subparagraph C Factors"). Congress did not prescribe a particular weight the arbitrator should ascribe to any one factor in a given case, but left the arbitrator to determine what weight each factor should have under the particular circumstances. This solution departed markedly from the approaches Congress left on the cutting room floor, including one—H.R. 5800, 116th Cong. (2d Sess. 2020) (on which the Departments' Opposition primarily relies)—that would have set the median contracted rate as the default payment rate.

In the September Rule, the Departments resurrected the congressionally rejected benchmark payment concept in the form of a "presumption" in favor of only one of the specified factors: the "qualifying payment amount" ("QPA"). Although Congress directed that the arbitrator "shall consider" all six Subparagraph C Factors "[i]n determining which offer is the payment to be applied," 42 U.S.C. § 300gg-111(c)(5)(C), the Departments rewrote the statute to

tell the arbitrator that she "*must select the offer closest to the [QPA]*" unless she determines that "credible information" "clearly demonstrates" that there is a "substantial likelihood" that the QPA is not the appropriate payment rate. 45 C.F.R. § 149.510(a)(2)(viii), (b)(4)(ii)(A) (emphasis added). The Departments and their *amici* may wish that Congress enacted this policy, but it is *not* the law that Congress passed. The September Rule thus violates a fundamental separation-of-powers tenet: agencies cannot rewrite statutes by adding material terms found nowhere in the text.

Evidently realizing they have run afoul of this bedrock principle, the Departments' response studiously avoids using the word "presumption." Their brief even goes so far as to disavow their prior characterization of the Rule as creating a "presumption" in favor of the QPA. *See* Opp. 19. While the Departments' desire to distance themselves from the Rule's actual operation is understandable, they cannot escape their own words. Some form of "presume" is used *seventeen* times to describe the status the September Rule affords the QPA, 86 Fed. Reg. 55,980, 55,984, 55,996-55,998, and 56,050-56,061 (Oct. 7, 2021), including ten times over a span of four pages under the heading "Selection of Offer," *id.* at 55,996-55,998. And at the same time as the Departments were filing briefs in this Court playing down the Rule's "presumption," they were issuing guidance doubling down on it: "In determining which payment offer to select, the certified IDR entity must begin with the **presumption that the QPA is the appropriate [out of network] rate**." Ex. A, U.S. Dep't of Health & Human Servs., *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities*, at 19 (Jan. 2022) ("HHS Guidance"); *see id.* at 20-22 (section titled "Standards for Rebutting the [QPA] Presumption").[1] As hard as they try to salvage this unlawful rule by calling it something that it is not, the Departments cannot now

[1] https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Federal-Independent-Dispute-Resolution-Process-Guidance-for-Certified-IDR-Entities.pdf.

"recast [their] earlier action to fall within the scope" of the No Surprises Act. *American Portland Cement All. v. E.P.A.*, 101 F.3d 772, 778 (D.C. Cir. 1996). This Court must evaluate this rule on the basis of the "agency action when undertaken"—"not on the agency's characterization after the fact." *Id*.

Even when the Departments defend the preferred status the September Rule affords the QPA, they hang their interpretation on the flimsiest of reeds: first, a single word in a statutory heading—"additional"—which they attempt to wrongly redefine to mean "subordinate"; second, the ordering of text in the Act, even though they point to no case in which placement trumps text; third, a fundamental misreading of circuit precedent embodying the clear interpretive principle that agencies may not elevate one statutory factor over others where Congress assigned no relative weights; and fourth, the legislative history of a *rejected* bill. Those feeble explanations leave only one conclusion: the Departments' interpretation of the Act is contrary to its text, design, history, and intent, and is therefore owed no deference.

Because the September Rule is *ultra vires*, and because Plaintiffs have submitted *uncontested* evidence that it will cause irreparable harm, this Court should immediately stay the provisions of the September Rule that require arbitrators to employ a presumption in favor of the QPA. In the alternative, this Court should grant summary judgment in Plaintiffs' favor and vacate this unlawful rule.

ARGUMENT

I. THE DEPARTMENTS' QPA PRESUMPTION IS CONTRARY TO LAW AND EXCEEDS THEIR STATUTORY AUTHORITY

A. The Departments Cannot Disavow The Rule's Presumption

The Departments' September Rule instructs arbitrators that, with rare exception, they "*must* select the offer closest to the" QPA. 45 C.F.R. § 149.510(b)(4)(ii)(A) (emphasis added). That

command establishes a straightforward "presumption that the QPA is the appropriate out-of-network rate." 86 Fed. Reg. at 55,996; *see also* Mot. 17-19.

Now, however, the Departments would have this Court believe that the September Rule does nothing more than sequence arbitrators' decisionmaking, directing them only to "*begin*[] with the qualifying payment amount, and then proceed[] to consider what the statute describes as 'additional' circumstances." Opp. 2 (emphasis added). That claim rings hollow because the Departments invoked a form of the word "presumption" with respect to the QPA seventeen times in the Rule's preamble—even going so far as to declare that "these interim final rules establish the QPA as the presumptive factor." *See, e.g.*, 86 Fed. Reg. at 55,997. It also conflicts with guidance the Departments recently issued to arbitrators, which includes an entire section titled "Standards for Rebutting the Presumption." *See supra* note 1. Betraying uneasiness with their own characterizations, the Departments argue that such statements are irrelevant because they do not appear in the regulatory text. Opp. 19. But courts "regularly rely upon the preamble in interpreting an agency rule. The purpose of the preamble, after all, is to explain what follows." *Public Citizen v. Carlin*, 184 F.3d 900, 911 (D.C. Cir. 1999) (citing *National Mining Ass'n v. E.P.A.*, 59 F.3d 1351, 1355 n.7 (D.C. Cir. 1995)).

More to the point, the regulatory text obviously *does* create a presumption: the offer closer to the QPA is taken as "correct[]," "subject to rebuttal by contrary evidence." *Presumption*, AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1395 (5th ed. 2018); *see* 86 Fed. Reg. at 55,996 (party with offer farther from QPA must "rebut the presumption" in favor of QPA). Although the Departments try to redefine "presumption" as merely a "reasonable shorthand" for sequenced decisionmaking (Opp. 19), a "presumption" is not just a starting point, but rather "an act or instance of taking something to be true." *Presumption*, NEW OXFORD AMERICAN

DICTIONARY 1383 (3d ed. 2010). And a presumption, unlike a mere starting point, constrains discretion. *E.g.*, *United States v. Lawrence*, 662 F.3d 551, 563 (D.C. Cir. 2011) ("Our standard of review is highly deferential, particularly given the rebuttable presumption of reasonableness that attaches to sentences within the Guidelines range.").

The September Rule goes further: not only does it conjure a presumption out of thin air, it erects significant barriers to overcoming it. Specifically, the Rule mandates that the arbitrator "*must* select the offer closest to the [QPA] *unless*" the arbitrator finds "credible information" that "*clearly* demonstrates" that the QPA is "*materially* different" from the appropriate payment rate. 45 C.F.R. § 149.510(b)(4)(ii)(A) (emphases added). The Rule defines "[m]aterial difference" as "a *substantial* likelihood that [an IDR arbitrator] . . . would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate." *Id.* § 149.510(a)(2)(viii) (emphasis added). Under the September Rule, then, the arbitrator is permitted to consider the non-QPA Subparagraph C Factors *only* to the extent they meet the Rule's triply heightened standards—"clearly," "materially," "substantial[ly]"—for overcoming the QPA presumption. And the arbitrator is "rare[ly]" expected to consider the non-QPA Subparagraph C Factors when actually determining which of the parties' offers reflects the proper payment amount. *See, e.g.*, 86 Fed. Reg. at 55,997. Notably, the Departments do not dispute that this is the case. *See* Opp. 17 (noting only that "[o]utliers are possible").[2]

[2] The Departments also do not dispute other features of the September Rule that bolster the QPA's presumptive effect. As plaintiffs explained (Mot. 18), the Rule requires arbitrators to consider the evidence related to the non-QPA factors with skepticism, even though the Rule affirmatively forbids the arbitrator from scrutinizing the QPA. Plaintiffs further explained (Mot. 9) that the September Rule places a special burden on arbitrators who deviate from the QPA, requiring a "detailed explanation" for why they did so.

B. The Departments' QPA Presumption Is Inconsistent With The Act

After attempting to disavow the September Rule's QPA presumption, the Departments ultimately argue that the Act empowers them to create such a presumption. That argument conflicts with the text, context, history, and intent of the Act.

1. The Departments' QPA Presumption Conflicts with the Act's Unambiguous Text.

It is a basic principle of statutory interpretation that agencies may not "rewrite a statute's plain text." *Landstar Express Am., Inc. v. Federal Mar. Comm'n*, 569 F.3d 493, 498 (D.C. Cir. 2009). Here, the Act states—no more, no less—that the arbitrator "shall" consider *all* the Subparagraph C Factors in determining which offer represents the appropriate payment rate, in every case. 42 U.S.C. § 300gg-111(c)(5)(C) ("In determining which offer is the payment to be applied pursuant to this paragraph, the [arbitrator] . . . shall consider" the Subparagraph C Factors.).

Under the September Rule, however, the arbitrator is now prohibited from simply "select[ing] one of the [parties'] offers" after considering the Subparagraph C factors, 42 U.S.C. § 300gg-111(c)(5)(A)(i), and instead "must select the offer closest to the" QPA, unless a heightened showing is met. 45 C.F.R. § 149.510(a)(2)(viii), (b)(4)(ii)(A). Although the Departments argue that Congress elevated the QPA above the other Subparagraph C Factors by describing the latter as "additional circumstances," Opp. 15-16, the word "additional" cannot bear the weight they now place on it.

For one, the word "additional" appears in only a statutory subheading. But while such headings can confirm a statue's meaning, "[a] subchapter heading cannot substitute for the operative text of the statute." *Citizens for Resp. & Ethics in Wash. v. F.E.C.,* 316 F. Supp. 3d 349, 396 (D.D.C. 2018) (quoting *Florida Dep't of Revenue v. Piccadilly Cafeterias, Inc.,* 554 U.S. 33,

47 (2008); *National Ctr. for Mfg. Scis. v. Department of Def.,* 199 F.3d 507, 511 (D.C. Cir. 2000)). Here, the operative text does *not* refer to the Subparagraph C Factors as "additional." Instead, the relevant text uses the word "any" to refer to the non-QPA factors, and incorporates those factors by reference in the very same paragraph where it otherwise identifies the QPA as one of the several factors that the arbitrator "shall consider." *See* 42 U.S.C. § 300gg-111(c)(5)(C)(i). Thus, the Departments' only textual argument cannot be squared with the actual operative text of the Act.[3]

Regardless, the ordinary meaning of "additional" is not "subordinate," but something that is "added." *See Additional*, OXFORD ENGLISH DICTIONARY 144 (2d ed. 1991) ("Existing in addition, coming by way of addition; added"); *Additional*, NEW OXFORD AMERICAN DICTIONARY 18 (3d ed. 2010) ("added, extra, or supplementary to what is already present or available").[4] A contract that recites, "See Additional Terms On Page Two," does not thereby imply that the second-page terms enjoy second-class status. By referring to the non-QPA factors as "[a]dditional circumstances" in a statutory heading, Congress did not expect the arbitrator to treat the offer closest to the QPA as presumptively correct, but rather expected her to weigh *all* factors—the non-QPA factors "in addition" to the QPA—in determining which offer reflects the appropriate payment rate under the particular circumstances of the arbitration.

The Departments cannot overcome this plain meaning by pointing out that the QPA is listed first in the Act. Mot. 25-26. "No accepted canon of statutory interpretation permits 'placement'

[3] As Plaintiffs argued (Mot. 17), moreover, to the extent the Court considers the statutory headings, the title "Considerations in determination" (in 42 U.S.C. § 300gg-111(c)(5)(C))—which does not conflict with the operative text—would confirm that *all* of the considerations listed in that subparagraph are on the same plane.

[4] The Departments point to a Ninth Circuit case that defined "additional" as "supplemental." Opp. 16 (quoting *In re Border Infrastructure Env't Litig.*, 915 F.3d 1213, 1223 (9th Cir. 2019)). But again, "supplemental" is simply "[s]omething added to complete a thing." *Supplement*, AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1751 (5th ed. 2018).

to trump text, especially where, as here, the text is clear[.]" *Padilla v. Rumsfeld*, 352 F.3d 695, 721 (2d Cir. 2003), *rev'd on other grounds sub nom. Rumsfeld v. Padilla*, 542 U.S. 426 (2004). And, as plaintiffs explained in their opening brief (*see* Mot. 25), the non-QPA factors were incorporated by reference in the same paragraph as the QPA factor, making the Department's emphasis on statutory placement nothing more than an attempt to elevate form over substance. Defendants offer no response. Instead, they rely on the unremarkable proposition that Congress can "prescribe a structure" for a decisionmaker to address a set of factors. Opp. 21. Had Congress done so here, the arbitrator would of course be obligated to follow it. But that is not what Congress did.

By naming *both* the QPA and non-QPA factors in the same provision as the factors to be considered in determining the appropriate payment "pursuant to this paragraph," 42 U.S.C. § 300gg-111(c)(5)(C), "Congress carefully avoided attaching any particular weights to the various concerns [listed in the statute] that must be taken into account," and made no "attempt to prescribe the relative weights that [decision-makers in individual cases] should assign to these various factors in determining reasonableness," *Public Serv. Co. of Ind. v. I.C.C.*, 749 F.2d 753, 763 (D.C. Cir. 1984). In these circumstances, controlling D.C. Circuit precedent precludes agencies from granting any one factor differential—let alone presumptive—status. *See id*. (agencies may not "select any *one* factor as controlling" where Congress did not assign relative weights); *American Corn Growers Ass'n v. E.P.A.*, 291 F.3d 1, 6 (D.C. Cir. 2002) ("Although no weights were assigned, the factors were meant to be considered together by the states. The language of § 169A(g)(2) can be read in no other way. To treat one of the five statutory factors in such a dramatically different fashion distorts the judgment Congress directed the states to make for each

BART-eligible source."). The No Surprises Act must be interpreted "against the backdrop" of this caselaw. *McQuiggin v. Perkins*, 569 U.S. 383, 398 n.3 (2013).

The two cases that the Departments cite do not disturb this well-established interpretive principle. In the first, *Ramirez v. I.C.E.*, 471 F. Supp. 3d 88 (D.D.C. 2020), the relevant statute directed that, once an unaccompanied noncitizen reached the age of 18, ICE officers should "consider placement [of the individual] in the least restrictive setting available *after* taking into account the alien's danger to self, danger to the community, and risk of flight," *id.* at 175 (emphasis added). The district court determined that by employing the term "after," Congress mandated a particular ordering for the ICE officers' decisionmaking: they first had to consider the three factors *before* they could consider placement in the least restrictive setting. But here, Congress used the simple conjunction "and" to link the factors the arbitrator must consider, not a temporal term like "after." *See* 42 U.S.C. § 300gg-111(c)(5)(C)(i).

Weyerhaeuser Co. v. Costle, 590 F.2d 1011 (D.C. Cir. 1978), on which *Ramirez* partially relies, is equally distinguishable. Two statutory provisions were at issue in *Weyerhaeuser*: the first directed an agency to consider two factors "in relation to" each other, while the second directed the agency to "take into account" a series of factors. *Id.* at 1045. The D.C. Circuit determined that by using the phrase "in relation to," Congress mandated a limited balancing test for the first set of factors. By contrast, because Congress "did not mandate any particular structure or weight" for the second set, Congress left it to the discretion of the decisionmaker—in that case, the agency—"to decide . . . how much weight to give each factor." *Id.* The provision at issue here is thus more analogous to *Weyerhaueser*'s second provision, given its mandate that the relevant

decisionmaker—in this case, the arbitrator—"shall consider" all the factors, without elevating one factor over any other.[5]

Neither of these two cases therefore undermines the bedrock interpretive principle—adopted in both *American Corn Growers Association*, 291 F.3d at 6, and *Public Service Company of Indiana*, 749 F.2d at 763—that where Congress has prescribed a set of factors without assigning any particular weights, the decisionmaker has discretion to determine how to weigh them in a given case.

Contrary to the Departments' assertion, this unweighted approach does not mean Congress gave arbitrators "unfettered discretion" in rendering a decision. Opp. 22. The arbitrator is constrained through various guardrails, first among them the required submission of offers from both sides, one of which the arbitrator must select. Congress chose this baseball-style arbitration to incentivize the submission of reasonable offers by the parties. There is nothing "unfettered" about having a choice of just two options. And although the arbitrator is free to consider additional information she requests or the parties submit, her discretion is further delimited by the three factors that the arbitrator "shall not" consider, along with the six factors that Congress mandated the arbitrator "shall" consider. 42 U.S.C. § 300gg-111(c)(5)(C), (D). The arbitrator, moreover, must have "sufficient medical, legal, and other expertise" to select an offer while operating within those boundaries. *Id.* § 300gg-111(c)(4)(A). When Congress prescribes such a multifactor test, "[e]ach factor must be given genuine consideration and some weight." *Public Serv. Co. of Ind.*,

[5] The Departments cite *Weyerhaeuser* solely for the proposition that Congress prescribed a structure by giving the QPA more attention in the No Surprises Act. Opp. 21. They do not contend that Congress gave them license to ascribe weights to the statutory factors because Congress did not specify a structure. With good reason: that characterization of *Weyerhaeuser*, which was advanced by the *dissent* in *American Corn Growers*, was rejected by the majority in that case. *See American Corn Growers Ass'n*, 291 F.3d at 6.

749 F.2d at 763. Yet by setting up the QPA as presumptively correct and imposing on the parties a "burden of rebutting it," the Departments "select[ed] … one factor as controlling," which they may not do. *Id.* at 757, 763.[6]

Finally, Congress knows how to textually create a rebuttable presumption when it wants to. It has done so elsewhere in the Public Health Service Act ("PHSA"), of which the Act forms a part. *See* Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, PUB. L. NO. 109-148, § 2, 119 Stat. 2680 (2005) (codified as amended at 42 U.S.C. § 247d-6d(a)(6)). It has done so nearly eighty times throughout the U.S. Code.[7] And it even did so elsewhere in the Consolidated Appropriations Act in which the No Surprises Act was passed. *See* Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 226, 134 Stat. 1182, 2208 (codified as amended at 15 U.S.C. § 1116), "Rebuttable Presumption of Irreparable Harm."

Citing a single out-of-circuit case, the Departments argue that one part of an omnibus law like the Consolidated Appropriations Act cannot serve as an interpretive guide for another part. Opp. 20 (citing *Restrepo v. Attorney Gen. of United States*, 617 F.3d 787, 793-794 (3d Cir. 2010)).

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[6] The Departments argue that "Congress also could have expressly" assigned discretion to the arbitrator to weigh the Subparagraph C Factors. Opp. 20. But especially given the "backdrop of existing law" against which Congress legislated, *McQuiggin*, 569 U.S. at 398 n.3, under which agencies are bound to respect Congress's choice to leave the weighing of the factors to the decisionmaker's discretion, this argument violates another well-established interpretive principle. The D.C. Circuit has long rejected the position that "regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency." *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1174 (D.C. Cir. 2003). Yet that is exactly what the Departments seem to contend here.

[7] *See, e.g.*, 4 U.S.C. § 120(a) ("rebuttable presumption"); 6 U.S.C. § 442(d)(1) ("rebuttable presumption"); 8 U.S.C. § 1158(b)(1)(iii) ("rebuttable presumption"); 12 U.S.C. § 371c(b)(11) "("rebuttable presumption"); 15 U.S.C. § 1116(a) ("rebuttable presumption"); 16 U.S.C. § 5509(e) ("rebuttable presumption"); 17 U.S.C. § 504(c)(3)(A) ("rebuttable presumption"); 18 U.S.C. § 981(i)(3) ("rebuttable presumption").

But the Supreme Court took the opposite view with respect to the exact same criminal and immigration provisions at issue in the Third Circuit. In a unanimous opinion, the Court found the fact that Congress amended the definition of "sexual abuse of a minor" under federal criminal law "in the same omnibus law that added sexual abuse of a minor to the [immigration statute]" to be persuasive evidence that the two laws shared the same definition. *Esquivel-Quintana v. Sessions*, 137 S. Ct. 1562, 1570-1571 (2017); *see Cabeda v. Attorney Gen. of United States*, 971 F.3d 165, 189-190 (3d Cir. 2020) (Krause, J., concurring in part and concurring in the judgment) ("*Esquivel-Quintana* has revealed that *Restrepo*'s statutory analysis was deeply flawed. . . . [*Restrepo*] rejected [the same-act] canon as inapplicable to omnibus legislation, concluding—without citing any precedent for this proposition—that terms used in separate and distinct statutes were not subject to the rule. . . . *Esquivel-Quintana* took a contrary approach." (internal quotation marks omitted)). Put simply, that Congress regularly creates presumptions in other laws throughout the U.S. Code and in the 2021 Consolidated Appropriations Act only makes the omission here more conspicuous.

2. The Departments' QPA Presumption Conflicts with the Act's Context.

A presumption in favor of the QPA also is at odds with the statutory context, and in particular the crucial choice Congress made to implement baseball-style arbitration. Under the Act, each party submits a single, final offer, and the arbitrator must choose, without deviation, one of those offers. 42 U.S.C. § 300gg-111(c)(5)(A)(i), (c)(5)(B)(i)(I). Because the parties' offers are final and non-negotiable, and because the arbitrator is constrained to choose one of them, baseball-style arbitration "creates an incentive for both parties to make reasonable proposals." Supplemental Statement of the United States in Support of Entry of the Final Judgment, at 3 n.4 ("Statement of the United States"), *United States v. Comcast Corp.*, No. 1:11-cv-00106 (RJL)

(D.D.C. Aug. 5, 2011), ECF No. 26; *e.g.,* Mark A. Lemley & Carl Shapiro, *A Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents*, 28 BERKELEY TECH. L.J. 1135, 1144 (2013) (baseball-style arbitration encourages "making reasonable proposals, because the party that asks for too much (or offers too little) risks losing the case altogether"); J. Gregory Sidak, *Court-Appointed Neutral Economic Experts,* 9 J. COMPETITION L. & ECONS 359, 389 (2013) (similar); Matt Mullarkey, *For the Love of the Game: A Historical Analysis and Defense of Final Offer Arbitration in Major League Baseball*, 9 VA. SPORTS & ENT. L.J. 234, 245 (2010) (similar).

The purpose of baseball-style arbitration is not to "begin with" (Opp. 15) or get to a particular number. *Cf. Stone v. U.S. Forest Serv.*, No. 03-cv-586-JE, 2004 WL 1631321, at *7 (D. Or. July 16, 2004) (noting that baseball-style arbitration "is not a procedure well-tailored" to the goal of calculating a property's fair market value). This style of arbitration leaves control over the numbers to the parties, who are incentivized to submit reasonable figures, slightly lower or higher than they might wish, based on their assessment of the relevant factors. The Departments' QPA presumption destroys this incentive structure, forcing the parties to submit proposals "anchor[ed]" to a regulatory benchmark. 86 Fed. Reg. 55,996. Because the parties know the arbitrator must presume that the QPA is the appropriate payment rate, insurers will have little incentive to offer a number higher than the QPA; indeed, commercial insurers will be incentivized by the presumption to make an offer *lower* than the QPA, safe in the knowledge that the arbitrator usually "must select" their below-QPA offer unless the provider's offer is even closer to the QPA. Providers, by contrast, will deviate from the QPA to their disadvantage, even if they sincerely believe the other Subparagraph C Factors demand a higher rate, given the triple-heightened burden the Departments placed on offers farther from the QPA. That is not the system enacted by Congress. Congress

instead adopted a process designed to rely on the parties, while encouraging them to moderate their offers. It is not for the Departments to substitute their judgment for Congress's.[8]

Grasping for contextual clues to support their QPA presumption, the Departments argue that the QPA must take priority because "it is difficult to imagine how the arbitrator could go about the decision-making process without starting with the qualifying payment amount." Opp. 18. This betrays a fundamental misunderstanding of how baseball-style arbitration works. Because the parties arrive with their final offers in hand—one of which the arbitrator must choose—what the arbitrator "starts" with is not the QPA *but the parties' numbers*. *See* Statement of the United States 3 n.4 ("Under baseball-style arbitration, each party submits its preferred price and other terms to the arbitrator, and the arbitrator selects the proposal that is most reasonable in light of relevant evidence.").[9]

The Departments' other arguments are equally unavailing. That the QPA plays a "central role" in patient cost-sharing shows only that Congress knew how to adopt a benchmark approach when it wanted to—and that it did not do so with respect to the arbitrator's payment determination. *See Salinas v. United States R.R. Ret. Bd.*, 141 S. Ct. 691, 697-698 (2021) (where, as here, "Congress includes particular language in one section of a statute but omits it in another section

[8] Although the Departments (like their *amici*) claim that their rule promotes predictability, Opp. 23, they do not cite anything to support their argument that Congress shared that goal. To the contrary, Congress's decision to adopt baseball-style arbitration—along with its creation of a 30-day pre-arbitration negotiation period to encourage open negotiation—suggests that Congress did not expect the parties to coalesce around one number.

[9] The extent of the Departments' misunderstanding of the Act's baseball-style arbitration process is further displayed in guidance they recently issued for IDR arbitrators, which advises that the arbitrator "must select one of the offers submitted by the disputing parties *or determine an alternate payment amount*." HHS Guidance 19 (emphasis added); *see also id.* at 25 (describing the "prevailing party" as "the party whose offer is selected *or whose offer is closest to the final payment amount*" (emphasis added)). But under the plain terms of the Act, the IDR arbitrator must "select" one party's offer, *see* 42 U.S.C. § 300gg-111(c)(5)(A)(i), (c)(5)(B)(i)(I), and has no authority to determine an "alternate payment amount."

of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion").

The Departments' brief likewise reads too much into Congress's request for quarterly reports pegged to the QPA. Opp. 18. "To accept [the Departments'] reasoning" regarding a reporting requirement "would be to allow the tail to wag the dog." *Allied Chem. & Alkali Workers of Am. v. Pittsburgh Plate Glass Co.*, 404 U.S. 157, 170-171 (1971). Moreover, it is just as plausible that Congress sought those reports in order to assess whether the QPA correctly reflected market rates. If anything, the reporting requirements cut against the Departments' reading because Congress notably did not impose such requirements on the *parties* when they submit their offers. *Compare* 42 U.S.C. § 300gg-111(c)(5)(B)(i)(I) (requiring parties to submit to the IDR entity "an offer for a payment amount" without any requirement to specify its relation to the QPA), *with id.* § 300gg-111(c)(7)(B)(iii) (requiring the Departments to publicly report the parties' offers "expressed as a percentage of the [QPA]"). Had Congress wished the QPA to exert a gravitational pull on the parties' offers or the arbitrator's decisionmaking process, it easily could have said so. The fact that it did not suggests that Congress did not wish the QPA to hold such sway.

Engaging in further speculation, the Departments' brief suggests that the QPA should take priority because "one would expect" that "ordinarily" it will already account for all the other Subparagraph C Factors. Opp. 17. But that was not the view of Congress, which surely would not have enumerated other specific factors for the arbitrator to consider if it thought the QPA already accounted for them or thought they were "immaterial," as the Departments' *amici* call them. *See* AHIP Amicus Br. at 4, ECF No. 62-1. Plaintiffs have already explained (Mot. 26) that where a statute mandates consideration of a particular factor, that factor must be individually considered even if it "has arguably [already been] considered" elsewhere. *United Parcel Serv.*,

Inc. v. Postal Regul. Comm'n, 955 F.3d 1038, 1042 (D.C. Cir. 2020). The Departments offer no response. *See Wilkins v. Jackson*, 750 F. Supp. 2d 160, 162 (D.D.C. 2010) ("It is well established that if a [party] fails to respond to an argument raised in a motion for summary judgment, it is proper to treat that argument as conceded.").

3. The Departments' QPA Presumption Is Inconsistent with the Act's Legislative History and Intent

Much like their attempt to minimize the September Rule's presumption, the Departments seek to write off the Act's legislative history. *See* Opp. 22. They contend, for example, that this Court should not examine the many rejected bills that would have imposed the very presumption they now try to slip through the regulatory backdoor. But "[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *I.N.S. v. Cardoza-Fonseca*, 480 U.S. 421, 442-443 (1987); *accord Doe v. Chao*, 540 U.S. 614, 622-623 (2004); *National Sec. Archive v. U.S. Dep't of Def.*, 880 F.2d 1381, 1384-1385 (D.C. Cir. 1989). Here, Congress rejected proposals that looked much more like the Departments' presumption-based approach. *See, e.g.*, Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019) ("A group health plan or health insurance issuer offering group or individual health insurance coverage shall pay providers, including facilities and practitioners, furnishing [certain] services[,] . . . the median in-network rate for such services."); No Surprises Act, H.R. 3630, 116th Cong. § 2(b) (2019) (proposing that insurers pay "the recognized amount," less patient copay or coinsurance); *id.* § 2(a) (defining "recognized amount" as either no more than the state-mandated amount plus patient copay or coinsurance or, for states without mandates, "at least the median

contracted rate").[10] Although Defendants claim Congress also rejected bills with plaintiffs' "preferred approach" (Opp. 22), they point to no bill—aside from the one Congress enacted—adopting baseball-style arbitration and directing arbitrators to consider a set of factors without giving categorical presumptive weight to any single one.

Left without text, context, or legislative history to support their QPA presumption, the Departments resort to purported legislative purpose. According to the Departments' narrative, Congress intended to put a thumb on the scales in favor of the QPA in order to drive down healthcare costs. But "[t]he most reliable guide to congressional intent"—"the legislation [that] Congress enacted," *Sierra Club v. E.P.A.*, 294 F.3d 155, 161 (D.C. Cir. 2002)—tells a different story. By encouraging parties to submit reasonable payment offers and directing arbitrators to account for both an objective rate *and* contextual factors, the Act seeks to balance the need for fair compensation to both healthcare providers and commercial insurers.

As the Act's principal architects recently explained, the IDR process was designed to represent a "careful balance." Letter from Chairman Neal and Ranking Member Brady of the House Ways and Means Committee to Department Secretaries, at 2 (Oct. 4, 2021), https://www.gnyha.org/wp-content/uploads/2021/10/2021.10.04-REN-KB-Surprise-Billing-Letter80.pdf. By "bias[ing] the IDR entity toward one factor (a median rate) as opposed to evaluating all factors equally as Congress intended," the September Rule "strays from the No Surprises Act in favor of an approach that Congress *did not* enact in the final law." *Id.*; *see also*

[10] *See also* Brief of Members of Congress as Amici Curiae in Support of Plaintiffs at 4-11, ECF No. 65 (recounting the Act's legislative history); Amici Curiae Brief of Hospital Associations in Support of Plaintiffs, ECF No. 27, at 7-19 (same); Brief Amicus Curiae of the Emergency Department Practice Management Association in Support of Plaintiffs' Motion for Stay or for Summary Judgment, ECF No. 46-1, at 7-13; (same); Amicus Curiae Brief by Physicians Advocacy Institute, Nine National Medical Specialty Societies, and Sixteen State Medical Associations in Support of Plaintiffs' Motion For Stay or Summary Judgment, ECF No. 64, at 7-10 (same).

Letter from Members of Congress to Department Secretaries, at 1 (Nov. 5, 2021), https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf (The September Rule's presumption-based approach for determining payment rates "do[es] not reflect the way the law was written, do[es] not reflect a policy that could have passed Congress, and do[es] not create a balanced process to settle payment disputes."). Congress was well aware that mandating a benchmark rate would destroy that balanced approach and eliminate the insurers' incentive to negotiate. *See* Brief of Members of Congress as Amici Curiae in Support of Plaintiffs, at 11-13, ECF No. 65 (discussing Congress's awareness that mandating a benchmark rate risked dropping average *in-network* provider payment rates by 15 percent to 20 percent). And even the Departments acknowledge that undercompensating providers could "threaten the[ir] viability," which "in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care, undermining the goals of the No Surprises Act." 86 Fed. Reg. at 56,044.

The Departments rely primarily on House Report 116-615, for H.R. 5800, 116th Cong. (2d. Sess. 2020), for their assertion that, aside from consumer protection, Congress had one goal and one goal alone—reducing healthcare costs—and that the QPA presumption was necessary to carry out that goal. As a preliminary matter, not only did Congress reject that bill, there is no indication that it adopted H.R. Rep. 116-615, or any other legislative report, for the Act.[11] But even if the

[11] Among other differences, Congress did not carry over two of H.R. 5800's key cost containment provisions to the enacted bill. *See* H.R. REP. NO. 116-615, pt. I, at 58. While H.R. 5800 set the median contracted rate as the default payment rate at the beginning of the parties' negotiations, *see, e.g.*, H.R. REP. NO. 116-615, pt. I, at 2 (§ 2(b)(1)(C)(iv)); *id*. at 29-30 (§ 4(a)), the Act does not establish any default payment rate, *see* 42 U.S.C. § 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K), (c)(1)(A). And while H.R. 5800 prohibited claims under $750 for providers like the Plaintiffs from entering arbitration (thus increasing the likelihood that they would be paid at the default median contracted rate), *see, e.g.*, H.R. REP. NO. 116-615, pt. I, at 31 (§ 4(b)(2)), the Act allows claims of any value to move to arbitration, *see* 42 U.S.C. § 300gg-111(c)(1)(B). Thus, even if H.R. 5800's House Report may be relevant in certain ways to the Act, its relevance for demonstrating Congress's concern for cost containment is questionable.

Departments are right about Congress's goals, their reliance on this Report is misplaced for several reasons.

First, the authorities the Departments invoke show that the Act *as a whole* is expected to contribute to a reduction in healthcare costs, even without a presumption in favor of the QPA. The Congressional Budget Office ("CBO") found that the Act is expected to reduce premiums by between .5 percent and 1 percent—but there is no indication that the CBO assumed a presumption in favor of the QPA in scoring the Act.[12] *See* CBO, *Estimate for Divisions O Through FF, H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260*, at 2-3 (Jan. 14, 2021), https://www.cbo.gov/system/files/2021-01/PL_116-260_div%20O-FF.pdf (discussion of Division BB). Indeed, the Departments acknowledged in the September Rule that the CBO analysis did not isolate the effect attributable even to the "Federal IDR process," 86 Fed. Reg. at 56,059, let alone the QPA presumption.

There are many other explanations for a reduction in costs and premiums aside from a QPA presumption. Because the Act prohibits balance bills to patients, such bills cannot be a basis for hiking rates. Moreover, the expert arbitrators are prohibited from considering certain factors that

[12] The Departments imply such a budgetary assumption by citing language from the CBO's scoring of yet another rejected bill, H.R. 5826. *See* Opp. 10 n.3. In H.R. 5826, however, the median contracted rate was the *only mandated factor*. *See* H.R. 5826, § 7(j)(5), 116th Cong. (2d Sess. 2020). It is therefore unsurprising that the CBO thought the median contracted rate would exert a gravitational pull on payment rates. *See CBO*, *H.R. 5826, the Consumer Protections Against Surprise Medical Bills Act of 2020, as Introduced on February 10, 2020: Estimated Budgetary Effects*, at 1 (Feb. 11, 2020), https://www.cbo.gov/system/files/2020-02/hr5826table.pdf (noting that arbitrators "would be instructed to look to the health plan's median payment rate" and that "average payment rates for both in- and out-of-network care would move toward the median in-network rate[.]"). In contrast, when scoring the Act that Congress actually passed, the CBO made no reference to the QPA or median contracted rate. *See* CBO, *Estimate for Divisions O Through FF, H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116-260*, at 2-3 (Jan. 14, 2021), https://www.cbo.gov/system/files/2021-01/PL_116-260_div%20O-FF.pdf (discussion of Division BB).

would be expected to drive up healthcare costs, such as "usual and customary" charges (*i.e.*, "the amount[s] providers in a geographic area usually charge for the same or similar medical service," 86 Fed. Reg. at 55,999) and what a provider would have billed absent the Act. *See* 42 U.S.C. § 300gg-111(c)(5)(D) (detailing factors arbitrators "shall not consider"); 86 Fed. Reg. at 55,999 (discussing prohibited considerations); H.R. REP. NO. 116-615, pt. I, at 57 (expressing concern that consideration of billed charges "[might] drive up consumer costs"). All of those things can be expected to reduce healthcare costs, without the need for the Departments' invented presumption.

Second, even taking the rejected bill's House Report at face value, it does not support premium reduction at all costs, but rather expresses a desire to achieve a carefully balanced IDR process to bridge the interests of multiple stakeholders. The Report explains that, "while meaningfully improving the affordability of care for millions, the bill was carefully crafted to strike a balance between the various concerns of stakeholders—including *providers*, *hospitals*, labor unions, health insurers, and employers—many of whom have divergent views on how to effectively address the issue of surprise billing." H.R. REP. NO. 116-615, pt. I, at 50-51 (emphasis added). And while the Report recognizes a benchmark's ability to "generally slow the rapid growth of health care costs," it also lauds the advantages of an arbitration process, which will "allow[] payment rates to vary more for specific circumstances and potentially adjust more easily over time." *Id.* at 57-58 (internal quotation marks omitted). Thus, the Report itself perfectly illustrates the basic legal principle that "[n]o legislation pursues its purposes at all costs." *American Exp. Co. v. Italian Colors Rest.*, 570 U.S. 228, 234 (2013).

Finally, the Report nowhere identifies a presumption in favor of the QPA as an appropriate way to reduce healthcare costs. To the contrary, in summarizing the factors an arbitrator should consider when determining the appropriate payment rate—factors that substantially overlap with

the Act's—the Report described arbitrators as "authorize[d] . . . to consider *several factors* in determining payment amounts, *including* the median contracted rate for a similar item or service furnished in the same geographic area, the level of training and experience of the provider, *and* extenuating circumstances such as the complexity of the specific case or the acuity of the patient." H.R. REP. NO. 116-615 at 60 (emphases added). In no way did the Report suggest that one factor was more important than others. *See* Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 116 (2012) ("With the conjunctive list, all [listed] things are required[.]"). The Report instead addressed cost containment by focusing on the danger that "non-market-based rates such as providers' billed charges" might "drive up consumer costs." H.R. REP. NO. 116-615 at 57. H.R. 5800, like the Act, thus would have prohibited arbitrators from considering providers' billed charges. *Compare id.* at 60, *with* 42 U.S.C. § 300gg-111(c)(5)(D).

For all these reasons, the Departments' retreat to purposivism should be rejected. Like many statutes that are the product of a "laborious," "cumbersome," and sometimes "frustrating" legislative process, *Coalition for Responsible Regulation, Inc. v. E.P.A.*, Nos. 09-1322, et al., 2012 WL 6621785, at *22 (D.C. Cir. Dec. 12, 2012) (Kavanaugh, J., dissenting from denial of rehearing en banc) (cited in *Utility Air Regul. Grp. v. E.P.A.*, 573 U.S. 302 (2014)), the Act that emerged from the legislative scrum may not have been the Departments' favored policy. But the *only* question for this Court is whether the Departments have stayed "within the statutory limits set by Congress"—not the boundaries that the Department wished Congress had enacted. *Id.*; *see Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016) ("Disagreeing with Congress's expressly codified policy choices isn't a luxury administrative agencies enjoy.").[13]

[13] Most of the *amicus* briefs submitted in support of the Departments ignore the actual text of the Act in favor of policy arguments. But it is, of course, not the role of *amici* to ask this Court

II. THE DEPARTMENTS' INTERPRETATION IS OWED NO DEFERENCE

The Departments' argument for *Chevron* deference fails because their September Rule interpreting the Act's "Payment determination" provision is inconsistent with the clear text and design of the statute, does not purport to resolve a statutory ambiguity, was adopted without notice and comment, and is otherwise unreasonable.

First, the Departments' interpretation of the Act is contrary to its plain and unambiguous meaning. A court will not defer to an agency's interpretation when "Congress has directly spoken to the precise question at issue." *American Fuel & Petrochemical Mfrs. v. E.P.A.*, 3 F.4th 373, 380 (D.C. Cir. 2021) (quoting *Chevron U.S.A., Inc. v. Natural Res. Def. Council Inc.*, 467 U.S. 837, 843 n.9 (1984)). Here, 42 U.S.C. § 300gg-111(c)(5) unambiguously speaks to the direct question at issue by including a detailed listing of the factors an arbitrator "shall" and "shall not" consider in making that determination. Indeed, the Departments have never argued—either in their briefs or the Rule itself—that Congress's language is even "ambiguous" and thus requiring agency implementation. *Cf.* Opp. 21 (arguing that Act gives Departments authority "to resolve any ambiguities," not that language is actually ambiguous); *id.* at 25-26 (similar); *id.* at 24 (defending Departments' authority to revolve "any statutory doubt").

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to choose their preferred policies over the text Congress actually enacted. And while the brief of *amici* Senator Patty Murray and Representative Frank J. Pallone contends that the text "appropriately gives *preeminence* to the QPA," Amici Curiae Brief of Congressional Committee Leaders in Support of Defendants' Cross-Motion for Summary Judgment/Opposition, at 10, ECF No. 73-1 (emphasis added), that assertion stands in marked contrast to how Senator Murray described the law shortly before it was passed, *see* Press Release, Senator Murray Announces Bipartisan Deal to Protect Patients, End Surprise Medical Bills (Dec. 11, 2020), https://www.murray.senate.gov/senator-murray-announces-bipartisan-deal-to-protect-patients-end-surprise-medical-bills/ (noting that the arbitrator is "*required to consider* the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, *and* any other information submitted by the parties" (emphases added)).

Second, the Departments' Rule is owed no deference because it did not "manifest[] [their] engagement in the kind of interpretive exercise to which review under *Chevron* generally applies." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 22 (D.C. Cir. 2019) (quoting *SoundExchange, Inc. v. Copyright Royalty Bd.*, 904 F.3d 41, 54 (D.C. Cir. 2018)); *see also Michigan v. E.P.A.*, 576 U.S. 743, 758 (2015). *Chevron* deference "is reserved for those instances when an agency recognizes that the Congress's intent is not plain from the statute's face," and "bring[s] its experience and expertise to bear in light of competing interests at stake." *Peter Pan Bus Lines, Inc. v. Federal Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006). In the September Rule, the Departments stated merely that theirs was the "best interpretation" of the Act's payment determination provisions based on the Act's contextual and structural features. 86 Fed. Reg. at 55,996. But an agency cannot claim deference when it does not rely on "its experience and expertise" to interpret a statute but instead merely "pars[es] . . . the statutory language," *PDK Laboratories Inc. v. U.S. D.E.A.*, 362 F.3d 786, 797-798 (D.C. Cir. 2004), or when it adopts a regulation "not based on the agency's own judgment but rather on the unjustified assumption that it was Congress's judgment that such a regulation is desirable or required," *Arizona v. Thompson*, 281 F.3d 248, 259 (D.C. Cir. 2002) (internal brackets and quotation marks omitted); *cf. Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1629 (2018) ("To preserve the balance Congress struck in its statutes, courts must exercise independent interpretive judgment.").

Third, Congress did not delegate any authority to the Departments to direct the arbitrator how to determine appropriate payment rates.[14] Instead, in the section titled "Payment determination," Congress conferred authority on the expert arbitrator, and the arbitrator alone, to

[14] The comment letters from the AMA and AHA cited by the Departments, *see* Opp. 26, say nothing about the Departments' authority to issue legislative rules on the weighting of the

select one of the payment offers, and mandated precise factors for the arbitrator to consider (and not consider) in making that selection. *See* 42 U.S.C. § 300gg-111(c)(5)(A) ("[T]he certified IDR entity shall . . . taking into account the considerations specified in subparagraph (C), select one of the offers[.]"); *see also id.* § 300gg-111(c)(4)(A) (the arbitrator must have "sufficient medical, legal, and other expertise" to assess the Subparagraph C Factors and make a payment determination).

In arguing that Congress conferred discretion on them to direct the arbitrator's consideration of the Subparagraph C Factors, the Departments rely on Congress's delegation to "establish by regulation one independent dispute resolution process." 42 U.S.C. § 300gg-111(c)(2)(A); *see* Opp. 24-26. But this general assignment of implementation authority for the Departments to stand up the IDR process surely does not amount to an invitation to direct the outcome of that process by altering the substantive parameters of the "Payment determination," which Congress chose to elaborate in an entirely different paragraph (paragraph (c)(5), not (c)(2)). As Plaintiffs explained in their Motion (at 30 & n.7), Congress's use of the word "establish" demonstrates that Congress did not give the Departments the free-ranging authority they claim to restructure the arbitrator's discretionary payment determinations. Yet again, the Departments offer no response.[15]

Subparagraph C Factors. Nor could they give rise to estoppel regardless, as their "preferred approach [was not] adopted by the agency." *South Coast Air Quality Mgmt. Dist. v. E.P.A.*, 472 F.3d 882, 892 (D.C. Cir. 2006).

[15] The grant of authority to the Departments to "establish" an IDR process (so clearly separated from Congress's specification of the substantive factors the arbitrator should consider) is also strikingly different from Congress's grant of authority to establish the "methodology" for insurers "to determine the [QPA]." 42 U.S.C. § 300gg-111(a)(2)(B)(i). There, Congress mandated certain substantive inputs the rulemaking "shall take into account," while also granting the Departments discretion regarding other considerations that "[s]uch methodology may account for." 42 U.S.C. § 300gg-111(a)(2)(B)(iv).

The Departments' argument regarding 42 U.S.C. § 300gg-111(c)(2)(A) is unclear. But to the extent they rely on the word "one" in "one independent dispute resolution process," that language is best understood as instructing the three different Departments and the Office of Personnel Management to establish a *single* arbitration process, as opposed to multiple, separate processes by department. The word "one" does not imply that the Departments were to enjoy complete control over the *substance* of the IDR, especially where Congress delegated that authority elsewhere. Similarly, to the extent the Departments rely on the word "process," that also cannot withstand scrutiny. Distinctions between process and substance are fundamental in the law, *e.g.*, *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 407 (2010), and presumptions have historically been considered substantive, not procedural, matters, *e.g.*, *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446 (1959). Ultimately, without any viable textual hook, the Departments cannot rely on 42 U.S.C. § 300gg-111(c)(2)(A) as the basis for rulemaking authority here. And they have no other explanation for why, as Plaintiffs pointed out (at 30), Congress explicitly assigned the Departments implementation authority elsewhere in the IDR provisions of the Act, *see, e.g.*, 42 U.S.C. §§ 300gg-111(c)(3)(A) & 300gg-111(c)(4)(A), but *not* in the subsection governing the arbitrator's "Considerations in determination," *see id.* § 300gg-111(c)(5)(C).

Fourth, "*Chevron* deference is not warranted where the regulation is 'procedurally defective'—that is, where the agency errs by failing to follow the correct procedures in issuing the regulation." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016); *see id.* ("[W]here a proper challenge is raised to the agency procedures, and those procedures are defective, a court should not accord *Chevron* deference to the agency interpretation."). The Departments' QPA-presumption rules are procedurally defective because they were issued without the notice and

comment required by the Administrative Procedure Act ("APA"). The Departments suggest (Opp. 28 n.11) that the only remedy for a procedural violation here is to remand the Rule back to the Departments to correct the defect. But *Encino Motorcars* itself remanded the case "for the Court of Appeals to interpret the statute in the first instance" without *Chevron* deference. 579 U.S. at 224. Contrary to the Departments' contention, the fact that the dispute was between two private parties rather than against an agency played no role in the Court's decision, nor did it deprive the judiciary of its duty to interpret the statute.

The Departments' arguments in defense of the procedures they used are unavailing. The Departments first argue that they were not required to provide notice or consider comments because the Act's organic statutes authorized them to "promulgate any interim final rules as the Secretary determines are appropriate to carry out" the respective statutes. Opp. 28 (quoting 42 U.S.C. § 300gg-92). That argument has been rejected by every court to consider it. *See Pennsylvania v. President of the U.S.*, 930 F.3d 543, 565-567 (3d Cir. 2019), *rev'd on other grounds sub nom. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020); *California v. Azar*, 911 F.3d 558, 578-580 (9th Cir. 2018); *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 17-19 (D.D.C. 2010). The APA's notice-and-comment requirement can be superseded only when a statute "does so expressly." 5 U.S.C. § 559; *see Association of Data Processing Serv. Orgs., Inc. v. Board of Governors of Fed. Rsrv. Sys.*, 745 F.2d 677, 686 (D.C. Cir. 1984) (Scalia, J.). Neither the Act nor its organic statutes did any such thing.

The Departments nonetheless claim that they satisfy the APA's "good cause" exception, 5 U.S.C. § 553(b)(B), because (1) insurers needed information to determine how much they would need to pay providers for out-of-network services and thus the amounts they would need to set as

premiums; and (2) providers needed advance notice on the types and nature of information they would need to develop to contemporaneously develop their claims. Opp. 29-30. Plaintiffs, however, challenge only the portion of the Departments' September Rule relating to the factors considered by the arbitrator in making the payment determination. Although the Rule altered the weighing of those factors, it did not require any information not already mandated by the Act itself.[16] The need to give insurers and providers advance notice of such information therefore cannot establish good cause.

Nor does a desire to provide regulatory guidance to affected parties sooner rather than later constitute "good cause." *See United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009). The Departments claim that doing so was necessary "to avoid increasing health care premiums," Opp. 29, but they made no such finding in the September Rule and thus cannot rely on that justification here. *See Michigan*, 576 U.S. at 758. In any event, the desire to fulfill a policy goal "is not the type of exigent circumstance that comes within the narrow 'good cause' exception," which is reserved for "emergency situations." *Chamber of Com. of U.S. v. S.E.C.*, 443 F.3d 890, 908 (D.C. Cir. 2006). Accordingly, the Departments failed to follow the correct procedures and *Chevron* deference is not warranted.[17]

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[16] In urging the Departments to give them sufficient time to implement the Act, Plaintiffs never asked the Departments to forgo notice and comment, and they certainly did not ask the Departments to forgo notice and comment with respect to a rule establishing a presumption in favor of the QPA. The Departments are therefore wrong to suggest that Plaintiffs have reversed course in this litigation on the September Rule's procedural propriety. *See* Opp. 27.

[17] Citing *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225 (D.C. Cir. 1994), the Departments contend (at 28) that forgoing notice-and-comment rulemaking is permissible where statutory deadlines are tight. But the lead time in that case was only five months, and the statutory scheme was especially "complex." 38 F.3d at 1237. Here, the Departments had "a substantial period of time within which to propose regulations"—more than a year—"the promulgation of which [they] knew was both necessary and forthcoming in the near future." *American Fed'n of Gov't Emps. v. Block,* 655 F.2d 1153, 1158 (D.C. Cir. 1981) (citing *Kollett v. Harris,* 619 F.2d 134

Finally, the September Rule could not even survive any *Chevron* Step Two inquiry. The Departments' interpretation is owed no deference because it is "unreasonable" in light of Congress's intentional balancing of the interests of both providers and insurers reflected in the statute's detailed list of factors for the arbitrator to consider (and not consider). *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). The Departments nonetheless contend that the QPA presumption is reasonable in light of Congress's purported goal of reducing premiums. But as the Departments themselves recognized in the September Rule, it is unclear whether the Act, let alone the arbitration process, will actually reduce premiums—and there is some evidence that the Act will increase premiums:

> The Congressional Budget Office estimated the provisions in the No Surprises Act are likely to reduce premiums by 0.5 percent to 1 percent in most years. In comparison, the CMS's Office of the Actuary (OACT) estimated the provisions are likely to increase premiums by 0.00 percent to 0.35 percent. *Neither of these estimates isolate the effect attributable to the Federal IDR process*.

86 Fed. Reg. at 56,059 (emphasis added) (footnotes omitted). And for all of the Departments' discussion of predictability of IDR outcomes, they cite no evidence that this was one of *Congress's* policy goals. Thus, when the Departments "replaced [the multiple statutory factors] with [a presumption] of [their] own choosing," they "went well beyond the bounds of [their] statutory authority" and adopted an unreasonable construction of the Act. *Utility Air Regul. Grp.,* 573 U.S. at 326 (internal quotation marks omitted). A court does not defer to an interpretation that "conflict[s] with the policy judgments that undergird the statutory scheme." *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994).

(1st Cir. 1980)). And there is nothing complex about how the No Surprises Act directs the arbitrator to apply the statutorily listed factors. In fact, no rule at all was needed because the statute itself governs how the factors must operate.

III. THE COURT SHOULD VACATE THE SEPTEMBER RULE OR ENTER A STAY PENDING REVIEW

Because Plaintiffs are already suffering and will continue to suffer irreparable harm unless and until this Court issues relief, they are entitled to either (1) an expedited summary judgment ruling that vacates the September Rule, or (2) a stay of the September Rule pending judicial review. Either remedy would alleviate their ongoing harm.[18]

A. The Court Should Vacate The Challenged Portions Of The September Rule

When agency action is found unlawful, "the practice of the court is ordinarily to vacate the rule." *Illinois Pub. Telecomms. Ass'n v. F.C.C.*, 123 F.3d 693, 693 (D.C. Cir. 1997). Indeed, vacatur is the default APA remedy when an agency exceeds its statutory authority or acts contrary to law. *See* 5 U.S.C. § 706 (the reviewing court "shall . . . set aside" unlawful agency action). In this case, both the "seriousness of the [September Rule]'s deficiencies" and "the disruptive consequences of an interim change that may itself be changed" require vacatur. *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-151 (D.C. Cir. 1993).

First, the Departments committed a serious error when they altered the statutory scheme Congress created for determining out-of-network payment rates. The September Rule's modification directly conflicts with the No Surprises Act. This fundamental legal error is not one that can be fixed on remand through further "substantia[tion]." Opp. 35 (quoting *Radio-Television News Dirs. Ass'n v. F.C.C.*, 184 F.3d 872, 888 (D.C. Cir. 1999)). Moreover, "deficient notice is a

[18] If the Court needs additional time to resolve record-dependent legal questions raised by Plaintiff Air Medical Services, Plaintiffs respectfully request that the Court issue expedited summary judgment on the overlapping claim challenging the Departments' QPA presumption. *See* FED. R. CIV. P. 56(a) ("A party may move for summary judgment, identifying *each claim* or defense — *or the part of each claim* or defense — on which summary judgment is sought." (emphasis added)).

'fundamental flaw' that almost always requires vacatur." *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) (citing *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009)). Because the September Rule's QPA presumption contravenes the Act, only vacating the presumption-based portions of the Rule will suffice.[19]

Second, the Departments are incorrect that vacatur will be "highly disruptive" and leave arbitrators "with no guidance as to how to proceed with their decision-making." Opp. 35. With arbitrations not yet having occurred, "[t]his is not a case in which the 'egg has been scrambled,' and it is too late to reverse course." *Allina*, 746 F.3d at 1110-1111 (citing *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002)). Further, the Act itself provides all the guidance arbitrators need to determine which of the parties' offers to select. Upon vacatur, arbitrators could apply the Act as written, weighing the Subparagraph C Factors in deciding between the two offers as a given case demands. Any arbitrations that implement the QPA presumption, by contrast, will be "highly disruptive" to Congress's chosen scheme. The Rule also leaves providers at the mercy of insurers who, equipped with the Rule's QPA presumption, can demand unreasonably low payment rates for both out-of-network and in-network rates with lasting effects on market dynamics and, thus, access to patient care. *See* Mot. 34-38 (describing provider declarations attesting to this harm).

[19] The Departments make the perplexing argument that even if the Court finds in Plaintiffs' favor, 45 C.F.R. § 149.510(c)(4)(vi)(B) should not be invalidated because Plaintiffs "offer no argument . . . to challenge [its] validity." Opp. 35 n.13. That provision, however, requires arbitrators, if and only if they select the offer farther from the QPA, to "include an explanation of the credible information that the certified IDR entity determined demonstrated that the [QPA] was materially different from the appropriate out-of-network rate." 45 C.F.R. § 149.510(c)(4)(vi)(B). The validity of this provision rises and falls with the validity of the QPA presumption. Nothing in the Departments' reporting obligations is to the contrary, as the Departments are not required to report anything about the IDR entities' reasoning. *See* 42 U.S.C. § 300gg-111(c)(7).

Finally, the Departments have informed another court that the final rule could be completed by May 2022. Defs.' Reply Mem. in Supp. of their Cross-Mot. for Summ. J., *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, No. 21-cv-425, at *16 (E.D. Tex. Feb. 2, 2022), ECF No. 104. That timeline is not a basis for remand rather than vacatur. As noted, the QPA presumption is so fundamentally contrary to law that it cannot be saved in a final rule. The Departments thus cannot credibly ask this Court to allow them to act unlawfully, even if it is only for just a few more months. In addition, the No Surprises Act provides that individual arbitration decisions are not subject to judicial review. *See* 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II). Consequently, any arbitration conducted during the period between this Court's decision and the final rule's issuance will be irreversible. Parties should not be forced to arbitrate under standards that manifestly violate the Act simply because the Departments hastily issued an illegal interim final rule.

B. Absent Immediate Vacatur, The Court Should Enter A Stay

An immediate stay of the challenged provisions of the September Rule is equally warranted given the ongoing irreparable harm Plaintiffs are suffering. In fact, because the Departments did not contest the evidence Plaintiffs submitted regarding irreparable harm, this Court would be well within its authority to issue the requested stay immediately. *See, e.g.*, *Shvartser v. Lekser*, 330 F. Supp. 3d 356, 361 (D.D.C. 2018) (no evidentiary hearing required on preliminary injunction motion where defendants raised no "genuine issues of material fact"); *see also* FED. R. CIV. P. 78(b) ("By rule or order, the court may provide for submitting and determining motions on briefs, without oral hearings."). Regardless, the Departments' attempts to dismiss Plaintiffs' irreparable

harm as premised on a misunderstanding of how the September Rule operates, or as too speculative because it involves the actions of third parties, fall flat.

First, the September Rule unmistakably places a heavy thumb on the scale in favor of the QPA, to the advantage of commercial insurers and the detriment of providers. Indeed, that is the Rule's very purpose, as the Departments argue, Opp. 10, 23-24, and it is also the reason why the commercial insurance industry supports the Departments, *see, e.g.*, AHIP Amicus Br., ECF No. 62-1; BCBS Amicus Br., ECF No. 80-1.

Beyond the imminent harms providers will suffer in arbitration, the Rule's presumption in favor of the QPA is *already* harming providers in contract negotiations. By allowing insurers to pay out-of-network providers at unfairly low rates, insurers are able to leverage the Rule and demand commensurately low rates from *in-network* providers, with the threat that they will cancel in-network agreements if providers do not capitulate. Mot. 34. Insurers' demands for lower contract payments are thus "a direct result of" the September Rule's QPA presumption. *Hunter v. F.E.R.C.*, 527 F. Supp. 2d 9, 14-15 (D.D.C. 2007) (Leon, J.) (emphasis omitted).

The Departments suggest that this harm is speculative, but Plaintiffs have provided unrebutted evidence of such demands in their stay motion. That evidence includes the declaration of Plaintiff Renown Health's Chief Transformation Officer, who explained that one insurer has already "explicitly stated" that it will "no longer contract for emergency services with" Renown Health in light of the September Rule. Sexton Decl. ¶ 24; *see Fox Television Stations, Inc. v. FilmOn X LLC*, 966 F. Supp. 2d 30, 50 (D.D.C. 2013) (finding irreparable harm to plaintiffs by defendants' unauthorized use of their content supported by sworn declaration that "cable companies ha[d] already referenced" unauthorized online streaming "in seeking to negotiate lower fees" with plaintiff copyright holders). It also includes the declaration of the Vice President of

Health System Contracting at UMass Memorial Health, who explains—based on her 22 years of experience at UMass Memorial Health and recent experience with a Massachusetts law similar to the September Rule's QPA presumption—that the September Rule will incentivize "national and local insurers in the Massachusetts market [to] soon similarly threaten to terminate their provider contracts if providers are unwilling to accept substantial rate reductions." Rossi Decl. ¶ 25. Plaintiff Dr. Squires similarly attested that the September Rule "appears to have empowered Blue Cross to demand that we accept in-network payment rates that are far below the value of our services." Squires Decl. ¶ 12. The Departments' brief generally disputes that the Rule's effect on these contract negotiations represents irreparable harm, but they have offered no counter-affidavits to dispute the immediate harmful effect the rule is actually having on Plaintiffs.

Numerous courts have found irreparable harm based on evidence that a defendant's actions will impede the ability to negotiate with counterparties not before the court.[20] Injuries to a party's position in contract negotiations are particularly harmful because of the impossibility of ever "recreat[ing] the atmosphere of free negotiations that would have existed in the absence of" such influences. *Iowa Utilities Bd. v. F.C.C.*, 109 F.3d 418, 425 (8th Cir. 1996); *see id.* at 422, 425 (finding irreparable harm where FCC's pricing rules were "confin[ing] and restrict[ing] the give and take characteristic of free negotiations"). Plaintiffs have demonstrated the same harm here.

[20] *E.g.*, *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 866 (9th Cir. 2017) (evidence that defendant's "service undermines the value of [plaintiffs'] copyrighted works . . . and negotiating leverage with licensees" supported irreparable harm finding); *WPIX, Inc. v. ivi, Inc.*, 691 F.3d 275, 285-286 (2d Cir. 2012) (evidence that defendant's retransmissions of plaintiffs' content would "weaken plaintiffs' negotiating position with advertisers" helped establish irreparable harm); *FilmOn X LLC*, 966 F. Supp. 2d at 50 (irreparable harm finding supported by evidence that defendant's unauthorized online streaming gave counterparties leverage "in seeking to negotiate lower fees" with plaintiff copyright holders).

The Departments respond by asserting that a stay of the September Rule's QPA presumption would have no impact on providers' negotiations with insurers because insurers will maintain a hard line based on their expectations as to the final outcome of this litigation and the Departments' rulemaking. Opp. 34. If the Departments were right that insurers would still expect the Rule ultimately to be upheld despite this Court's grant of a stay, that would merely provide reason for this Court to expeditiously grant summary judgment. But their assertion defies the lessons of the many cases cited above granting motions for *preliminary injunctions* (or stays) based on irreparable harm related to impacts on negotiations with third-parties. And, at bottom, the government would have this Court believe that insurers coincidentally began demanding reimbursement cuts or threatening to cancel contracts at exactly the same time the Departments issued the September Rule. Commonsense counsels otherwise. A ruling from this Court that Plaintiffs are likely to succeed on the merits would demonstrate to insurers that the Departments' interpretation of the No Surprises Act is contrary to law, thereby depriving insurers of undue leverage and restoring balance in contract negotiations.

The Departments' further arguments lack merit. Although they contend that Plaintiffs unreasonably delayed in seeking a stay two months after the September Rule's effective date, Opp. 32-33, there was no delay: Plaintiffs sought a stay on the same day they filed their complaint, and asked for the Court to grant relief within approximately three months, *i.e.*, by March 1, 2022. The Departments cite no cases where a gap of just two months between a rule's issuance and the filing of a preliminary injunction was deemed unreasonable. *Cf. RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1211-1212 (10th Cir. 2009) (two-year delay acceptable); *Ideal Indus., Inc. v. Gardner Bender, Inc.*, 612 F.2d 1018, 1025 (7th Cir. 1979) (fifteen-month delay acceptable).

In addition, "waiting to file for preliminary relief until a credible case for irreparable harm can be made [was] prudent rather than dilatory." *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 245 (D.D.C. 2014) (*quoting Arc of Cal. v. Douglas*, 757 F.3d 975, 991 (9th Cir. 2014)). Plaintiffs were not on notice that the September Rule would have immediate irreparable consequences until November and December 2021, when insurers started informing providers that they were going to use the Rule as the basis to reduce contracted rates or discontinue contracts for certain services altogether. *See, e.g.*, Mot. 34-35; Sexton Decl. ¶ 24 (citing a December 2, 2021 negotiation). Likewise, Plaintiffs had originally hoped the Departments would address their concerns during the notice and comment period, but public statements from the Departments eventually made clear that the September Rule was unlikely to change. Mot. 10-11. In any event, "[d]elay is but one factor in the irreparable harm analysis," *Gordon v. Holder*, 632 F.3d 722, 725 (D.C. Cir. 2011), and any minor "delay" here in no way undermines the genuine harm that Plaintiffs face.

Lastly, the Departments' arguments about the balance of equities and public interest are a rehash of their other meritless contentions and should be similarly rejected. Critically, they do not dispute that undercompensating providers "could lead to participants, beneficiaries and enrollees not receiving needed medical care," 86 Fed. Reg. at 56,044, or that "[t]here is clearly a robust public interest in safeguarding prompt access to health care," *Whitman-Walker Clinic, Inc. v. United States Dep't of Health & Hum. Servs.*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020). Nor do the Departments dispute that the public interest favors discontinuance of unlawful government action and safeguarding patient access to quality care. These stay factors thus strongly favor Plaintiffs.

CONCLUSION

For the foregoing reasons, this Court should grant as soon as possible, and before March 1, 2022, (i) a stay pending judicial review of the provisions of the September Rule that require

IDR entities to employ a presumption in favor of the offer closest to the QPA, or in the alternative, (ii) summary judgment in Plaintiffs' favor vacating the challenged provisions of the September Rule.

Respectfully submitted,

Dated: February 8, 2022

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EXHIBIT A

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

January 2022

Table of Contents

1. General Information and Background

1.1 Background

Effective January 1, 2022, the No Surprises Act[1] (NSA) 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 facility, provider, 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 only the in-network cost-sharing amount for these services. Health plans, issuers, and Federal Employees Health Benefits (FEHB) Program Carriers[3,4] 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 payment[5] 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 must enter into a 30-business-day open negotiation period to determine an alternate payment amount. If that the 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 (or cases in the event of batched claims) and items or services received and determine the final payment amount.

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*,[6] (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] Unless otherwise noted, group health plans, health insurance issuers offering group and individual coverage and FEHB carries are all referred to as health plans or plans in this document.
[5] 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 may 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.
[6] Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55980 (October 7, 2021), https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf.

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 July 13, 2021, *Requirements Related to Surprise Billing; Part I*[7] (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, as defined in Appendix A; and
- Air ambulance services furnished by OON providers of air ambulance services.

The interim final rules implementing the Federal IDR Process 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 or facility or provider of air ambulance 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

[7] 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.

provides a method for determining the total amount payable for OON items and services, the state process will govern, rather than the Federal method for determining the OON rate under the NSA.

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.

Steps Preceding the Federal IDR Process

TIMELINE	SUMMARY OF STEPS
Start:	A furnished covered item or service results in a charge for emergency items or services from an OON provider or facility, a charge for non-emergency items or services from an OON provider at an in-network facility, or for air ambulance services from an OON provider of air ambulance services.
Within 30 calendar days	**Initial Payment or Notice of Denial of Payment** Must be sent by the plan, issuer, or carrier no later than *30 calendar days* after a clean claim is received.
30 business days	**Initiation of Open Negotiation Period** An open negotiation period must be initiated within *30 business days* 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, issuer, or carrier.
	Open Negotiation Period Parties must exhaust a *30 business-day* open negotiation period before either party may initiate the Federal IDR Process.

Federal IDR Process Overview

TIMELINE	SUMMARY OF STEPS
4 business days	**Federal 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 *4 business days* after the close of the open negotiation period. Such notice should include the initiating party's preferred certified IDR entity, if applicable.
6 business days after initiation	**Selection of Certified IDR Entity** If the initiating party selects a preferred IDR entity, the non-initiating party can accept the initiating party's preferred certified IDR entity or object and propose another certified IDR entity. A lack of response from the non-initiating party **within 3 business days** will be deemed to be acceptance of the initiating party's preferred certified IDR entity. If the parties do not agree on a certified IDR entity, this step also includes timeframes for the initiating party to notify the Departments that they should randomly select a certified IDR entity on their behalf. If necessary, the Departments will make a selection no later than *6 business days* after IDR initiation. The certified IDR entity may bill/invoice the parties for administrative fees at the time of selection (administrative fees are due from both parties by time of offer submission).
3 business days after selection	**Certified IDR Entity Requirements** Once selected, within *3 business days*, the certified IDR entity must submit an attestation that it does not have a conflict of interest and determine that the Federal IDR Process is applicable.
10 business days after selection	**Submission of Offers and Payment of Certified IDR Entity Fee** Parties must submit their offers not later than *10 business days* after selection of the certified IDR entity. Each party must pay the certified IDR entity fee, which the certified IDR entity will hold in a trust or an escrow account, and the administrative fee when submitting its offer.
30 business days after selection	**Selection of Offer** A certified IDR entity has *30 business days* after its date of selection to determine the payment amount and notify the parties and the Departments of its decision. The certified IDR entity must select one of the offers.
30 calendar/ business days after determination	**Payments Between Parties of Determination Amount & Refund of Certified IDR Entity Fee** Any amount due from one party to the other party must be paid not later than *30 calendar days* after the determination by the certified IDR entity. The certified IDR entity must refund the prevailing party's certified IDR entity fee paid within *30 business days* after the determination.

2. Open Negotiations

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

- Emergency services furnished by an OON provider or facility subject to the NSA; or air ambulance services furnished by an OON provider of air ambulance services; or OON provider services furnished at an in-network facility; and
- Furnished to a covered 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 definition of QPA at Section 7.2.1. below).

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;
- The service code 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.[8]

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

- The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and

[8] See "Open Negotiation Period Notice" at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/no-surprises-act.

- 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.

If the open negotiation notice is not properly provided to the other 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 through the Federal IDR portal[9] at https://www.nsa-idr.cms.gov. Additionally, if either party believes that the other party is not in compliance with the balance billing protections, they may file a complaint with the No Surprises Help Desk at 1-800-985-3059. 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 6.

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**[10] 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 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

[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] 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.

portal at https://www.nsa-idr.cms.gov. 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 Federal IDR Initiation

The **Notice of IDR Initiation** sent by the initiating party to the other party, may be accessed through the Federal IDR portal at https://www.nsa-idr.cms.gov, and may be sent electronically (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, or plan);
- 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 or service (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 or 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.

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, as described above. 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 occur within the **3-business day** period for the selection of the certified IDR. 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

When 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 include an explanation of the reason for objecting and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity within the **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 below 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.

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 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 via the Federal IDR portal 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 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.

Ultimately, 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** 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.

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

[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.

provided for in the *Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act*). If there are insufficient 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

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 below in Section 4.6.1. The certified IDR entity must also determine whether the Federal IDR Process as described below in Section 4.6.2.

A certified IDR entity:
1) Must attest to being free of conflicts of interest, and
2) Determines Federal IDR Process applicability to the dispute.

See Sections 4.6.1 and 4.6.2 for more details.

4.6.1 *Conflicts of Interest*

After the certified IDR entity is selected either by the parties or by the Departments, it must attest to meeting the conflicts of interest requirements, described below in this Section 4.6.1. If the certified IDR entity cannot attest to meeting these requirements, it 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. 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 above.

A certified IDR entity **must not have any conflicts of interest** with respect to either party to a payment determination. Specifically, neither the 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 the requirements described in 18 U.S.C. §§ 207(b), (c), and (e).[12]

4.6.2 *Determining Applicability of the Federal IDR Process to 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, 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 SSA, 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 and Bundled Payment Arrangements

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 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 the same 90-calendar-day cooling off period, as described in Section 8.1.

[12] 18 U.S.C. § 207 imposes restrictions on former officers, employees, and elected officials of the executive and legislative branches. 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.

In the case of qualified IDR items or services that are billed by a provider, facility, or provider of air ambulance services as part of a bundled arrangement, or where a plan makes an initial payment as a bundled payment (or specifies that a denial of payment is made on a bundled payment basis), those qualified items or services may be submitted and considered as part of one payment determination.

4.8 Payment of Administrative Fees

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 to later remit to the Departments. Applicable regulations require the parties to pay the administrative fee when the certified IDR entity is selected. Thus, as an operational matter, administrative fees may be billed by the certified IDR entity at the time of selection and must be collected by the time of offer submission (see Section 5.3). 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 Submission of Offers to the Certified IDR Entity

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 7.2.1) 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 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;
  - Facilities must specify whether the facility has 50 or fewer 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; and
  - Plans must provide the QPA for the applicable year for the same or similar item or service as the qualified IDR item or service.

5.2 Federal IDR Portal

Any requests for and submission of information related to the offer must be made through the Federal IDR portal at https://www.nsa-idr.cms.gov.

5.3 Payment of Certified IDR Entity Fees

Each party **must pay the certified IDR entity fee** to the certified IDR entity with the submission of their offer. See Section 10 for additional information on the certified IDR entity fee.

5.4 Consequences for Failure to Submit an Offer

At the time at which offers from both parties should have been submitted, if one party has not submitted an offer, the certified IDR entity will accept the other party's offer.

6. 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, including if applicable, payments to the provider, facility, provider of air ambulance services, or plan, cannot be extended. Payments of the administrative fee and certified entity fee may be granted if an extension of the timeline for the submission of offers is granted due to extenuating circumstances. 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 on a case-by-case basis 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 plans, issuers, providers, facilities, and providers of air ambulance services to comply with time-period requirements.

- **How to request an extension:** Parties may request an extension, and provide applicable attestations, by submitting a **Request for Extension Due to Extenuating Circumstances** through the Federal IDR portal, 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 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 stop the Federal IDR Process, and all of its timelines continue to apply unless and until an extension is granted, so the parties should continue to meet deadlines to the extent possible.

- **Extensions for IDR Entities:** A certified IDR entity can request an extension of its deadline due to an "extenuating circumstance" by contacting the Departments through the Federal IDR portal.

7. Payment Determination: Selection of Offer

7.1 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;
- After considering the QPA, 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 in 26 CFR 54.9816-8T(c)(4)(i)(A), 29 CFR 2590.716-8(c)(4)(i)(A), or 45 CFR 149.510(c)(4)(i)(A), the certified IDR entity must select the offer closest to the QPA, unless the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate OON rate, based on the additional circumstances allowed under 26 CFR 54.9816-8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716-8(c)(4)(iii)(B) through (D), or 45 CFR 149.510(c)(4)(iii)(B) through (D) with respect to the qualified IDR item or service.
- Notify all parties to the determination and the Departments of the selection of the offer;
- Provide a written decision to all parties regarding the determination; and
- If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate OON rate, based on certain allowed considerations, as discussed below in Section 7.2.

7.2 Consideration of the QPA

7.2.1 *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] The QPA generally will reflect standard market rates arrived at through typical contract negotiations (through arms-length negotiations between

[13] 86 FR 36872 (July 13, 2021).

providers, facilities, and providers of air ambulance services and plans, issuers, or their service providers) and should therefore be a reasonable OON rate in most circumstances.

Selection of Offer – Baseball Style Arbitration:
The certified IDR entity must select one of the offers submitted by the disputing parties or determine an alternate payment amount. The certified IDR entity determination is final and legally binding.

- **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. The party may also submit information demonstrating that the QPA is not the appropriate OON rate to the certified IDR entity, in keeping with the requirements described in Section 5.1.
- As noted below, after determining that the Federal IDR Process applies, the certified IDR entity is responsible **only for** considering whether the information presented by the parties is credible, and, if credible (and not related to prohibited factors, as described in Section 7.4.3), whether the information submitted demonstrates that the QPA is materially different from the appropriate OON rate, in order to rebut the presumption that the QPA is the appropriate OON rate, except when offers are equally distant from the QPA in opposing directions, as described in Section 7.2.2.

7.2.2 *Certified IDR Entity: When and How to Apply the QPA*

In determining which payment offer to select, the certified IDR entity must begin with **the presumption that the QPA is the appropriate OON rate** for the qualified IDR item or service under consideration.

The certified IDR entity **must select the offer closest to the QPA**, **unless credible information** submitted by either party in relation to the offer (see Section 5.1) **clearly demonstrates** that the QPA is **materially different** from the appropriate OON rate for the qualified IDR item or service, based on the additional circumstances described below.

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 qualified IDR items or services, which could be either offer submitted.

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. The certified IDR entity must do so even if it does not select the offer closest to the QPA for a particular qualified IDR item or service due to the factors listed below, but does select the offer closest to the QPA for other qualified IDR items and services within the batch or bundle.

7.3 Standards for Rebutting the Presumption - Credible Information and Material Difference from the QPA

Information is considered **credible** if, upon critical analysis, the information is worthy of belief and is trustworthy. A **material difference** exists when there is a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information significant in determining the OON rate and would view the information as showing that the QPA is not the appropriate OON rate.

7.4 Consideration of Information Requested by the Certified IDR Entity or Provided by Either Party Related to Either Offer

As noted above (Section 7.2.2), the certified IDR entity must begin its selection of offers by presuming that the QPA is an appropriate OON rate. However, **the certified IDR entity must also consider additional 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 is submitted in connection to an offer of either party.
- **Third**, the certified IDR entity must not consider information on prohibited factors, described further below at Section 7.4.3.

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 offer submitted by the parties that relates to the circumstances** described below; that does not include information on prohibited factors (see Sections 7.4.1, 7.4.2, and 7.4.3 described below). This 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 in 26 CFR 54.9816-8T(c)(4)(i)(A), 29 CFR 2590.716-8(c)(4)(i)(A), or 45 CFR 149.510(c)(4)(i)(A).

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.

7.4.1 *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 below (see **Table 1**). The certified IDR entity must consider credible information submitted to determine if it demonstrates that the QPA is materially different from the appropriate OON rate (unless the information relates to a factor that the certified IDR entity is prohibited from considering).

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

Circumstance/Factor
1. **The level of training, experience, and quality and outcomes measurements** of the provider or facility that furnished the qualified IDR item or service. • Credible information must clearly 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, and that this information was not considered in the calculation of the QPA. • The level of training or experience of a provider does not justify an OON rate higher than the offer closest to the QPA unless the provider demonstrates that the level of training or experience impacted patient care and outcome. For example, the OON payment amount for the simple repair of a superficial wound (CPT codes 12001-12007) in most cases would not necessitate a rate higher than the QPA just because a provider has 30 years of experience versus 10 years of experience. Alternatively, for example, if the plan's contracted rates included risk-sharing, bonus, penalty, or other incentive-based or retrospective payments that were excluded for purposes of calculating the QPA for the items and services as required by the July 2021 interim final rules, a party may provide evidence as to why the provider's or facility's quality or outcome measures support an OON rate that is different from the QPA, and the certified IDR entity should consider whether this additional information requires it to select an OON rate that is higher (in the case of a bonus) or lower (in the case of a penalty) than the offer closest to the QPA.
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. • Credible information must clearly demonstrate the QPA is materially different from the appropriate OON rate. For example, the QPA may be unreasonably high (provider or facility market dominance) or unreasonably low (plan market dominance).

Circumstance/Factor

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.
• Credible information about patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee must clearly demonstrate that the QPA is materially different from the appropriate OON rate for the qualified IDR item or service.
• In many cases, service codes and modifiers reflecting patient acuity and complexity of a service will already be reflected in the QPA.
  • Therefore, information for this factor should only be considered in rare instances such as:
  i. Outliers (where the intensity of care exceeds what is typical for the code);
  ii. The QPA is considered too high for qualified IDR items or services that have become less complex over time; or
  iii. The parties disagree on what service code or modifier accurately describes the qualified IDR item or service (for example, downcoding, so that, upon review, the service code or modifier submitted is adjusted to something the plan believes to be more appropriate and which results in lower reimbursement).

4. **The teaching status, case mix, and scope of services** of the facility that furnished the qualified IDR item or service, if applicable: • Credible information must demonstrate the teaching status, case mix, or scope of services of the OON facility was in some way critical to the delivery of the item or service and not adequately accounted for in the QPA. • For example, a certified IDR entity could consider the trauma level of a hospital when the dispute involves trauma care or qualified IDR items or services that could not be performed at a lower-level hospital, but only to the extent the QPA does not otherwise reflect this factor.
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 must 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.

7.4.2 *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 below (see **Table 2**). As with non-air ambulance qualified IDR items or services, the certified IDR entity should only consider this information to the extent the certified IDR entity determines that either party submitted credible information that clearly demonstrates that the QPA is materially different from the appropriate OON rate.

Table 2: Air Ambulance Services – Additional Circumstances

Circumstance/Factor
1. **The quality and outcomes measurements** of the provider of air ambulance services that furnished the services. • Credible information about the quality and outcomes measurements of the provider of air ambulance services that furnished the services must clearly demonstrate that the QPA is materially different from the appropriate OON rate.

Circumstance/Factor
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. • 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, must clearly demonstrate that the QPA is materially different from the appropriate OON rate.
3. **The level of training, experience, and quality of medical personnel** that furnished the air ambulance services. • Credible information about whether the level of training, experience, and quality of medical personnel that furnished the air ambulance services clearly demonstrates the QPA is materially different from the appropriate OON rate.
4. **The air ambulance vehicle type, including the clinical capability level of such vehicle**. • Certified IDR entities must 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 may not consider whether the air ambulance is fixed wing or rotary wing, as that will be reflected in the QPA. • Certified IDR entities must consider whether credible information that 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.
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). • 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 must clearly demonstrate that the QPA is materially different from the appropriate OON rate for a particular air ambulance service.
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. • 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, must clearly demonstrate that the QPA is materially different from the appropriate OON rate for such air ambulance services.

7.4.3 *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 and 149.420 (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.

8. 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 following:

- The certified IDR entity's determination of the payment amount and the underlying rationale for its determination; and
- If the certified IDR entity does not choose the offer closest to the QPA, an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate OON rate, based on the allowable considerations. This explanation is not required if the certified IDR entity chooses between two offers that are equally distant from the QPA in opposing directions.

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 final and legally binding.

8.1 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 or whose offer is closest to the final payment amount, must be paid not later than **30 calendar days** after the determination by the certified IDR entity, as follows:

If payment is owed by a plan to the provider, facility, or provider of air ambulance services…	***If the plan is owed a refund…***
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 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 certified IDR entity must refund the prevailing party the IDR entity fee within 30 calendar 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 IDR entity fee.

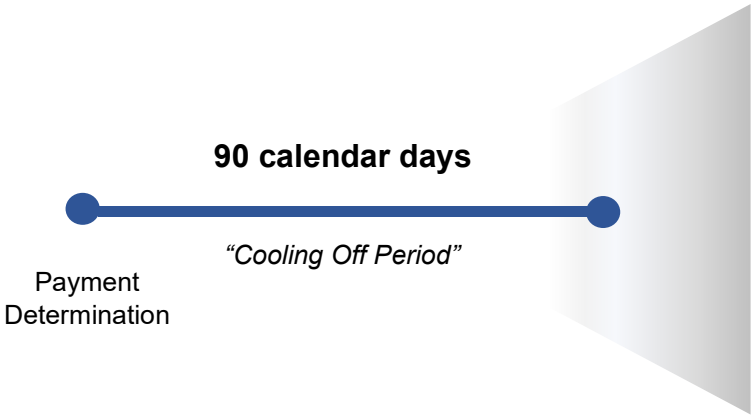
the parties agree otherwise on a method for allocating the applicable fee.

- **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.

  NOTE:

"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.



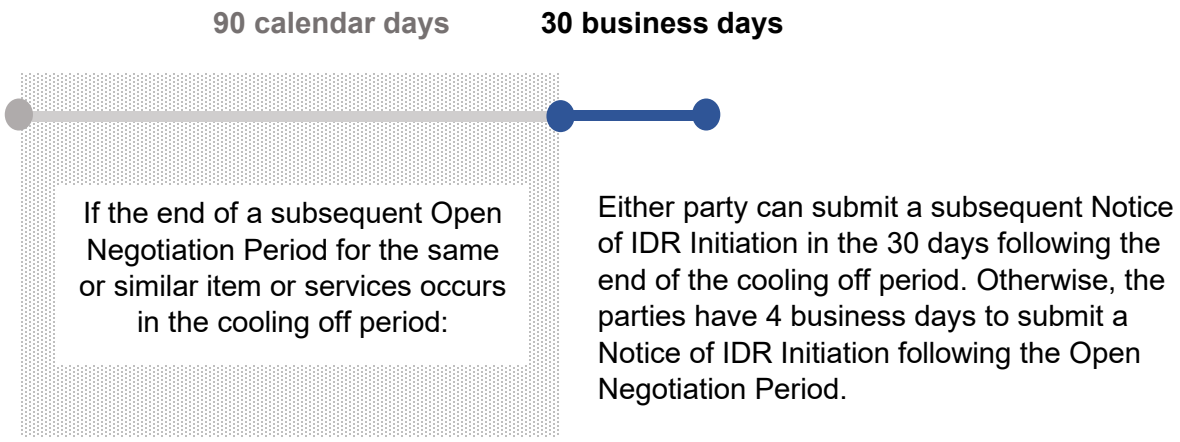
When does the "cooling off period" apply to subsequent IDR initiations?

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.

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.

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



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.

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 Not 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	Number of Notices submitted to the certified IDR entity during the immediately preceding month. The number of these Notices for the immediately preceding month with respect to which a final determination was made.	Same.
Administrative Fees Collected on Behalf of the Departments	Number of determinations for which the certified IDR entity collected administrative fees from the 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 in the case of settlements) or the administrative fees that are collected on behalf of the Departments.	Same.
Final Determinations	For each determination issued during the immediately preceding month, a description of the qualified IDR items and services included in the Notice of IDR Initiation, with relevant billing and service codes.[14]	Same.

[14] This information should include the relevant billing and service codes, such as the CPT, HCPCS, or DRG codes if applicable.

Category of Information	Reporting for Qualified IDR Items and Services That Are Not Air Ambulance Services:	Reporting for Air Ambulance Qualified IDR Services:
	The amount of the offers submitted by each party and the selected offer, expressed as both a dollar amount and as a percentage of the QPA, and whether the offer selected was submitted by the plan, or provider or facility.[15]	Same. Whether the offer selected was the offer submitted by the plan, or by the provider of air ambulance services.
	The certified IDR entity's rationale for its decision, including the extent to which the decision relied on criteria other than the QPA.	Same.
	The name and address for each plan, and provider or facility.	Same, for each plan, and provider of air ambulance services.
	The number of business days that lapsed between selection of the certified IDR entity and the determination of the OON rate.	Same.
	The relevant geographic region for purposes of the QPA for the qualified IDR items and services with respect to the Notices of IDR Initiation received.	Different. The point of pick-up (as defined in 42 CFR 414.605) for the services included in the Notice of IDR Initiation.
	Practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service.	Different. Air ambulance vehicle type, including the clinical capability level of such vehicle, to the extent this information has been provided to the certified IDR entity.

[15] Reporting may vary depending on how offers are submitted for batched items and services. If one batch of services included services to which two different QPAs applied, and the parties each submitted an offer for all batched services, the certified IDR entity must report each offer as a dollar amount and as a percentage of both QPAs. However, if instead each party submitted two offers – one that applied to the services for which one QPA applied and one that applied to the services for which the other QPA applied – then the certified IDR entity is required to report each offer separately and must express each offer as a dollar amount and as a percentage of the applicable QPA. When the QPA differs within a group of batched items and services, the certified IDR entity also must include whether the OON rate (or various OON rates, when more than one OON rate is selected) exceeded the applicable QPA.

Category of Information	Reporting for Qualified IDR Items and Services That Are Not Air Ambulance Services:	Reporting for Air Ambulance Qualified IDR Services:
Provider Practice and/or Facility Size	Size of the provider practices and size of the facilities submitting Notices of IDR Initiation during the immediately preceding month, as required to be provided to the certified IDR entity.[16]	Not applicable.

10. Federal IDR Process Fees

10.1 Administrative Fee

- The administrative fee is 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 are allowed to be billed/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 are to 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 fees are due when the party submits their 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 flat fee. The written proposal must include:
    - The alternative flat fee the IDR entity seeking certification or certified IDR entity believes is appropriate;
    - A description of the circumstances that require an alternative flat fee; and
    - A description of how the alternative flat fee will be used to mitigate the effects of these circumstances. Note that the certified IDR entity may not charge a fee that is

[16] The certified IDR entity must specify whether the provider practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees or more than 500 employees. For facilities, the certified IDR entity must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees.

not within the approved limits as set forth in guidance unless the certified IDR entity receives written approval from the Departments to charge a flat 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**.

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 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.

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.

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, 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.

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 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 subcontractors 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.[17]

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).

[17] "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.

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 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 may not 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 and Administrative Entity 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 the 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.

(5) "***Health care facility (facility)***" means with respect to a group health plan or group health insurance coverage, 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.

(12) ***"Qualifying Payment Amount (QPA)"*** generally means the median of contracted rates for a specific item or service in the same geographic region within the same insurance market, increased by an inflation index. For more on the methodology for calculation the qualifying payment amount see here.[18]

(13) "***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.

[18] Note that the link is to 29 CFR 2590.716-6, methodology for calculating the QPA for group health plans subject to Department of Labor rules. The corresponding methodology for group and individual health insurance markets subject to the jurisdiction of HHS is found at 42 CFR 149.140. The corresponding methodology for group health plans subject to the jurisdiction of the Department of the Treasury is found at 26 CFR 54.9816-6T.

Appendix B – Process Step Summary and Associated Notices

All standard notice templates related to surprise billing can be found on the Department of Labor website.

PROCESS STEP SUMMARY	FEDERAL MODEL IDR NOTICE
Before the Federal IDR Process:	
1. **Covered item or service results in:** an OON provider or emergency facility charge, an OON provider charge for items/services at an in-network facility, or an OON charge for air ambulance services.	None
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 *30 calendar days* after a clean claim is submitted. This information 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.	None
3. **Open negotiation period:** Parties must exhaust a *30-business-day* open negotiation period before either party may initiate the Federal IDR Process. This period must be initiated within *30 business days* 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.	Open Negotiation Notice
Federal IDR Process:	
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 *4 business days* after the close of the open negotiation period (or within 30 business days after a cooling off period, if applicable). Such notice includes the initiating party's preferred certified IDR entity.	Notice of IDR Initiation
5. **Selection of certified IDR entity:** Once the Federal IDR Process is initiated: - *Within 3 business days:* If the non-initiating party does not object to the initiating party's preferred certified IDR entity (included in the IDR initiation notice), 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. - *Within the next business day following the 3-business-day selection period:* 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. - *Within 6 business days from IDR initiation:* If the parties cannot agree on selection of a certified IDR entity, the Departments will randomly select a certified IDR entity. Administrative fees are allowed to be billed/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	Notice of Certified IDR Entity Selection (or Failure to Select)*

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.	
6. **Certified IDR Entity requirements:** Following selection, the certified IDR entity must: - *Attest on conflicts of interest:* 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 *3 business days*. - *Determination of Federal IDR Process applicability:* The certified IDR entity must notify both the Departments and the parties within *3 business days* if it determines the Federal IDR Process does not apply.	None
7. **Submission of offers:** Parties must submit their offers not later than *10 business days* after certified IDR entity selection.	Federal Independent Dispute Resolution (IDR) Process Notice of Offer Data Elements
8. **Payment of Certified IDR Entity fees:** Certified IDR entity fees are collected by the certified IDR entity upon submission of the offers (if not previously paid). .	None
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, as soon as possible, but not later than *3 business days* 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 *30 business days* 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 most of the time periods above 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 *30 calendar days* 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 *30 business* days 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.

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.

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.

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

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