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[4830-01-P; 4120-01-P]

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206-AO48

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG-122319-22]

RIN 1545-BQ55

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AC17

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 149

[CMS-9897-P]

RIN 0938-AV15

Federal Independent Dispute Resolution Operations

AGENCY: Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document sets forth proposed rules related to certain provisions of the No Surprises Act regarding the Federal independent dispute resolution (IDR) process, which was established as part of the Consolidated Appropriations Act, 2021 (CAA). These proposed rules

would set forth new requirements relating to the disclosure of information that group health plans and health insurance issuers offering group or individual health insurance coverage must include along with the initial payment or notice of denial of payment for certain items and services subject to the surprise billing protections in the No Surprises Act. These proposed rules would also require plans and issuers to communicate information by using claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs), as specified in guidance, when providing any paper or electronic remittance advice to an entity that does not have a contractual relationship with the plan or issuer. This document also proposes to amend certain requirements related to the open negotiation period preceding the Federal IDR process, the initiation of the Federal IDR process, the Federal IDR dispute eligibility review, and the payment and collection of administrative fees and certified IDR entity fees. This document also proposes to define bundled payment arrangements, amend requirements related to batched items and services, and amend the rules for extensions of timeframes due to extenuating circumstances. Additionally, this document proposes to require plans and issuers to register in the Federal IDR portal. In accordance with Federal law, a summary of these rules may be found at *https://www.regulations.gov/*.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Department of the Treasury, the Department of Labor, the Department of Health and Human Services (the Departments), and the Office of Personnel Management. Please do not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments are posted on the

internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, refer to file code RIN 0938-AV15. Because of staff and resource limitations, the Departments cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9897-P,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9897-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Padma Babubhai Shah, Office of Personnel Management, at 202-606-4056; Shira B. McKinlay, Internal Revenue Service, Department of the Treasury, at 202-317-5500; Elizabeth Schumacher or Shannon Hysjulien, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; Zarah Ghiasuddin or Bryan Kirk, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301-492-4308.

Customer Service Information: Information from the Office of Personnel Management (OPM) on health benefits plans offered under the Federal Employees Health Benefits (FEHB) Program can be found on the OPM website (*http://www.opm.gov/healthcare-insurance/healthcare/*). Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website (*www.dol.gov/agencies/ebsa*). In addition, information from the Department of Health and Human Services (HHS) on private health insurance coverage and coverage provided by non-Federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (*http://www.cms.gov/marketplace*), information on health care reform can be found at *http://www.healthcare.gov*, and information on surprise medical bills can be found at *http://www.cms.gov/nosurprises*.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The Departments post comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view

public comments. The Departments will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. The Departments continue to encourage individuals not to submit duplicative comments. The Departments will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Preventing Surprise Medical Bills and Establishing the Federal IDR Process under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was enacted.[1] Title I, also known as the No Surprises Act, and title II (Transparency) of Division BB of the CAA amended chapter 100 of the Internal Revenue Code (Code), Part 7 of the Employee Retirement Income Security Act (ERISA), and title XXVII of the Public Health Service Act (PHS Act). The No Surprises Act provides Federal protections against surprise billing by limiting out-of-network cost sharing and prohibiting balance billing in many of the circumstances in which surprise bills most frequently arise. In particular, the No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. Section 102 of the No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act, which contain limitations on cost sharing and requirements regarding the timing of initial payments and notices of denial of payment by plans and issuers for emergency services furnished by nonparticipating providers and nonparticipating emergency facilities, and for non-emergency services furnished by nonparticipating providers with respect to patient visits to participating

[1] Pub. L. 116-260 (Dec. 27, 2020).

health care facilities, generally defined as hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgical centers.[2]

Section 103 of the No Surprises Act established a Federal IDR process that plans and issuers and nonparticipating providers and facilities may utilize to resolve certain disputes regarding out-of-network rates under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act.

Section 105 of the No Surprises Act added section 9817 of the Code, section 717 of ERISA, and section 2799A-2 of the PHS Act. These sections contain limitations on cost sharing and requirements for the timing of initial payments and notices of denial of payment by plans and issuers for air ambulance services furnished by nonparticipating providers of air ambulance services and allow plans and issuers and nonparticipating providers of air ambulance services to utilize the Federal IDR process.

The No Surprises Act also added provisions to title XXVII of the PHS Act in a new part E that apply to health care providers, facilities, and providers of air ambulance services, such as prohibitions on balance billing for certain items and services and requirements related to disclosures about balance billing protections.

The Departments of the Treasury, Labor, and HHS (the Departments), along with the Office of Personnel Management (OPM), are issuing regulations in phases that implement provisions of the No Surprises Act and have issued multiple rulemakings since 2021 to implement various provisions. More specifically relevant to this proposed rulemaking, the Departments and OPM issued interim final rules (July 2021 interim final rules[3] and October

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[2] Section 102(d)(1) of the No Surprises Act amended the Federal Employees Health Benefits Act, 5 U.S.C. 8901 *et seq.,* by adding a new subsection (p) to 5 U.S.C. 8902. Under this new provision, each FEHB Program contract must require a carrier to comply with requirements described in sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A-1 and 2799A-2 of the PHS Act (as applicable) in the same manner as these provisions apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

[3] 86 FR 36872 (July 13, 2021).

2021 interim final rules[4]), and the Departments issued final rules (August 2022 final rules[5]) implementing provisions of sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A-1 and 2799A-2 of the PHS Act. These rules implement provisions to protect consumers from surprise medical bills for emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to participating facilities[6] in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services. These rules also implement provisions to establish a Federal IDR process to determine payment amounts when there is a dispute between plans or issuers and providers, facilities, or providers of air ambulance services about the out-of-network rate for these services in cases where a specified State law or an applicable All-Payer Model Agreement does not provide a method for determining the total amount payable.

The July 2021 interim final rules and October 2021 interim final rules generally apply to plans and issuers (including grandfathered health plans) for plan years (in the individual market, policy years) beginning on or after January 1, 2022, and to health care providers, facilities, and providers of air ambulance services for items and services furnished during plan years (in the individual market, policy years) beginning on or after January 1, 2022.[7] The August 2022 final rules became effective October 25, 2022, and are applicable for items and services provided or furnished on or after October 25, 2022, for plan years (in the individual market, policy years) beginning on or after January 1, 2022. As discussed in sections I.D and I.F of this preamble, certain provisions of these rules relating to the methodology for calculating the qualifying payment amount (QPA), the information that a certified IDR entity must consider in making a

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[4] 86 FR 55980 (Oct. 7, 2021).
[5] 87 FR 52618 (Aug. 26, 2022).
[6] References to a "participating facility" in this preamble mean a "participating health care facility," as defined at 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30.
[7] The interim final rules also include interim final regulations under 5 U.S.C. 8902(p) issued by OPM that specify how certain provisions of the No Surprises Act apply to health benefit plans offered by carriers under the Federal Employees Health Benefits Act. These provisions apply to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022. The disclosure requirements at 45 CFR 149.430 regarding patient protections against balance billing are applicable as of January 1, 2022.

payment determination, the establishment of the administrative fee to use the IDR process, and certain restrictions on the qualified IDR items or services that may be considered jointly as part of a batched determination have been vacated[8] by the United States District Court for the Eastern District of Texas (District Court). On September 26, 2023, the Departments published the Federal IDR Process Administrative Fee and Certified IDR Entity Fee Ranges Proposed Rules (IDR Process Fees proposed rules)[9] to amend the administrative fee and certified IDR entity fee provisions in the October 2021 interim final rules to provide additional guidance and promote transparency in the administrative fee calculation and certified IDR fee ranges. If finalized, the rules would apply for disputes initiated on or after the later of the effective date or January 1, 2024.

B. July 2021 Interim Final Rules

The July 2021 interim final rules implement sections 9816(a)-(b) and 9817(a) of the Code, sections 716(a)-(b) and 717(a) of ERISA, and sections 2799A-1(a)-(b), 2799A-2(a), 2799A-7, 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act.

The No Surprises Act directs the Departments to specify the information that a plan or issuer must share with a nonparticipating provider or nonparticipating emergency facility when determining the QPA. Therefore, 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) require that plans and issuers make certain disclosures about the QPA with each initial payment or notice of denial of payment, and that plans and issuers provide certain additional information upon the request of the provider, facility, or provider of air ambulance services. This information must be provided in writing, either on paper or electronically, to a nonparticipating provider, facility, or provider of air ambulance services, as applicable, when the QPA serves as the recognized amount.

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[8] *See Tex. Med. Ass'n*, *et al.* v. *U.S. Dep't of Health and Human Servs*., 587 F. Supp. 3d 528 (E.D. Tex. 2022) (*TMA I*), *Tex. Med. Ass'n, et al.* v. *U. S. Dep't of Health and Human Servs.,* Case No. 6:22-cv-372 (E.D. Tex.) (Feb. 6, 2023) (*TMA II*), *Tex. Med. Ass'n, et al. v. U.S. Dep't of Health and Human Servs*., Case No. 6:22-cv-450-JDK (E.D. Tex. Aug. 24, 2023) (*TMA III*), and *Tex. Med. Ass'n, et al. v. U. S. Dep't of Health and Human Servs.,* Case No. 6:23-cv-00059-JDK, (E.D. Tex. Aug. 3, 2023) (*TMA IV*).

[9] 88 FR 65888 (Sept. 26, 2023).

With an initial payment or notice of denial of payment, a plan or issuer must provide the QPA for each item or service involved, as well as a statement certifying that based on the determination of the plan or issuer: (1) the QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and (2) each QPA shared with the provider, facility, or provider of air ambulance services was determined in compliance with the methodology outlined in the July 2021 interim final rules.[10]

A plan or issuer is also required to provide a statement that if the provider, facility, or provider of air ambulance services wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider, facility, or provider of air ambulance services may contact the appropriate person or office to initiate open negotiation, and that if the 30-day open negotiation period does not result in an agreement on the payment amount, generally, the provider, facility, or provider of air ambulance services may initiate the Federal IDR process within 4 days after the end of the open negotiation period.[11] The plan or issuer must provide contact information, including a telephone number and email address, for the appropriate office or person for the provider, facility, or provider of air ambulance services to contact to initiate open negotiation for purposes of determining a payment amount (inclusive of cost sharing) for the item or service.[12]

In addition, upon request by the provider or facility,[13] a plan or issuer must provide in a timely manner information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the specific items and services and whether the QPA for those items

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[10] 86 FR 36888; 26 CFR 54.9816-6T(d)(1)(iii), 29 CFR 2590.716-6(d)(1)(iii), and 45 CFR 149.140(d)(1)(iii). For guidance regarding the certification statement in light of the decision in *TMA III*, *see* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, Office of Personnel Management, *FAQs about Consolidated Appropriations Act, 2021 Implementation Part 62* (Oct. 6, 2023), Q3, available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-62.pdf* and *https://www.cms.gov/files/document/faqs-part-62.pdf*.

[11] 86 FR 36899; 26 CFR 54.9816-6T(d)(1)(iv), 29 CFR 2590.716-6(d)(1)(iv), and 45 CFR 149.140(d)(1)(iv).

[12] 86 FR 36899; 26 CFR 54.9816-6T(d)(1)(v), 29 CFR 2590.716-6(d)(1)(v), and 45 CFR 149.140(d)(1)(v).

[13] As discussed further in section II.C. of this preamble, this proposed rule would add a reference to providers of air ambulance services in 26 CFR 54.9816-6T(d)(2), 29 CFR 2590.716-6(d)(2), and 45 CFR 149.140(d)(2).

and services was determined using underlying fee schedule rates or a derived amount.[14] If an eligible database was used to determine the QPA, upon request by the provider or facility, the plan or issuer must provide information to identify which database was used.[15] Similarly, if a related service code was used to determine the QPA for an item or service billed under a new service code, upon request by the provider or facility the plan or issuer must provide information to identify which related service code was used.[16]

Finally, upon request by the provider or facility, the plan or issuer must provide a statement, if applicable, that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments that were excluded for purposes of calculating the QPA for the items and services involved.[17]

C. October 2021 Interim Final Rules and Related Guidance

The October 2021 interim final rules implement the Federal IDR process under sections 9816(c) and 9817(b) of the Code, sections 716(c) and 717(b) of ERISA, and sections 2799A-1(c) and 2799A-2(b) of the PHS Act. The Federal IDR process may be used by group health plans and health insurance issuers offering group or individual health insurance coverage and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for certain items and services. These are emergency services, non-emergency services furnished by nonparticipating providers for patient visits to certain participating facilities (unless an individual has been provided notice and waived the individual's balance billing protections, in accordance with 45 CFR 149.410 or 149.420, as applicable), and air ambulance services furnished by nonparticipating providers of air ambulance services, for

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[14] 26 CFR 54.9816-6T(d)(2)(i), 29 CFR 2590.716-6(d)(2)(i), and 45 CFR 149.140(d)(2)(i). Under the July 2021 interim final rules, plans and issuers are required to calculate the QPA using underlying fee schedule rates or derived amounts when the plan or issuer has sufficient information to calculate the median of its contracted rates but the payments under the contractual agreements are not on a fee-for-service basis (such as bundled or capitation payments). 86 FR 36893; 26 CFR 54.9816-6T(b)(2)(iii), 29 CFR 2590.716-6(b)(2)(iii), 45 CFR 149.140(b)(2)(iii). Plans and issuers are not otherwise permitted to use underlying fee schedule rates or derived amounts to calculate the QPA.

[15] 86 FR 36899; 26 CFR 54.9816-6T(d)(2)(ii), 29 CFR 2590.716-6(d)(2)(ii), and 45 CFR 149.140(d)(2)(ii).

[16] 86 FR 36899; 26 CFR 54.9816-6T(d)(2)(iii), 29 CFR 2590.716-6(d)(2)(iii), and 45 CFR 149.140(d)(2)(iii).

[17] 86 FR 36899; 26 CFR 54.9816-6T(d)(2)(iv), 29 CFR 2590.716-6(d)(2)(iv), and 45 CFR 149.140(d)(2)(iv).

situations in which neither an All-Payer Model Agreement under section 1115A of the Social Security Act nor a specified State law as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30 applies.

To implement the Federal IDR process, the October 2021 interim final rules include requirements governing the 30-business-day open negotiation period; the initiation of the Federal IDR process; the Federal IDR process following initiation, including the selection of a certified IDR entity, submission of offers, payment determinations, and written decisions; costs of the Federal IDR process; certification of IDR entities, including the denial or revocation of certification of an IDR entity; and the collection of information related to the Federal IDR process from certified IDR entities to satisfy reporting requirements under the statute.

To be eligible for the Federal IDR process, the subject of the dispute must be a qualified IDR item or service as defined in 26 CFR 54.9816-8T(a)(2)(xi), 29 CFR 2590.716-8(a)(2)(xi), and 45 CFR 149.510(a)(2)(xi). The October 2021 interim final rules define "qualified IDR item or service" to mean an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816-4T, 29 CFR 2590.716-4, or 45 CFR 149.110, for which the exception under 45 CFR 149.410(b) (regarding receipt of notice and consent to waive surprise billing protections) does not apply. A qualified IDR item or service may also be an item or service furnished by a nonparticipating provider at a participating health care facility subject to the requirements of 26 CFR 54.9816-5T, 29 CFR 2590.716-5, and 45 CFR 149.120, for which the exception under 45 CFR 149.420(c)-(i) (regarding receipt of notice and consent to waive surprise billing protections) does not apply. For an item or service to be considered a qualified IDR item or service, the provider, facility, or provider of air ambulance services or plan or issuer, as applicable, must submit a valid notice of IDR initiation through the Federal IDR portal for the item or service. The notice of IDR initiation is not valid if the 30-business-day open negotiation period under 26 CFR 54.9816-8T(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1) has not elapsed or an agreement on the payment amount has

been reached. The term "qualified IDR item or service" also includes air ambulance services furnished by nonparticipating providers of air ambulance services subject to the protections of 26 CFR 54.9817-1T, 29 CFR 2590.717-1, and 45 CFR 149.130, as these services are defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30, for which the open negotiation period under 26 CFR 54.9816-8T(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1) has elapsed, no agreement on the payment amount has been reached, and a valid notice of IDR initiation has been submitted after the 30-business-day open negotiation period has been satisfied.

The term "qualified IDR item or service" does not include items and services for which the out-of-network rate is determined by an All-Payer Model Agreement under section 1115A of the Social Security Act or by reference to a specified State law. Additionally, this term does not include an item or service submitted by the initiating party that is subject to the 90-calendar-day suspension period (also referred to as the "cooling-off period") under 26 CFR 54.9816-8T(c)(4)(vii)(B), 29 CFR 2590.716-8(c)(4)(vii)(B), and 45 CFR 149.510(c)(4)(vii)(B) except to the extent that it is submitted during the subsequent 30-business-day period, as allowed under the October 2021 interim final rules.[18]

The open negotiation period may be initiated by either party during the 30-business-day period beginning on the day the nonparticipating provider, facility, or nonparticipating provider of air ambulance services receives either an initial payment or a notice of denial of payment for an item or service.[19] In order for a plan, issuer, provider, facility, or provider of air ambulance services to know when it is a party to an open negotiation and the item or service for which the payment is to be negotiated, the party initiating the open negotiation period must provide written

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[18] In the case of a determination made by a certified IDR entity, the party that submitted the initial notification initiating the Federal IDR process may not submit a subsequent notification 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 notification during the 90-calendar-day period following the determination (the "cooling off period").

[19] As clarified in the July 2021 interim final rules, the initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances, prior to the beginning of any open negotiations or initiation of the Federal IDR process. *See* 86 FR 36900-36901.

notice to the other party of its intent to negotiate using a standardized form, referred to as an open negotiation notice. The open negotiation notice must include information sufficient to identify the item or service subject to negotiation, including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and the contact information of the party sending the open negotiation notice. The open negotiation notice must be sent during the 30-business-day period beginning on the day the initial payment or notice of denial of payment from the plan or issuer regarding such item or service was received and must be provided in writing. The party sending the open negotiation notice may satisfy this requirement by providing the notice to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) the party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and (2) the notice is provided in paper form free of charge upon request. The 30-business-day open negotiation period begins on the day on which the open negotiation notice is first sent by a party.

As stated in the preamble to the October 2021 interim final rules, parties should be able to provide effective notice because the parties have already made initial contact (that is, the provider, facility, or provider of air ambulance services has transmitted a bill to the plan or issuer, and the plan or issuer sent an initial payment or a notice of denial of payment to the provider, facility, or provider of air ambulance services).[20] The Departments encouraged the parties to take reasonable measures to ensure that actual notice is provided, such as by confirming that the email address is correct, and cautioned that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments or a certified IDR entity 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

[20] 86 FR 55980, 55990.

party sending the open negotiation notice to meet the open negotiation requirement of the October 2021 interim final rules. In guidance, the Departments clarified how a provider, facility, or provider of air ambulance services should proceed if the plan or issuer fails to disclose information necessary to initiate the open negotiation period when providing the initial payment or notice of denial of payment and whether providers, facilities, or providers of air ambulance services are required to use a plan's or issuer's online portal to submit an open negotiation notice.[21]

The October 2021 interim final rules provide that if the parties have not negotiated an agreement on the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.[22] To initiate the Federal IDR process, the initiating party must submit the standard notice of IDR initiation to the other party and to the Departments. As stated in the preamble of the October 2021 interim final rules, this notice must be provided to the Departments and the other party on the same day.[23] The notice of IDR initiation must include: (1) information sufficient to identify the qualified IDR items and services (and whether the qualified IDR items or services are designated as batched items and services), including the furnishing date(s) and location(s) of the item or service, the type of qualified IDR item or service (such as emergency services, post-stabilization professional services, hospital-based services), corresponding service and place-of-service code(s), the amount of cost sharing allowed, and the amount of the initial payment made by the plan or issuer for the qualified IDR item or service, if applicable; (2) the names and contact information of the parties involved, including email addresses, phone numbers, and mailing addresses; (3) the State where the qualified IDR item or service was furnished; (4) the commencement date of the open negotiation

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[21] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55, Q20 and Q21* (Aug. 19, 2022), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-55.pdf* and *https://www.cms.gov/files/document/faqs-part-55.pdf.*
[22] 86 FR 55991; 26 CFR 54.9816-8T(b)(2)(i), 29 CFR 2590.716-8(b)(2)(i), and 45 CFR 149.510(b)(2)(i).
[23] 86 FR 55991.

period; (5) the initiating party's preferred certified IDR entity; (6) an attestation that the item or service is a qualified IDR item or service within the scope of the Federal IDR process; (7) the QPA; (8) information about the QPA as described in 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d); and (9) general information describing the Federal IDR process as specified by the Departments.[24] The general information should include a description of the scope of the Federal IDR process and key deadlines in the Federal IDR process, including the dates to initiate the Federal IDR process, how to select a certified IDR entity, and the process for selecting an offer.[25] The Departments have developed a form that parties must use to satisfy this requirement to provide general information describing the Federal IDR process.

Under section 9816(c)(1)(B) of the Code, section 716(c)(1)(B) of ERISA, and section 2799A-1(c)(1)(B) of the PHS Act, the date of initiation of the Federal IDR process is the date of the submission of the notice of IDR initiation or another date specified by the Departments that is not later than the date of receipt of the notice of IDR initiation by both the other party to the dispute and the Departments. The October 2021 interim final rules establish that the initiation date of the Federal IDR process is the date of receipt of the notice of IDR initiation by the Departments.[26]

Under the October 2021 interim final rules, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable) may jointly select a certified IDR entity no later than 3 business days following the date of the IDR initiation.[27] As previously stated, the initiating party will select its preferred certified IDR entity in the notice of IDR initiation. The party in receipt of the notice of IDR initiation (non-initiating party) may agree or object to the preferred certified IDR entity identified by the initiating party in the notice of IDR initiation. If the non-initiating party does

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[24] 26 CFR 54.9816-8T(b)(2)(iii)(A), 29 CFR 2590.716-8(b)(2)(iii)(A), and 45 CFR 149.510(b)(2)(iii)(A).
[25] 86 FR 55991.
[26] *Id*.
[27] 86 FR 55991 through 55992, 26 CFR 54.9816-8T(c)(1)(i), 29 CFR 2590.716-8(c)(1)(i), and 45 CFR 149.510(c)(1)(i).

not object within 3 business days of the date of initiation of the Federal IDR process, the preferred certified IDR entity identified in the notice of IDR initiation will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If the non-initiating party objects, that party must timely notify the initiating party of the objection and propose an alternative preferred certified IDR entity. The initiating party must then agree or object to the alternative preferred certified IDR entity. If the initiating party fails to object to the alternative preferred certified IDR entity within 3 business days of the date of initiation of the Federal IDR process, the alternative preferred certified IDR entity proposed by the non-initiating party will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If both parties agree on and select a certified IDR entity or fail to agree upon a certified IDR entity within the specified timeframe, the initiating party must notify the Departments by electronically submitting the notice of the certified IDR entity selection or failure to select (as applicable), no later than 1 business day after the end of the 3-business-day period (or in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal. If the parties fail to jointly select a certified IDR entity, the Departments will then randomly select a certified IDR entity not later than 6 business days after the date of initiation of the Federal IDR process and will notify the parties of the selection. In addition, in instances in which the non-initiating party believes that an item or service is not eligible for the Federal IDR process, the non-initiating party must notify the Departments through the Federal IDR portal within the same timeframe that the notice of certified IDR entity selection or failure to select is required (or in other words, 4 business days after the date of initiation of the Federal IDR process) and provide information that demonstrates why an item or service is not eligible for the Federal IDR process.

After being notified of selection (either by the parties or the Departments), certified IDR entities are required within 3 business days of selection to attest that they do not have a conflict of interest as specified under 26 CFR 54.9816-8T(c)(1)(ii), 29 CFR 2590.716-8(c)(1)(ii), and 45

CFR 149.510(c)(1)(ii). Certified IDR entities are also required to review the information submitted in the notice of IDR initiation and any additional requested information to determine whether the dispute is for a qualified IDR item or service, as defined in 26 CFR 54.9816-8T(a)(2)(xi), 29 CFR 2590.716-8(a)(2)(xi), and 45 CFR 149.510(a)(2)(xi), that is eligible for the Federal IDR process, including whether an All-Payer Model Agreement or specified State law applies. If an item or service is not a qualified IDR item or service eligible for the Federal IDR process, certified IDR entities must notify the Departments and the parties within 3 business days of making this determination.

The October 2021 interim final rules provide that, not later than 30 business days after the selection of a certified IDR entity, the certified IDR entity must select one of the offers submitted by either party to the dispute to be the out-of-network rate for the qualified IDR item or service.[28] For each qualified IDR item or service, the total plan or coverage payment is the amount by which this out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service (with any initial payment made by the plan or issuer counted toward the total plan or coverage payment).

The October 2021 interim final rules also provided that, after considering the QPA, the statutory factors under sections 9816(c)(5)(C)(ii) and 9817(b)(5)(C)(ii) of the Code, sections 716(c)(5)(C)(ii) and 717(b)(5)(C)(ii) of ERISA, and sections 2799A-1(c)(5)(C)(ii) and 2799A-2(b)(5)(C)(ii) of the PHS Act, additional information requested by the certified IDR entity from the parties, and all of the additional credible information submitted by the parties that was not prohibited information under 26 CFR 54.9816-8T(c)(4)(v), 29 CFR 2590.716-8(c)(4)(v), and 45 CFR 149.510(c)(4)(v), the certified IDR entity must select the offer closest to the QPA, unless the certified IDR entity determined that the credible information submitted by the parties clearly demonstrated that the QPA was materially different from the appropriate out-of-network rate, or

[28] 26 CFR 54.9816-8T(c)(4)(ii), 29 CFR 2590.716-8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii).

the offers were equally distant from the QPA but in opposing directions.[29] In those situations, the October 2021 interim final rules required the certified IDR entity to select the offer that the certified IDR entity determined best represented the value of the item or service, which could be either party's offer.[30] However, as discussed in sections I.D. and I.F. of this preamble, the District Court vacated portions of these rules related to certified IDR entity determinations.[31]

The October 2021 interim final rules also provide that not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must notify parties to the dispute of the selection of the offer and provide a written decision,[32] which must be submitted to the parties and the Departments through the Federal IDR portal.[33]

Section 9816(c)(3)(A) of the Code, section 716(c)(3)(A) of ERISA, and section 2799A–1(c)(3)(A) of the PHS Act direct the Departments to specify criteria under which multiple qualified IDR items and services are permitted to be considered jointly as part of a single determination ("batched determination" or "batched dispute") by a certified IDR entity for purposes of encouraging the efficiency (including minimizing costs) of the Federal IDR process. These sections further require that items and services may be considered as part of a batched determination only if the items and services are furnished by the same provider or facility; payment for the items and services is required to be made by the same group health plan or health insurance issuer; such items and services are related to the treatment of a similar condition; and the items and services were furnished during the 30-day period following the date on which the first item or service included in the batched determination was furnished, or during an alternative period as determined by the Departments, for use in limited situations, such as by the consent of the parties or in the case of low-volume items and services, to encourage procedural efficiency and minimize health plan and provider administrative costs. The October

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[29] 86 FR 55995.
[30] *Id.*
[31] *TMA I* and *TMA II*.
[32] 86 FR 55995, 26 CFR 54.9816-8T(c)(4)(ii), 29 CFR 2590.716-8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii).
[33] The Federal IDR portal is available at *https://www.nsa-idr.cms.gov and must be used throughout the Federal IDR process to maximize efficiency and reduce burden*.

2021 interim final rules implemented these requirements for batched determinations at 26 CFR 54.9816–8T(c)(3)(i), 29 CFR 2590.716–8(c)(3)(i), and 45 CFR 149.510(c)(3)(i), which are subject to the certified IDR entity fee for batched determinations.[34]

The October 2021 interim final rules also establish requirements related to the costs of the Federal IDR process. Under the October 2021 interim final rules, each party must pay a non-refundable administrative fee for participating in the Federal IDR process.[35] The certified IDR entity may invoice the parties for the administrative fee at the time the certified IDR entity is selected, and the parties must pay the administrative fee by the time of offer submission.[36] The administrative fee is paid by each party to the certified IDR entity and remitted to the Departments.[37] Under the October 2021 interim final rules, the administrative fee was to be established annually through guidance in a manner such that the total administrative fees collected for a year are estimated to be equal to the amount of expenditures estimated to be made by the Departments to carry out the Federal IDR process for that year.

Additionally, under the October 2021 interim final rules, each party must also pay a certified IDR entity fee to the certified IDR entity at the time that the party submits its offer.[38] However, the non-prevailing party is ultimately responsible for the full certified IDR entity fee, which is retained by the certified IDR entity for the services it performed.[39] The certified IDR entity fee that was paid by the prevailing party is returned to the prevailing party by the certified IDR entity within 30 business days following the date of the payment determination.[40] If the

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[34] 86 FR 55994. *See also* the October 2021 interim final rules in which the Departments defined "batched items and services" as "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." 86 FR 55987

[35] 26 CFR 54.9816-8T(d)(2)(i), 29 CFR 2590.716-8(d)(2)(i), and 45 CFR 149.510(d)(2)(i).

[36] *See* Federal Independent Dispute Resolution (IDR) Process Guidance for Disputing Parties, available at: *https://www.cms.gov/files/document/rev-102822-idr-guidance-disputing-parties.pdf*.

[37] 26 CFR 54.9816-8T(e)(2)(ix), 29 CFR 2590.716-8(e)(2)(ix), and 45 CFR 149.510(e)(2)(ix). The No Surprises Act directed the Departments to jointly establish one Federal IDR process. To operationalize the Federal IDR process, HHS collects administrative fees for all disputes initiated under the Federal IDR process, including the administrative fees paid in connection with the Federal IDR process for health plans that are subject to the Code or ERISA.

[38] 26 CFR 54.9816-8T(d)(1)(ii), 29 CFR 2590.716-8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii).

[39] 26 CFR 54.9816-8T(d)(1)(i), 29 CFR 2590.716-8(d)(1)(i), and 45 CFR 149.510(d)(1)(i).

[40] 26 CFR 54.9816-8T(d)(1)(ii), 29 CFR 2590.716-8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii).

parties reach an agreement after initiating the Federal IDR process but before the certified IDR entity makes a payment determination, the certified IDR entity fee is split evenly between the parties, unless the parties agree on an alternative method for allocating the certified IDR entity fee.[41] Similarly, if the initiating party withdraws a dispute after a certified IDR entity has been assigned but before the certified IDR entity makes a payment determination, responsibility for the certified IDR entity fee is split evenly between the parties.[42] In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute. In these cases, the party with the fewest determinations in its favor is considered the non-prevailing party and is responsible for the full certified IDR entity fee. If each party prevails in an equal number of determinations, the certified IDR entity fee is split evenly between the parties. Under the October 2021 interim final rules, the Departments set certified IDR entity fee ranges annually through guidance.

D. Litigation Regarding the July 2021 and October 2021 Interim Final Rules and Related Guidance

On October 28, 2021, the Texas Medical Association, a trade association representing physicians, and a Texas physician filed a lawsuit against the Departments and OPM (*TMA I*),[43] stating that certain provisions of the October 2021 interim final rules relating to the certified IDR entities' consideration of the QPA, as well as additional factors related to items and services that are not air ambulance services, should be vacated. Plaintiffs argued that the October 2021 interim final rules ignored Congress's intent that certified IDR entities weigh the QPA and other factors without favoring any factor, and the plaintiffs stated that as a result, the rules would skew IDR results in favor of plans and issuers. On February 23, 2022, the District Court issued a memorandum opinion and order that vacated portions of the October 2021 interim final rules

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[41] 26 CFR 54.9816-8T(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii).

[42] *See https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/patient-provider-dispute-resolution-administrative-fee-cy-2023.pdf*.

[43] *Tex. Med. Ass'n, et al. v. U.S. Dep't of Health and Human Servs.*, 587 F. Supp. 3d 528 (E.D. Tex. 2022).

governing aspects of the Federal IDR process related to non-air ambulance qualified IDR items or services including: (1) the definition of "material difference"; (2) the requirement that a certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that credible information submitted by either party under 26 CFR 54.9816-8T(c)(4)(i), 29 CFR 2590.716-8(c)(4)(i), and 45 CFR 149.510(c)(4)(i) clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for non-air ambulance qualified IDR items or services, or if the offers are equally distant from the QPA but in opposing directions; (3) the requirement that the certified IDR entity may only consider the additional information submitted by either party to the extent that the credible information related to the circumstances under 26 CFR 54.9816-8T(c)(4)(i), 29 CFR 2590.716-8(c)(4)(i), and 45 CFR 149.510(c)(4)(i) clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for non-air ambulance qualified IDR items or services; (4) the dispute resolution examples; and (5) the requirement that, 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 out-of-network rate, based on the factors certified IDR entities are permitted to consider for the qualified IDR item or service.[44]

On April 27, 2022, LifeNet, Inc., a provider of air ambulance services, filed a lawsuit against the Departments and OPM (*LifeNet*)[45] seeking the vacatur of additional provisions of the October 2021 interim final rules applicable to air ambulance services. In particular, LifeNet alleged that the requirement codified in the last sentence of 26 CFR 54.9817-2T(b)(2), 29 CFR 2590.717-2(b)(2), and 45 CFR 149.520(b)(2), which specifies the certified IDR entity may consider information submitted by a party only if the information "clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate,"

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[44] *Id*.
[45] *LifeNet, Inc. v. U.S. Dep't of Health and Human Servs.,* 617 F.Supp.3d 547 (E.D. Tex. July 26, 2022).

should be vacated. On July 26, 2022, the District Court issued a memorandum opinion and order vacating this language.[46]

On November 30, 2022, the Texas Medical Association, Tyler Regional Hospital, and a Texas physician filed a lawsuit (*TMA III*)[47] against the Departments and OPM, asserting that the July 2021 interim final rules, including the provisions of the regulations governing the methodology for calculating the QPA, and certain related guidance documents were in conflict with the statutory language. On August 24, 2023, the District Court issued a memorandum opinion and order[48] that vacated certain portions of the July 2021 interim final rules and associated regulatory provisions[49] and portions of guidance documents,[50] including portions related to the methodology for calculating the QPA and interpretations for certified IDR entities related to the processing of disputes for air ambulance services.

On January 30, 2023, the Texas Medical Association, Houston Radiology Associated, Texas Radiological Society, Tyler Regional Hospital, and a Texas physician filed a lawsuit (*TMA IV*)[51] against the Departments and OPM, asserting that the December 2022 fee guidance[52] and the October 2021 interim final rules were unlawfully issued without notice and comment rulemaking and were arbitrary and capricious.[53] On August 3, 2023, the District Court issued a

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[46] *Id.*
[47] *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health and Human Servs.,* Case No. 6:22-cv-00450-JDK (E.D. Tex. November 30, 2022).
[48] *See* Memorandum Opinion and Order, *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health and Human Servs.,* No. 6:22-cv-00450-JDK (E.D. Tex. August 24, 2023).
[49] Specifically, the District Court vacated certain provisions of 54.9816-6T and 54.9817-1T, 29 CFR 2590.716-6 and 2590.717-1, and 45 CFR 149.130 and 149.140. The District Court also vacated 5 CFR 890.114(a), insofar as it requires compliance with the vacated regulations and guidance.
[50] Specifically, the District Court vacated *FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55* (Aug. 19, 2022), Q14 and 15, as well as portions of *Technical Guidance for Certified IDR Entities* at 2-3 (Aug. 18, 2022).
[51] *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health and Human Servs.,* Case No. 6:23-cv-00059-JDK, (E.D. Tex. Jan. 30, 2023).
[52] Centers for Medicare & Medicaid Services (Dec. 23, 2022). *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act: Change in Administrative Fee. https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.*
[53] *See* Motion for Summary Judgment and Reply in Support of Summary Judgment, p. 1, *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health and Human Servs.,* No. 6:23-cv-00059-JDK (E.D. Tex. March 27, 2023).

memorandum opinion and order[54] that vacated the portion of the December 2022 fee guidance increasing the administrative fee for the Federal IDR process to $350 per party for disputes initiated during the calendar year beginning January 1, 2023. The District Court also vacated certain provisions of the October 2021 interim final rules setting forth the batching criteria under which multiple IDR items or services are treated as related to the "treatment of a similar condition."[55] In light of the *TMA IV* order, on August 3, 2023, the Departments instructed certified IDR entities to pause all work in the Federal IDR portal until the Departments updated Federal IDR process guidance, systems, and related documents to make them consistent with the *TMA IV* order. Subsequently, on August 7, 2023, the Departments directed certified IDR entities to resume processing all single and bundled disputes for which the administrative fee had already been paid and all batched disputes for which the certified IDR entity had already determined the dispute eligible and administrative fees had been paid (or the deadline for collecting fees had expired) before August 3, 2023.[56] On August 8, 2023, the Departments directed certified IDR entities to resume processing single and bundled disputes initiated in 2022 for which the administrative fee had not been paid before August 3, 2023. On August 11, 2023, the Departments released guidance to reflect the *TMA IV* order related to the administrative fee and to clarify the administrative fee amount for 2023.[57] On the same date, the Departments directed

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[54] *See* Memorandum Opinion and Order, *Tex. Med. Ass'n. v. U.S. Dep't of Health and Hum. Servs,* No. 6:23-cv-00059-JDK (E.D. Tex. August 3, 2023).

[55] Specifically, the District Court vacated the requirement under 26 CFR 54.9816-8T(c)(3)(i)(C), 29 CFR 2590.716-8(c)(3)(i)(C), and 45 CFR 149.510(c)(3)(i)(C) that for a qualified IDR item and service to be considered the same or similar item and service, it must be billed under the same service code or a comparable code under a different procedural code system, such as the Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable

[56] For the purposes of the Federal IDR process, the Departments in guidance interpreted a bundled payment arrangement to be an arrangement under which: (1) a provider, facility, or provider of air ambulance services bills for multiple items or services under a single service code; or (2) a plan or issuer makes an initial payment or denial of payment to a provider, facility, or provider of air ambulance services under a single service code that represents multiple items or services (e.g., a DRG). *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of Treasury, Federal Independent Dispute Resolution (IDR) Process Technical Assistance for Certified IDR Entities, August 2022, *available at https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf.* These rules, discussed in section II.A. of this preamble, propose to codify that definition in the regulations.

[57] Centers for Medicare & Medicaid Services (Aug. 11, 2023). *Federal Independent Dispute Resolution (IDR) Process Administrative Fee FAQs*. *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/no-surprises-act-independent-dispute-resolution-administrative-fee-frequently-asked-questions.pdf.*

certified IDR entities to resume processing single and bundled disputes initiated in 2023 for which the administrative fees had not been paid before August 3, 2023.

As a result of the *TMA III* order issued on August 24, 2023, the Departments again paused all IDR-related activities in order to evaluate the District Court's order and review current Federal IDR processes, templates, and system functions necessary to comply with the order. On September 5, 2023, the Departments directed certified IDR entities to resume making eligibility and conflict-of-interest determinations for all single and bundled disputes submitted on or before August 3, 2023, and encouraged disputing parties to continue engaging in open negotiations. On September 21, 2023, the Departments directed certified IDR entities to resume processing all single and bundled disputes submitted on or before August 3, 2023. On October 6, 2023, the Departments and OPM released "FAQs About Consolidated Appropriations Act, 2021 Implementation Part 62"[58] to provide guidance in light of the *TMA III* order. On the same day, the Departments reopened the Federal IDR portal for the initiation of certain new single and bundled disputes. At the time of this proposed rulemaking and in accordance with the *TMA III* and *TMA IV* orders, the Departments plan to release guidance to clarify how certified IDR entities should determine whether a dispute is appropriately batched.

E. August 2022 Final Rules

The August 2022 final rules included amendments to remove from the regulations the language vacated by the District Court in *TMA I* and *LifeNet*,[59] as described in section I.D. of this preamble. In addition, the August 2022 final rules amended and finalized certain disclosure requirements related to information that plans and issuers must share about the QPA under the July 2021 interim final rules.[60] The August 2022 final rules also amended and finalized select

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[58] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, Office of Personnel Management, *FAQs about Consolidated Appropriations Act, 2021 Implementation Part 62* (Oct. 6, 2023), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-62.pdf* and *https://www.cms.gov/files/document/faqs-part-62.pdf*.
[59] 87 FR 52622.
[60] 87 FR 52622-52623.

provisions of the October 2021 interim final rules on the information to be considered by a certified IDR entity when it makes a payment determination under the Federal IDR process.[61]

Specifically, the Departments amended and finalized parts of the July 2021 and October 2021 interim final rules related to: (1) the information that must be disclosed about the QPA under 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) to address downcoding; (2) the certified IDR entity's consideration of the statutory factors when making a payment determination under the Federal IDR process at 26 CFR 54.9816-8T(c)(4)(iii)-(iv) and 54.9817-2T(b)(2), 29 CFR 2590.716-8(c)(4)(iii)-(iv) and 2590.717-2(b)(2), and 45 CFR 149.510(c)(4)(iii)-(iv) and 149.520(b)(2); and (3) the certified IDR entity's written decision at 26 CFR 54.9816-8T(c)(4)(vi)(B), 29 CFR 2590.716-8(c)(4)(vi)(B), and 45 CFR 149.510(c)(4)(vi)(B).

For the information that must be disclosed with the QPA, the August 2022 final rules require that if a QPA is based on a downcoded service code or modifier, in addition to the information already required to be provided with an initial payment or notice of denial of payment, a plan or issuer must provide a statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and which modifiers were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded. The August 2022 final rules define the term "downcode," as described in the preamble to the October 2021 interim final rules, to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services.[62]

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[61] 87 FR 52628.
[62] 87 FR 52626.

The August 2022 final rules also provided that in determining which offer to select during the Federal IDR process, the certified IDR entity must consider the QPA for the applicable year for the same or similar item or service and then must consider all additional information submitted by a party to determine which offer best reflects the appropriate out-of-network rate, provided that the information relates to the party's offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and does not include information that the certified IDR entity is prohibited from considering in making the payment determination under section 9816(c)(5)(D) of the Code, section 716(c)(5)(D) of ERISA, and section 2799A-1(c)(5)(D) of the PHS Act. For this purpose, the preamble to the August 2022 final rules stated that information requested by a certified IDR entity, or submitted by a party, would be information relating to a party's offer if it tends to show that the offer best represents the value of the item or service under dispute. The August 2022 final rules required the certified IDR entity to evaluate whether the information relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The August 2022 final rules clarified that in considering this additional information, the certified IDR entity should evaluate whether the information that is offered is credible and should not give weight to information that is not credible. The appropriate out-of-network rate must be the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.

Additionally, the August 2022 final rules provided that when considering the additional information under 26 CFR 54.9816-8(c)(4)(iii), 29 CFR 2590.716-8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii), the certified IDR entity should evaluate the information and should not give weight to that information if it is already accounted for by any of the other information submitted by the parties, to avoid weighting the same information twice.

For the written decision, the August 2022 final rules require the certified IDR entity to include what information the certified IDR entity used to determine that the offer selected as the

out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted in accordance with the rules. The August 2022 final rules required that if the certified IDR entity relied on additional information in selecting an offer, its written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the QPA.

F. Litigation Regarding the August 2022 Final Rules

On September 22, 2022, the Texas Medical Association, Tyler Regional Hospital, a Texas physician, LifeNet, Inc., Air Methods Corporation, Rocky Mountain Holdings, LLC, and East Texas Air One, LLC filed a lawsuit against the Departments (*TMA II*),[63] asserting that certain provisions of the August 2022 final rules relating to the certified IDR entities' consideration of the QPA, as well as additional factors, should be vacated. Plaintiffs argued that the August 2022 final rules unlawfully conflict with the No Surprises Act in the same manner as the vacated provisions of the October 2021 interim final rules—that is, such rules improperly restrict arbitrators' discretion and unlawfully tilt the arbitration process in favor of the QPA. On February 6, 2023, the District Court issued a memorandum opinion and order that vacated portions of the August 2022 final rules related to the certified IDR entity's consideration of the statutory factors when making a payment determination under the Federal IDR process at 26 CFR 54.9816-8(c)(4)(iii)-(iv) and 54.9817-2(b)(3), 29 CFR 2590.716-8(c)(4)(iii)-(iv) and 2590.717-2(b)(3), and 45 CFR 149.510(c)(4)(iii)-(iv) and 149.520(b)(3) and part of the provision related to the certified IDR entity's written decision at 26 CFR 54.9816-8(c)(4)(vi)(B), 29 CFR 2590.716-8(c)(4)(vi)(B), and 45 CFR 149.510(c)(4)(vi)(B). The vacated portions of the rules include: (1) the requirement that certified IDR entities consider the QPA and then the additional statutory factors under 26 CFR 54.9816-8(c)(4)(iii)(B)(1)-(5) and 54.9817-2(b)(3), 29 CFR

[63] *Tex. Med. Ass'n, et. al.* v. *U. S. Dep't of Health and Human Servs.,* Case No. 6:22-cv-372 (E.D. Tex. February 06, 2023) (*TMA II*). Air Methods Corporation, Rocky Mountain Holdings, LLC, and East Texas Air One, LLC are providers of air ambulance services.

2590.716-8(c)(4)(iii)(B)(1)-(5) and 2590.717-2(b)(3), and 45 CFR 149.510(c)(4)(iii)(B)(1)-(5) and 149.520(b)(3); (2) the provision that a certified IDR entity should evaluate whether the information submitted under 26 CFR 54.9816-8(c)(4)(iii)(B)-(D) and 54.9817-2(b)(3), 29 CFR 2590.716-8(c)(4)(iii)(B)-(D) and 2590.717-2(b)(3), and 45 CFR 149.510(c)(4)(iii)(B)-(D) and 149.520(b)(3) is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination, and the certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the QPA or another factor; (3) the dispute resolution examples; and (4) the requirement that, if the certified IDR entity relies on additional information in selecting an offer, its written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the QPA.

As a result of the *TMA II* order, on February 10, 2023, the Departments instructed certified IDR entities to hold all payment determinations until the Departments updated Federal IDR process guidance, systems, and related documents to make them consistent with the *TMA II* order.[64] Subsequently, the Departments directed certified IDR entities to resume making payment determinations on February 27, 2023, for disputes involving an item or service furnished before October 25, 2022 (the effective date of the August 2022 Final Rules).[65] On March 17, 2023, the Departments released updated guidance[66] to reflect the *TMA II* order and directed certified IDR entities to resume making payment determinations in accordance with the guidance for disputes involving items or services furnished on or after October 25, 2022.

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[64] Centers for Medicare & Medicaid Services. (February 10, 2023). *Payment Disputes Between Providers and Health Plans, Notices. https://www.cms.gov/nosurprises/help-resolve-payment-disputes/payment-disputes-between-providers-and-health-plans.*

[65] Centers for Medicare & Medicaid Services. (February 27, 2023). *Payment Disputes Between Providers and Health Plans, Notices. https://www.cms.gov/nosurprises/help-resolve-payment-disputes/payment-disputes-between-providers-and-health-plans.*

[66] Centers for Medicare & Medicaid Services. (March 2023*). Federal Independent Dispute Resolution (IDR) Process for Certified IDR Entities (Revised). https://www.cms.gov/files/document/federal-idr-guidance-idr-entities-march-2023.pdf and Federal Independent Dispute Resolution (IDR) Process for Disputing Parties (Revised). https://www.cms.gov/files/document/federal-idr-guidance-disputing-parties-march-2023.pdf.*

On April 6, 2023, the Departments filed a notice of appeal to the United States Court of Appeals for the Fifth Circuit from the District Court's order granting summary judgement to the plaintiffs and denying summary judgment to the Departments.

G. Federal IDR Process Administrative Fee and Certified IDR Entity Fee Ranges 2023 Proposed Rules

In light of *TMA IV* and to promote transparency in the administrative fee calculation, the Departments published the IDR Process Fees proposed rules on September 26, 2023. The IDR Process Fees proposed rules propose to amend the October 2021 interim final rules to provide that the administrative fee would be set in notice and comment rulemaking rather than annual guidance, propose an administrative fee amount that, if finalized, would apply for disputes initiated on or after the later of the effective date of the IDR Process Fees proposed rules or January 1, 2024, and propose a methodology that the Departments would use to calculate the administrative fee in the future. Additionally, the IDR Process Fees proposed rules would propose to amend the October 2021 interim final rules to provide that the certified IDR entity fee ranges for single and batched determinations would be set in notice and comment rulemaking rather than annual guidance, propose the certified IDR entity fee ranges for single and batched determinations, including a fixed tiered fee for batched disputes, and propose the considerations that the Departments would use to calculate the certified IDR entity fee ranges in the future. If finalized, the proposed certified IDR entity fee ranges and fixed tiered fees would apply for disputes initiated on or after the later of the effective date of the IDR Process Fees proposed rules or January 1, 2024. If finalized, the proposed administrative fee and certified IDR entity fee ranges would remain in effect until changed by subsequent rulemaking.

H. The Federal IDR Process to Date

On April 15, 2022, the Departments launched the Federal IDR portal to accept disputes regarding the appropriate out-of-network rate for claims subject to the surprise billing protections of the No Surprises Act. From April 15, 2022 to July 1, 2023, disputing parties submitted over

489,000 disputes. In the first year of operations, disputing parties submitted 14 times the number of disputes that the Departments had expected to receive in an entire calendar year.[67,68] Due to this unexpectedly high volume, the limited number of certified IDR entities,[69] the complexity of determining disputes' eligibility for the Federal IDR process, and a large number of ineligible disputes submitted, it is taking certified IDR entities longer than the timeframes established under the No Surprises Act and the October 2021 interim final rules to process payment disputes. Further, the District Court's successive orders have resulted in multiple temporary closures of the Federal IDR portal, requiring the Departments to alter guidance, implement significant system updates, and communicate changes to disputing parties and certified IDR entities to comply with the orders. These interruptions to the Federal IDR process have exacerbated delays and required certified IDR entities and disputing parties to rapidly adjust to changing operations and guidance. Accordingly, a large number of disputes still await payment determinations.

Several factors are likely contributing to the high volume of initiated disputes. First, providers, facilities, and providers of air ambulance services[70] have alleged that plans' and issuers' QPA calculations are sometimes artificially low and are even at times lower than Medicare rates. Providers, facilities, and providers of air ambulance services further allege that plans and issuers are making initial payments based on these artificially low QPAs, which incentivizes providers, facilities, and providers of air ambulance services to use the Federal IDR process for a larger number of items and services than they otherwise would.

A second factor contributing to the high volume of disputes is that the disputing parties are not yet able to predict how disputes will be resolved by certified IDR entities. As the

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[67] Federal Independent Dispute Resolution Process – Status update. Available at: *https://www.cms.gov/files/document/federal-idr-processstatus-update-april-2023.pdf.*

[68] In the regulatory impact analysis of the October 2021 interim final rules, the Departments estimated that 17,333 disputes involving non-air ambulance services and 4,899 disputes involving air ambulance services would be submitted to the Federal IDR process during the first year of implementation.

[69] *https://www.cms.gov/nosurprises/help-resolve-payment-disputes/certified-idre-list.*

[70] For purposes of these proposed rules, unless otherwise stated, whenever the Departments are referring to providers, facilities, and providers of air ambulance services, the Departments are referring to nonparticipating providers, facilities, and providers of air ambulance services.

Departments stated in the preamble to the October 2021 interim final rules, a Federal IDR process with predictable outcomes will reduce the use of the Federal IDR process over time because, if outcomes are predictable in advance, parties will generally prefer to reach an agreement in line with the predicted outcome outside of the Federal IDR process to avoid the administrative costs of utilizing the process.

Third, disputing parties are failing to engage in meaningful open negotiations. Parties representing providers, facilities, providers of air ambulance services, plans, and issuers have all asserted that they experience challenges in negotiating with other parties during the 30-business-day open negotiation period, resulting in low levels of engagement during open negotiation. This lack of engagement has resulted in relatively few disputes being settled outside of the Federal IDR process, contributing to a higher-than-expected volume of disputes being initiated in the Federal IDR process. As discussed later in this section, interested parties also shared that the lack of meaningful engagement in open negotiation contributes to inefficiencies within the Federal IDR process, because disputing parties that fail to engage in open negotiation may not exchange information that would facilitate the Federal IDR process, such as contact information and other required disclosures, or may exchange only incomplete information.

Fourth, the District Court's successive rulings have necessitated multiple temporary shutdowns of the Federal IDR process to comply with the District Court's orders. Each shutdown has halted parts, or all, of the Federal IDR process, interrupting the advancement of ongoing disputes through the process and preventing new disputes from being submitted. Reopening the Federal IDR portal each time has required the Departments to draft new guidance, engage in new rulemaking, implement significant system updates, and communicate changes to disputing parties and certified IDR entities. These interruptions to the Federal IDR process have exacerbated delays and required certified IDR entities and disputing parties to rapidly adjust to changing operations and guidance, which causes confusion regarding the current state of the

process while certified IDR entities and disputing parties adapt to new or different processes, such as those discussed in section I.D. of this preamble related to the *TMA III* order.

Finally, initiating parties are submitting a large number of disputes that are not eligible for the Federal IDR process, leading to both a high volume of dispute submissions and slow processing of disputes. Certified IDR entities have indicated to the Departments that determining the eligibility of disputes for the Federal IDR process is more time-consuming and burdensome than they expected. In fact, certified IDR entities report spending 50 to 80 percent of their time working on eligibility determinations. From April 15, 2022 to July 1, 2023, non-initiating parties challenged the eligibility of 190,465 disputes for the Federal IDR process, and certified IDR entities found 59,604 disputes ineligible. A dispute is not eligible for the Federal IDR process unless it concerns an item or service that meets the definition of a qualified IDR item or service.[71] Ineligible disputes often involve an item or service that is not a qualified IDR item or service because it is covered by a health plan or coverage that is not subject to the surprise billing protections of the No Surprises Act, such as Medicare or Medicaid, or because the item or service is subject to a specified State law or an All-Payer Model Agreement. Additionally, many batched disputes were found ineligible due to the initiating party incorrectly batching items or services in a manner that did not comply with the regulations, such as batching claims paid by different plans or issuers.[72] Certified IDR entities have similarly reported encountering incorrectly bundled disputes for which providers are attempting to submit, for example, an emergency room facility code as a bundled code with various item and service codes included as line items, rather than properly submitting a single service code (for example, a Diagnosis-Related Group (DRG) code under which a provider, facility, or provider of air ambulance services can bill for multiple items or services).[73] Disputes are also ineligible when the disputing parties have failed to satisfy the 30-business-day open negotiation period requirements specified

[71] 26 CFR 54.9816-8T(a)(2)(xi), 29 CFR 2590.716-8(a)(2)(xi), and 45 CFR 149.510 (a)(2)(xi).
[72] 26 CFR 54.9816-8T(c)(3)(i)(B), 29 CFR 2590.716-8(c)(3)(i)(B), and 45 CFR 149.510(c)(3)(i)(B).
[73] 26 CFR 54.9816-8T(c)(3)(ii), 29 CFR 2590.716-8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii).

under 26 CFR 54.9816-8T(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1) or have failed to initiate the Federal IDR process within 4 business days after the end of the 30-business-day open negotiation period as specified under 26 CFR 54.9816-8T(b)(2)(i), 29 CFR 2590.716-8(b)(2)(i), and 45 CFR 149.510(b)(2)(i).

The Departments' review of the disputes submitted to date and feedback received from interested parties and certified IDR entities via letters, email communication and listening sessions shows a pattern of initiating parties submitting ineligible disputes to the Federal IDR process due to miscommunication or a lack of communication between the disputing parties. The Departments intended that sufficient information would be communicated through the disclosures that plans and issuers are required to provide with their initial payment or notice of denial of payment or would be subsequently communicated during the required 30-business-day open negotiation period to identify whether the item(s) or service(s) involved in the dispute is a qualified IDR item(s) or service(s). Plans and issuers assert that providers, facilities, and providers of air ambulance services submit overwhelming numbers of ineligible disputes that overload the plans' and issuers' ability to identify and respond to dispute initiations, while providers, facilities, and providers of air ambulance services assert that plans and issuers do not provide required contact information and disclosures in a clear and convenient manner and fail to respond to their notices initiating open negotiation.

Although plans and issuers are required to provide disclosures with the initial payment or notice of denial of payment containing information related to the QPA and contact information to initiate open negotiations, providers, facilities, and providers of air ambulance services have reported difficulty locating this information. The inability of providers, facilities, and providers of air ambulance services to locate required disclosures has led to confusion about how they should contact and engage in open negotiations with the plan or issuer and ultimately submit the dispute to the Federal IDR process. If disputing parties fail to share the required information, or if they provide inaccurate information, certified IDR entities will have incomplete or inaccurate

information when making eligibility determinations. As a result, certified IDR entities must dedicate additional resources and conduct outreach to determine eligibility. Many interested parties have stated that the exchange of key information in a more standardized fashion, such as through the inclusion of the information on electronic remittance advice (ERA) transactions, discussed in greater detail in section II.B. of this preamble, would ensure that disputing parties have timely access to complete and accurate information and therefore help reduce the number of ineligible disputes submitted to the Federal IDR process. This is primarily because disputing parties would have timely access to the information they need to determine whether (1) an item or service is a qualified IDR item or service and (2) it is in their interest to initiate the Federal IDR process regarding such item or service. The Departments are of the view that timely access to that type of information would help reduce the overall number of ineligible disputes, resulting in more manageable workloads for certified IDR entities and more efficient dispute processing overall.

Additionally, providers and facilities have raised concerns that the existing disclosure rules do not require plans and issuers to provide information necessary for determining whether the item or service is subject to a specified State law, an All-Payer Model Agreement, or the Federal IDR process for determining the out-of-network rate. In particular, providers, facilities, and providers of air ambulance services have identified significant challenges in determining whether a claim involves a plan that is a self-insured group health plan subject to ERISA (and, if the claim involves an item or service covered by the No Surprises Act, is therefore generally subject to the Federal IDR process) or a fully-insured plan to which a specified State law or All-Payer Model Agreement may apply.[74] The Departments also are aware that there are further

[74] The July 2021 interim final rules allow self-insured group health plans, including self-insured non-Federal governmental plans, to voluntarily opt in to a State law that provides for a method for determining the total amount payable under such a plan, where a State has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)-(d) of the Code, section 716(a)-(d) of ERISA, and section 2799A-1(a)-(d) of the PHS Act. A self-insured plan that has chosen to opt-in to a State law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities, providers, and providers of air ambulance services that are covered by the specified State law.

challenges in identifying whether a plan subject to ERISA has opted into a specified State law and, separately, whether a specific item or service, or specific provider, facility, or provider of air ambulance services, is subject to a given specified State law or All-Payer Model Agreement. Additionally, providers, facilities, and providers of air ambulance services have identified difficulties in determining the correct legal business name of the plan or issuer. As a result, when initiating the Federal IDR process, providers, facilities, and providers of air ambulance services may initiate their dispute against the wrong party or may incorrectly batch claims that were paid by different plans or issuers.

To address the high volume of disputes submitted to the Federal IDR process and the growing backlog of cases, the Departments have provided ongoing technical assistance to certified IDR entities and disputing parties by issuing guidance as well as performing research and outreach on dispute eligibility determinations.[75] In addition, the Departments have implemented Federal IDR portal system enhancements. These system enhancements, such as enabling non-initiating parties to submit supporting documentation to contest dispute eligibility within their response to the notice of IDR initiation, allow the Departments to collect information regarding dispute eligibility earlier in the process to identify whether the eligibility requirements are met. However, despite the efforts to date, the Departments and certified IDR entities continue to experience challenges related to determining eligibility for the Federal IDR process, such as delays due to necessary outreach by the certified IDR entities to the disputing parties to obtain or verify information regarding the eligibility of a dispute.

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[75] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury, Federal Independent Dispute Resolution (IDR) Process Technical Assistance for Certified IDR Entities, August 2022, *available at https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf.*

I. Scope and Purpose of Rulemaking

This proposed rulemaking is intended to address specific issues that are critical to ensuring the timely rendering of payment determinations and to address feedback from interested parties and certified IDR entities to improve the functioning of the Federal IDR process.

These proposed rules are intended to address some of the common communication issues between disputing parties, including those stemming from a lack of clarity as to whether items and services are qualified IDR items and services covered by the No Surprises Act. These proposed rules would impose requirements and create incentives for parties to engage with one another during the open negotiation period, which would help reduce the volume of ineligible disputes being submitted. Specifically, these proposed rules would make changes to the information that plans, issuers, providers, facilities, and providers of air ambulance services must share before initiating the Federal IDR process by including proposals at 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100 to require plans and issuers to provide claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) when providing any paper or electronic remittance advice in response to a claim for payment for health care items or services furnished by an entity with which it does not have a direct or indirect contractual relationship. Additionally, the Departments propose amendments at 26 CFR 54.9816-6, 29 CFR 2590.716-6, and 45 CFR 149.140 to the information that must be disclosed about the QPA. These proposed rules would also establish new requirements at 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, which would require plans and issuers to register with the Federal IDR portal to better enable a provider, facility, or provider of air ambulance services to identify the appropriate plan or issuer with which it has a dispute and determine whether its coverage of an item or service that is the subject of the dispute is subject to a specified State law, an All-Payer Model Agreement, or the Federal IDR process for determining the out-of-network rate.

To further facilitate communication and improve open negotiations, these proposed rules would amend the open negotiation process that precedes the Federal IDR process. Specifically, at 26 CFR 54.9816-8(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1), these proposed rules would amend the content requirements of the standard open negotiation notice, would establish requirements related to an open negotiation response notice, and would clarify the timing for when the open negotiation period begins. These proposed rules would also amend the process for initiating the Federal IDR process. Specifically, at 26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2), these proposed rules would amend the content of the notice of IDR initiation and establish new requirements for a notice of IDR initiation response from the non-initiating party. At 26 CFR 54.9816-8T(b)(3), 29 CFR 2590.716-8(b)(3), and 45 CFR 149.510(b)(3) these proposed rules would also establish a new manner for providing notices to the other party and the Departments.

These proposed rules would also provide additional clarity regarding timeframes within the Federal IDR process. The No Surprises Act includes timeframes by which certain steps of the Federal IDR process must be completed. For example, the parties to a dispute must jointly select a certified IDR entity not later than the last day of the 3-business-day period following the date of the initiation of the Federal IDR process, and if the parties fail to jointly select a certified IDR entity, the Departments must select a certified IDR entity not later than 6 business days after the date of IDR initiation.[76] While the No Surprises Act also provides detailed timeframes for certain other steps in the process, the steps that must be conducted before a payment determination can be issued are not as clearly defined, such as when a certified IDR entity must conduct a conflict-of-interest review and must determine whether an item or service is a qualified IDR item or service, as defined in 26 CFR 54.9816-8T(a)(2)(xi), 29 CFR 2590.716-8(a)(2)(xi), and 45 CFR 149.510(a)(2)(xi), and eligible for the Federal IDR process. Therefore, the provisions in these proposed rules would adjust certain steps and establish associated timeframes (see Table 1). This

[76] Section 9816(c)(4)(F) of the Code, section 716(c)(4)(F) of ERISA, and section 2799A-1(c)(4)(F) of the PHS Act.

includes proposed provisions related to establishing a process for the preliminary selection of the certified IDR entity and the final selection of the certified IDR entity as set out in 26 CFR 54.9816-8(c)(1), 29 CFR 2590.716-8(c)(1), and 45 CFR 149.510(c)(1), in order to account for the time it takes certified IDR entities to confirm that they do not have a conflict of interest with either party. To allow more time for certified IDR entities to conduct eligibility reviews, these proposed rules would include proposed amendments to the Federal IDR process eligibility review proposed in 26 CFR 54.9816-8T(c)(2), 29 CFR 2590.716-8(c)(2), and 45 CFR 149.510 (c)(2). As discussed in section I.H. of this preamble, eligibility reviews have proven to be complex and time consuming. In extenuating circumstances, such as when dispute volume is high, it may be more appropriate for the Departments, rather than certified IDR entities, to conduct eligibility reviews to facilitate quicker dispute processing. Therefore, these proposed rules would establish a departmental eligibility review process in proposed paragraph 26 CFR 54.9816-8(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510 (c)(2)(ii). Further, to support eligibility determinations, conflict-of-interest reviews, or payment determinations, the Departments propose requirements for the submission of additional information from the disputing parties at 26 CFR 54.9816-8(c)(2)(iii), 29 CFR 2590.716-8(c)(2)(iii), and 45 CFR 149.510(c)(2)(iii). To clarify and establish a standard process for disputes to be withdrawn from the Federal IDR process, the Departments propose four conditions in which a dispute may be withdrawn at 26 CFR 54.9816-8(c)(3)(i), 29 CFR 2590.716-8(c)(3)(i), and 45 CFR 149.510(c)(3)(ii). To further adjust timeframes and processes associated with the Federal IDR process, these proposed rules would include proposed amendments related to submission of offers and payment determination and notification at 26 CFR 54.9816-8(c)(5), 29 CFR 2590.716-8(c)(5), and 45 CFR 149.510(c)(5); the collection of the certified IDR entity fee at 26 CFR 54.9816-8(d)(1), 29 CFR 2590.716-8(d)(1), and 45 CFR 149.510(d)(1); and the collection of the administrative fee, including a process for setting a reduced administrative fee for low-dollar amount disputes and for non-initiating parties in cases of ineligible disputes, at 26 CFR

54.9816-8(d)(2), 29 CFR 2590.716-8(d)(2), and 45 CFR 149.510(d)(2). These proposed rules also include provisions to expand upon situations in which Federal IDR process timeframes may be waived due to extenuating circumstances at 26 CFR 54.9816-8T(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g).

Lastly, to address concerns regarding the vacated batching provision at 26 CFR 54.9816-8T(c)(3)(i)(C), 29 CFR 2590.716-8(c)(3)(i)(C), and 45 CFR 149.510(c)(3(i)(C) and to create more efficiencies in the process, these proposed rules at 26 CFR 54.9816-8(c)(4), 29 CFR 2590.716-8(c)(4), and 45 CFR 149.510(c)(4) would include provisions that would allow for more flexibility in batching multiple items or services in a single dispute.

It is the Departments' intention that the implementation of the proposed provisions in these proposed rules, if finalized, would lead to a more efficient Federal IDR process and more timely payment determinations.

TABLE 1: The Federal IDR Process Under These Proposed Rules[77]

Steps Preceding the Federal IDR Process	
Timeframe	**Summary of Steps**
Start	A furnished item or service results in a charge for emergency items or services from a nonparticipating provider or nonparticipating emergency facility, for non-emergency items or services from a nonparticipating provider at a participating health care facility, or for air ambulance services from a nonparticipating provider of air ambulance services.
Within 30 calendar days after the bill for the services is transmitted	**Initial Payment or Notice of Denial of Payment** The plan or issuer determines whether the services are covered, and if the services are covered, sends to the provider, facility, or provider of air ambulance services an initial payment or notice of denial of payment no later than 30 calendar days after a bill is transmitted.
30 business days after the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment	**Initiation of Open Negotiation Period** An open negotiation period must be initiated within 30 business days beginning on the day the 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 or issuer. To initiate the open negotiation period, a party must submit a written open negotiation notice and supporting documentation to the other party and to the Departments via the Federal IDR portal.
30 business days	**Open Negotiation Period** Parties must exhaust a 30-business-day open negotiation period before either party may initiate the Federal IDR process.

[77] For a chart outlining the Federal IDR Process under the current regulations, *see* the Federal IDR Process Guidance for Disputing Parties at *https://www.cms.gov/files/document/federal-idr-guidance-disputing-parties-march-2023.pdf*.

Within the first 15 business days of the open negotiation period	**Open Negotiation Response Notice** The party in receipt of the open negotiation notice must provide to the other party and to the Departments as soon as practicable, but no later than the 15th business day of the 30-business-day open negotiation period, a written notice and supporting documentation in response to the open negotiation notice (open negotiation response notice).

Federal IDR Process Overview

Timeframe	Summary of Steps
4 business days after the close of the open negotiation period	**Initiation of Federal IDR Process** Either party can initiate the Federal IDR process by submitting a notice of IDR initiation to the non-initiating party and to the Departments within the 4-business-day period beginning on the 1st business day after the close of the open negotiation period. The notice must include the initiating party's preferred certified IDR entity.
3 business days after IDR initiation	**Notice of IDR Initiation Response** Within 3 business days of receipt of the notice of IDR initiation, the non-initiating party must submit the notice of IDR initiation response form, attesting to whether the Federal IDR process applies to the item(s) or service(s) included in the notice of IDR initiation. The non-initiating party must agree or object to the preferred certified IDR entity identified in the notice of IDR initiation by indicating its agreement or objection in the notice of IDR initiation response. If the non-initiating party objects to the preferred certified IDR entity identified in the notice of IDR initiation, the non-initiating party must designate an alternative preferred certified IDR entity.
3-6 business days after IDR initiation	**Preliminary Selection of the Certified IDR Entity** The date of the preliminary selection of the certified IDR entity will be 3 business days after the date of IDR initiation if the parties are considered to have jointly selected a certified IDR entity. The date of preliminary selection of the certified IDR entity will be 6 business days after the date of IDR initiation if the parties are considered to have failed to jointly select a certified IDR entity.
2 business days after preliminary selection of the certified IDR entity	**Administrative Fee Collection from the Initiating Party** The initiating party must pay the administrative fee directly to the Departments within 2 business days of the date of preliminary selection of the certified IDR entity. If the initiating party fails to pay its administrative fee, the dispute will be closed.

3 business days after preliminary selection of the certified IDR entity	**Certified IDR Entity Conflict-of-Interest Review and Attestation** Once preliminarily selected, the certified IDR entity has 3 business days to submit an attestation that it does not have a conflict of interest. If a preliminarily selected certified IDR entity notifies the Departments that it does not meet the conflict-of-interest requirements or does not respond within 3 business days of being preliminarily selected, the Departments will randomly preliminarily select another certified IDR entity. Random selection will occur no later than the first business day after notification from the certified IDR entity or if the preliminary selection of the certified IDR entity fails to respond, no later than one business day after the end of the 3-business-day period.
1 business day after conflict-of-interest attestation	**Final Selection of the Certified IDR Entity** The date of final selection of the certified IDR entity is the date that the Departments provide notice to the parties that the preliminarily selected certified IDR entity does not have a conflict of interest. This date will be no later than 1 business day after the conflict-of-interest attestation.
5 business days after final selection of the certified IDR entity	**Eligibility Review** The certified IDR entity that was finally selected must review the information in the notice of IDR initiation, notice of IDR initiation response, and any additional information and determine whether the item or service is a qualified IDR item or service that is eligible for the Federal IDR process. The certified IDR entity must notify the Departments and both parties of its determination within 5 business days after the date of final selection of the certified IDR entity.
2 business days after eligibility determination	**Administrative Fee Collection from the Non-Initiating Party** The non-initiating party must pay the administrative fee directly to the Departments within 2 business days of an eligibility determination.
10 business days after final selection of the certified IDR entity	**Submission of Offers and Payment of Certified IDR Entity Fee** Parties must submit their offers to the certified IDR entity not later than 10 business days after the date of final 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) no later than the date a disputing party submits its offer. If a party fails to pay the certified IDR entity fee, the party's offer will not be considered received.
30 business days after final selection of the certified IDR entity	**Selection of Offer** A certified IDR entity has 30 business days from the date of final selection of the certified IDR entity 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 submitted.
30 calendar days after payment determination	**Payments Between Parties of Payment Determination Amount** Any amount due from one party to the other party must be paid not later than 30 calendar days after the payment determination by the certified IDR entity.
30 business days after the payment determination	**Refunding the Certified IDR Entity Fee to the Prevailing Party**

	The certified IDR entity must refund the prevailing party's certified IDR entity fee within 30 business days after the payment determination.

II. Overview of the Proposed Rules—Departments of the Treasury, Labor, and HHS

A. Definition of Bundled Payment Arrangement

Section 9816(c)(3)(B) of the Code, section 716(c)(3)(B) of ERISA, and section 2799A-1(c)(3)(B) of the PHS Act state that the Departments shall provide that, in the case of items and services which are included by a provider or facility as part of a bundled payment, such items and services included in such bundled payment may be part of a single determination. The October 2021 interim final rules specify that in the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or if a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination and are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.[78] The preamble to the October 2021 interim final rules describes a bundled payment arrangement as an instance in which a group health plan or health insurance issuer pays a provider, facility, or provider of air ambulance services a single payment for multiple items or services furnished during an episode of care to a single patient.[79] To clarify how certified IDR entities can identify a dispute that includes a bundled payment arrangement, the Departments provided a definition for a bundled payment arrangement in the *August 2022 Technical Assistance for Certified IDR Entities*.[80] In that guidance, the Departments clarified that a single payment to one provider, facility, or provider of air ambulance services for multiple items or services must be made at the service code level for the entire bundle in order to be considered a bundled payment and therefore be treated as a single payment determination for the multiple

[78] 86 FR 55994.
[79] Id.
[80] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. (August 2022). *Technical Assistance for Certified IDR Entities*. *https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf.*

items and services under the Federal IDR process. The Departments defined a bundled payment arrangement at the service code level because service codes are the principal mechanism by which health care services and supplies are identified and reimbursed. These rules propose to codify the clarification set forth in the *August 2022 Technical Assistance for Certified IDR Entities*. Specifically, the Departments propose to amend 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30 by defining the term "bundled payment arrangement" as an arrangement under which: (1) a provider, facility, or provider of air ambulance services bills for multiple items or services furnished to a single patient under a single service code that represents multiple items or services (for example, a DRG code); or (2) a plan or issuer makes an initial payment or notice of denial of payment to a provider, facility, or provider of air ambulance services under a single service code that represents multiple items or services furnished to a single patient (for example, a DRG code).

For example, the *August 2022 Technical Assistance for Certified IDR Entities*, the *National Correct Coding Initiative (NCCI) Policy Manual*[81] explains that if a physician performs bilateral mammography, the provider shall report (or for the purpose of the Federal IDR process, the provider shall bill) Current Procedural Terminology (CPT) code 77066 (*Diagnostic mammography... bilateral*). The provider should not submit CPT code 77065 (*Diagnostic mammography... unilateral*) with 2 UOS or CPT code 77065 LT (*unilateral left breast mammography*) plus CPT code 77065 RT (*unilateral right breast mammography*). Under this example, the provider performed multiple services, and therefore, if the services are billed or reimbursed under one service code (CPT code 77066), all services performed under that service code (CPT codes 77065 LT and 77065 RT) may be considered a bundled payment arrangement for purposes of the Federal IDR process.

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[81] The NCCI, developed by the Centers for Medicare & Medicaid Services, promotes correct national coding methodologies. Although created for the purpose of reducing improper Medicare Part B payments, the NCCI policy manual is also used by commercial payers. CMS. (Feb. 28, 2023). *Medicare National Correct Coding Initiative (NCCI) Edits*. *https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare/medicare-ncci-policy-manual*.

Further, under current rules at 26 CFR 54.9816-8T(c)(3)(ii), 29 CFR 2590.716-8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii), bundled payment arrangements can be submitted as a single dispute and are subject to certified IDR entity fees for a single dispute rather than the higher fees for batched disputes (which may include multiple items or services from different claims between the same provider and plan but reflect the same service code or a similar code under a different procedural coding system).

To further clarify the process for resolving IDR disputes for bundled payment arrangements, the Departments propose an amendment that would remove the language in the October 2021 interim final rules stating that a bundled payment arrangement is subject to the rules for batched determinations. While a bundled payment arrangement by definition is billed by the same provider or group of providers, facility, or same provider of air ambulance services and paid by the same group health plan or health insurance issuer, not all requirements for batched determinations[82] apply to bundled payment arrangements.

The Departments solicit comment on the definition and treatment of bundled payment arrangements. The Departments also solicit comment on examples of service or procedural codes other than DRGs that would meet the proposed definition of a bundled payment arrangement.

B. Use of CARCs and RARCs

1. Existing Payment Communication Practice and Requirements

As described in section I.E. of this preamble, plans and issuers are currently required to disclose certain information to providers, facilities, and providers of air ambulance services when making an initial payment or notice of denial of payment when the recognized amount is the QPA.[83] The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the

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[82] 26 CFR 54.9816– 8T(c)(3), 29 CFR 2590.716–8(c)(3), and 45 CFR 149.510(c)(3).

[83] 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d). As explained in section II.C. of this preamble, the Departments are proposing the following amendments to 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) to reflect that the concept of the recognized amount is not applicable to providers of air ambulance services: (1) requiring plans and issuers to disclose the QPA and certain information about the QPA when cost sharing is calculated using the QPA for an air ambulance service; and (2) requiring plans and issuers to provide these disclosures when the recognized amount (or with respect to air ambulance services, the amount on

adoption of electronic standards for certain health care transactions, including health care payment and remittance advice. Under HIPAA and regulations implementing the electronic transaction standards, these disclosures, when transmitted from a plan or issuer to a provider, facility, or provider of air ambulance services,[84] meet the definition of a health care remittance advice transaction.[85] Therefore, plans and issuers must comply with the Accredited Standards Committee (ASC) X12 implementation guide adopted at 45 CFR 162.1602 when electronically transmitting the QPA disclosures required under 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) to a provider, facility, or provider of air ambulance services.[86] Further, plans and issuers are required to send remittance information electronically upon the request of a provider, facility, or provider of air ambulance services, regardless of whether the requesting individual or entity is in the plan's or issuer's network or otherwise affiliated with the plan or issuer.[87] When remittance advice is transmitted electronically, it is commonly referred to as an ERA.

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which cost sharing is based) is the QPA or the amount billed by the provider, facility, or provider of air ambulance services.

[84] HIPAA requirements related to health care remittance advice transactions apply to "covered entities," including "health plans" (which generally include plans and issuers) and "health care providers" (which include providers, facilities, and providers of air ambulance services that transmit any health information in electronic form in connection with an electronic transaction for which a standard has been adopted under HIPAA). 45 CFR 160.102 and 45 CFR 160.103. For purposes of continuity with the rest of this preamble, this section uses the terms "plan" and "issuer" to refer to entities that are subject to HIPAA requirements that apply to "health plans" and the term "providers, facilities, and providers of air ambulance services" to refer to entities that are subject to HIPAA requirements that apply to "health care providers." However, self-administered group health plans with fewer than 50 participants are excluded from the term "health plan" under 45 CFR 160.103 and are not subject to HIPAA requirements.

[85] 45 CFR 162.1601 ("The health care electronic funds transfers (EFT) and remittance advice transaction is the transmission of either of the following for health care: (a) The transmission of any of the following from a health plan to a health care provider: (1) Payment. (2) Information about the transfer of funds. (3) Payment processing information. (b) The transmission of either of the following from a health plan to a health care provider: (1) Explanation of benefits. (2) Remittance advice.").

[86] The ASC X12N 835 Version 5010 (835 transaction) is the current HIPAA standard that plans and issuers must use to electronically transmit explanation of benefits or remittance advice information to providers and facilities. As discussed later in this section II.B. of this preamble, the current ASC X12 standards predate, and therefore do not address, the No Surprises Act requirements.

[87] 45 CFR 162.925(a)(1). *See also* Gerhardt, C. (March 22, 2022). *Guidance on health plans' payment of health care claims using Virtual Credit Cards (VCCs) and adopted HIPAA standards for Health Care Electronic Funds Transfers (EFT) and Electronic Remittance Advice (ERA) transactions*. Centers for Medicare & Medicaid Services. *https://www.cms.gov/files/document/guidance-letter-vcc-eft-era.pdf.* HIPAA regulations require that a covered entity conduct a transaction as a standard transaction when using electronic media to transmit a transaction for which the Secretary has adopted a standard (*see* 45 CFR 162.923(a)). HIPAA regulations also require a health plan to conduct transactions as standard transactions when requested to do so (*see* 45 CFR 162.925(a)(1)). HIPAA does not, however, obligate a health plan to conduct a transaction(s) that it would not otherwise conduct.

An ERA explains how a plan or issuer has adjusted claim charges based on factors like contract agreements, secondary payers, benefits coverage, and expected cost sharing.[88] As noted earlier in this preamble section with reference to QPA disclosures, all ERAs must comply with the ASC X12 835 transaction standard adopted by HHS under 45 CFR 162.1602. The X12 835 implementation guide mandates the use of CARCs and RARCs to communicate remittance information (as opposed to any other code systems, such as proprietary codes developed by individual plans and issuers).[89] The terms "CARC" and "RARC" are not defined in Federal statute but are described in the ASC X12 835 implementation guide and the Council for Affordable Quality Healthcare Committee on Operating Rule for Information Exchange (CAQH CORE) operating rule adopted at 45 CFR 162.1603(a)(4). CARCs explain why a claim or service line was paid differently than it was billed.[90] RARCs provide additional explanations for an adjustment already described by a CARC or convey information about remittance processing. RARCs are either "supplemental," meaning that they provide additional explanation for an adjustment already described by a CARC, or "informational," meaning they convey information about remittance processing and are never related to a specific adjustment or CARC.[91] The lists of approved CARCs and RARCs are maintained by separate committees (the CARC Committee and the RARC Committee) designated by HHS to review requests to add, remove, or modify existing CARCs and RARCs. The HIPAA operating rule adopted at 45 CFR 162.1603(a)(4) requires plans and issuers to use a uniform set of CARCs and RARCs for defined business scenarios. Updated lists of approved CARCs and RARCs, along with an updated list of approved code combinations and business scenarios, are published three times each year.[92]

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[88] Centers for Medicare & Medicaid Services. (June 16, 2022). *Health Care Payment and Remittance Advice and Electronic Funds Transfer. https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Transactions/HealthCarePaymentandRemittanceAdviceandElectronicFundsTransfer*.
[89] CARCs and RARCs are required by the ASC X12 835 transaction standard and are not currently required to be used on paper remittance advice.
[90] X12. (Nov. 16, 2022). *Claim Adjustment Reason Codes*. *https://x12.org/codes/claim-adjustment-reason-codes*.
[91] X12. (March 1, 2023). *Remittance Advice Remark Codes*. *https://x12.org/codes/remittance-advice-remark-codes*.
[92] CAQH CORE. (n.d). *Ongoing Maintenance of the CORE Code Combinations*. *https://www.caqh.org/core/ongoing-maintenance-core-code-combinations.*

The RARC Committee has approved a set of specific RARCs that convey information related to the No Surprises Act, including which of the No Surprises Act provisions apply to a claim, how cost sharing was calculated under the No Surprises Act, and whether a payment for a claim was an initial or final payment calculated in accordance with the No Surprises Act.[93] These RARCs are currently available for use by plans and issuers, although the existing No Surprises Act-specific RARCs do not address all required QPA disclosures. The current standards and operating rules that govern ERA transactions under HIPAA were adopted prior to the enactment of the No Surprises Act and do not include specific requirements that dictate which combinations of CARCs and RARCs must be used to communicate claim adjudication information in business scenarios anticipated by the No Surprises Act.[94]

Plans and issuers consequently convey the disclosures required under the No Surprises Act to providers, facilities, and providers of air ambulances through a variety of methods, including electronic and paper remittance advice. These disclosures, if more effectively communicated, would provide providers, facilities, and providers of air ambulance services with more accessible information to determine whether they may initiate open negotiation and the Federal IDR process. However, in part because plans and issuers are not able to transmit all of the required disclosures through standard transactions,[95] such as the ASC X12 835 transaction, providers, facilities, and providers of air ambulance services have reported to the Departments that they are not always aware of, or cannot understand, the disclosures even when the plan or

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[93] X12. (March 1, 2023). *Remittance Advice Remark Codes. https://x12.org/codes/remittance-advice-remark-codes* (complete list of approved RARC codes including No Surprises Act-specific codes); and Centers for Medicare & Medicaid Services. (March 1, 2022). *Remittance Advice Remark Codes Related to the No Surprises Act*. (unofficial reference list of No Surprises Act-specific RARC codes).

[94] The ASC X12 835 transaction standard requires health plans to convey information about the adjudication of a claim using CARCS and RARCS. The Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, adopted at 45 CFR 162.1603 requires plans to use specified combinations of CARCs and RARCs in certain business scenarios. CAQH CORE. (August 2022). *CAQH CORE Payment and Remittance (835) Uniform Use of CARCs and RARCs Rule, Version PR.1.1. https://www.caqh.org/sites/default/files/core/Payment-Remittance-CARCs-RARCs-Rule.pdf.*

[95] "Standard transaction" means a transaction that complies with an applicable standard and associated operating rules adopted under the HIPAA Administrative Simplification requirements at 45 CFR part 162. 45 CFR 162.103.

issuer claims to have met the disclosure requirements.[96] Moreover, the Departments' ability to assess how often CARCs and RARCs are used to convey information related to the No Surprises Act is limited due to the minimal available data on uptake and the absence of guidance, standards, or operational rules specifying how these codes must be used. Informal feedback from providers, facilities, and providers of air ambulance services and plans and issuers suggests that some plans and issuers are using some of these codes, including when providing paper remittance advice, but there is not yet widespread usage.

2. Proposal to Require CARCs and RARCs to Improve Communication Between Plans and Issuers and Providers, Facilities, and Providers of Air Ambulance Services

Gaps in communication between plans and issuers and providers, facilities, and providers of air ambulance services contribute to inefficiencies in resolving disputes in the Federal IDR process. The Departments have identified the following areas of confusion, reported by plans, issuers, providers, facilities, providers of air ambulance services, and certified IDR entities, which are also consistent with the Departments' experience administering the Federal IDR process: (1) whether the consumer protections against balance billing and out-of-network cost sharing under the No Surprises Act apply to an item or service; (2) how cost sharing and the out-of-network rates are determined (that is, through an All-Payer Model Agreement, specified State law, or the Federal rules); (3) how and with whom to initiate open negotiations; and (4) which items or services eligible for the Federal IDR process can be batched or bundled into one dispute.

To address communication challenges described in section II.B.1. of this preamble, the Departments propose new disclosure rules at 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100. These proposed provisions would require plans and issuers to use CARCs and RARCs, as specified in guidance issued by the Departments (and discussed elsewhere in this

[96] For example, the Departments are aware of some cases where providers, facilities, and providers of air ambulance services used third parties to process remittances and did not realize the process for viewing the remittances through those third parties was filtering out information related to the No Surprises Act. Similarly, some providers, facilities, and providers of air ambulance services may view electronic remittance advice without realizing plans and issuers provided the QPA and related information on paper remittance advice.

section II.B. of this preamble), or as required under any applicable adopted standards and operating rules under 45 CFR part 162, to communicate information related to whether a claim for an item or service furnished by an entity that does not have a direct or indirect contractual relationship with the plan or issuer with respect to the furnishing of such item or service under the plan or coverage is subject to the provisions of 26 CFR 54.9816 and 54.9817; 29 CFR 2590.716 and 2590.717; or 45 CFR part 149, subparts B, E, or F. To improve the functioning of the Federal IDR process and ensure timely rendering of payment determinations, the Departments are of the view that providers, facilities, and providers of air ambulance services need information to understand not only when items and services are subject to the No Surprises Act, but also when they are not, to avoid submission of ineligible disputes to the Federal IDR process.

The Departments have the authority under section 9816(a)(2)(B)(ii) of the Code, section 716(a)(2)(B) of ERISA, and section 2799A-1(a)(2)(B)(ii) of the PHS Act to establish through rulemaking the information that a plan or issuer must share with a provider or facility when making a determination of the QPA, including the form and manner of such disclosures.[97] The Departments also have authority under section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act to issue such regulations as may be necessary and appropriate to carry out the provisions of chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act, including the provisions directing the Departments to establish the Federal IDR process.

Under these authorities, the Departments propose to require plans and issuers to use CARCs and RARCs to convey specific information about the No Surprises Act when a plan or

[97] The No Surprises Act does not include the same language addressing disclosures to providers of air ambulance services. However, the July 2021 interim final rules implemented the statute's cost-sharing requirements for air ambulance services by requiring that plans and issuers base any coinsurance and deductible for air ambulance services furnished by a nonparticipating provider of air ambulance services on the lesser of the QPA or the billed amount for the services. 86 FR 36884. Therefore, the July 2021 interim final rules also applied the requirement to make disclosures regarding the QPA with respect to providers of air ambulance services. As stated in the preamble to the July 2021 interim final rules, the Departments recognize that providers of air ambulance services subject to the surprise billing rules (as well as providers and emergency facilities) need transparency regarding how the QPA was calculated in order to inform the open negotiation process and the decision whether to initiate the Federal IDR process and what offer to submit. 86 FR 36898.

issuer provides a paper or electronic remittance advice to any entity with which it does not have a direct or indirect contractual relationship with respect to the furnishing of an item or service under the plan or coverage. Specifically, under these proposed rules, a plan or issuer would be required to use CARCs and RARCs in accordance with guidance issued by the Departments when, with respect to an entity with which it does not have a direct or indirect contractual relationship, the plan or issuer provides a paper or electronic remittance advice to a provider, facility, or provider of air ambulance services for an initial payment, notice of denial of payment, or total plan or coverage payment required under the No Surprises Act.

These proposed requirements would also apply to plans and issuers when sending remittance advice to entities with which they do not have a direct or indirect contractual relationship with respect to items and services to which the No Surprises Act surprise billing requirements do not apply, in order to convey that the No Surprises Act does not apply.

Requiring plans and issuers to use approved CARCs and RARCs to convey information related to the No Surprises Act on both electronic and paper remittance advice would better facilitate the flow of information between plans and issuers and providers, facilities, and providers of air ambulance services and increase efficiencies in the processing of claims subject to the No Surprises Act's surprise billing protections. This requirement would also assist providers, facilities, and providers of air ambulance services in identifying items and services that are not eligible for the Federal IDR process as early as the initial payment or notice of denial of payment, thereby reducing the submission of ineligible payment disputes to the Federal IDR process. This would decrease the need for outreach by certified IDR entities and allow them to concentrate resources on making payment determinations for eligible disputes.

In addition, the Departments anticipate that the proposed requirement to use CARCs and RARCs would provide valuable information to certified IDR entities in determining whether disputing parties agree on the eligibility of a dispute for the Federal IDR process after it has been submitted. As described in section II.D.1. of this preamble, the Departments propose to require

that the open negotiation notice include a copy of the initial payment or notice of denial of payment, which would, under the proposal described in this section of this preamble, include CARCs and RARCs related to the No Surprises Act. The Departments also propose, as described in section II.D.1. of this preamble, to require the open negotiation notice be submitted to the Departments through the Federal IDR portal. This would help ensure that, even if a plan or issuer does not respond to a notice of IDR initiation, the certified IDR entity has access to certain information regarding whether the plan or issuer believes the dispute could be eligible for the Federal IDR process, thereby avoiding unnecessary or duplicative outreach to the parties when possible.

As discussed in section V.D. of this preamble, requiring the use of CARCs and RARCs as described in these proposed rules would result in an increase in burden for plans (or their third party administrators (TPAs)) and issuers, as they would need to implement and automate the use of new CARCs and RARCs. However, because all plans and issuers that provide ERA transactions subject to the HIPAA Administrative Simplification requirements already are required to use CARCs and RARCs, the Departments anticipate that most plans and issuers would generally have the capacity to provide No Surprises Act-specific CARCs and RARCs. The Departments seek comment on any circumstances in which it would not be possible for a plan or issuer to determine whether an item or service included on a remittance advice is, or is not, subject to the Federal IDR process at the time the remittance advice is issued to a provider, facility, or provider of air ambulance services. The Departments also seek comment on the technical and operational steps that would be necessary to initially implement new No Surprises Act-specific CARCs and RARCs, including for plans and issuers that do not currently use CARCs and RARCs, or that are currently able to accommodate only one CARC and RARC combination per line item.

The Departments propose that certain procedural aspects of this proposal would be implemented through guidance issued by the Departments.[98] Should the proposal described in this section of the preamble be finalized, the Departments would be authorized to require plans and issuers to use CARCs and RARCs to communicate information related to whether a claim for an out-of-network item or service is or is not subject to the surprise billing provisions of the No Surprises Act. The guidance issued under this authority would identify specific CARCs and RARCs and describe the specific circumstances in which the identified CARCs and RARCs must be used. As discussed in section II.B.1. of this preamble, this approach also mirrors the existing framework under HIPAA, in which required CARC and RARC code combinations are issued through guidance, as authorized by regulation. This would provide the Departments with the flexibility to specify the use of CARCs and RARCs, including new No Surprises Act-specific RARCs that may be developed in the future, while the Departments work to address communication challenges affecting the surprise billing provisions of the No Surprises Act. It would also provide flexibility for the Departments to discontinue the use of certain CARCs and RARCs should the information communicated using those CARCs and RARCs become readily available to providers, facilities, or providers of air ambulance services through a different mechanism or otherwise become unnecessary. As discussed in more detail in section II.H.1. of this preamble, the Departments propose that plans and issuers would have a period of time following the issuance of guidance to implement the use of CARCs and RARCs in accordance with the guidance.

HHS is not proposing changes to the HIPAA transaction standards (such as the X12 835 standard) or operating rules in these proposed rules. HHS continues to monitor the implementation of the No Surprises Act in order to determine whether future changes to the HIPAA transaction standards and operating rules, in accordance with the mandated HIPAA

[98] This proposal would not alter HHS' authority under HIPAA to implement future guidance with respect to electronic remittance advice or to adopt new or modified standards or operating rules in accordance with Title XI Part C – Administrative Simplification of the Social Security Act.

standards and operating rules development and adoption processes,[99] might provide a long-term mechanism for facilitating communication related to the No Surprises Act between plans and issuers and providers, facilities, and providers of air ambulance services.

The Departments are of the view that it would be beneficial to standardize No Surprises Act-related communications between plans and issuers and providers, facilities, and providers of air ambulance services, regardless of whether the information is transmitted using HIPAA standard transactions. Therefore, under this proposal, the Departments would issue guidance regarding the use of CARCs and RARCs in both electronic transactions as well as formats outside the purview of the HIPAA transaction standards, including paper remittance advice. While CARCs and RARCs have not been widely used to transmit information outside of ERA transactions, the Departments understand that some plans and issuers routinely communicate with providers, facilities, and providers of air ambulance services using paper remittance advice and other formats outside the purview of the HIPAA transaction standards.

In addition to the RARCs related to the No Surprises Act described previously in this section of the preamble that have been approved for use, the Departments are assessing whether additional CARCs or RARCs could be helpful for improving communication between parties about how out-of-network claims are being processed in relation to the No Surprises Act. For example, the Departments are considering whether it would be beneficial to require the use of CARCs and RARCs when plans and issuers have insufficient information to determine coverage for a claim from a nonparticipating provider of air ambulance services.[100] The Departments are also considering whether it would be beneficial to require the use of RARCs that could be used to provide any of the information required to be disclosed about the QPA under 26 CFR

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[99] Sections 1172 and 1173 of the Social Security Act and 45 CFR 162.910.

[100] In *TMA III*, the District Court vacated the language in 26 CFR 54.9817-1T(b)(4)(i), 29 CFR 2590.717-1(b)(4)(i), and 45 CFR 149.130(b)(4)(i), that stated with respect to air ambulance services, "For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services." *See* Memorandum Opinion and Order, *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health and Hum. Servs.,* No. 6:22-cv-00450-JDK (E.D. Tex. August 24, 2023). Because a plan or issuer may not have the information necessary to decide a claim for payment within the 30-calendar-day period, the Departments are considering whether CARCs and RARCs may be useful in such circumstances.

54.9816-6T(d), 26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d). It also may be helpful to have a RARC that specifies that the No Surprises Act surprise billing protections do not apply. In addition, a large proportion of the disputes determined ineligible for the Federal IDR process by certified IDR entities involve items or services that providers, facilities, or providers of air ambulance services batched improperly because they did not realize that a TPA was administering coverage for multiple self-insured plans rather than a single issuer or group health plan, and the items and services were thus ineligible to be batched.[101] Certified IDR entities have determined that other disputes are ineligible for the Federal IDR process because the self-insured plan involved in the dispute had voluntarily opted in to a specified State law.[102] A RARC that could clearly identify a payer as a self-insured plan may reduce the number of disputes that are initiated and determined ineligible on the basis of a batching or jurisdictional error. The Departments solicit comment on whether and what information not conveyed in the existing RARCs would be helpful to convey through the creation of additional RARCs related to the No Surprises Act's surprise billing provisions.

The Departments are aware that some States require issuers to use CARCs and RARCs to communicate information about State surprise billing laws. The Departments seek comment regarding experience with these requirements, including whether such requirements have been effective, and any challenges related to implementing such requirements. Should these proposed rules be finalized, the Departments note that nothing in these proposed rules would prevent a State from requiring that issuers use specific CARCs or RARCs in addition to those specified in the No Surprises Act-specific Federal guidance that the Departments would be authorized to issue; nor would a State or other entity be prevented from engaging with the relevant committees

[101] 26 CFR 54.9816-8T(c)(3)(i)(B), 29 CFR 2590.716-8(c)(3)(i)(B), and 45 CFR 149.510(c)(3)(i)(B).
[102] *See* discussion in section I.H. of of this preamble related to the provisions of the July 2021 interim final rules that allow self-insured group health plans, including self-insured non-Federal governmental plans, to voluntarily opt into a specified State law.

to request the creation or use of a CARC or RARC in addition to those specified in such guidance.

Prior to the enactment of the No Surprises Act, out-of-network providers, facilities, and providers of air ambulance services commonly sought reimbursement directly from patients rather than from a plan or issuer, requiring a participant, beneficiary, or enrollee to then seek reimbursement for all or part of the cost of the out-of-network service directly from their plan or issuer. Because the No Surprises Act prohibits nonparticipating providers, facilities, and providers of air ambulance services from billing or holding liable a participant, beneficiary, or enrollee for an amount greater than the applicable in-network cost-sharing requirement for items and services subject to the No Surprises Act, direct billing of patients is now largely limited to items and services to which surprise billing protections in the No Surprises Act do not apply. The Departments understand that requiring the plan or issuer to convey CARC or RARC information related to eligibility for such processes to a participant, beneficiary, or enrollee in this circumstance would represent an administrative burden on the plan or issuer without any clear benefit to the participant, beneficiary, or enrollee. In addition, such a requirement would not further the aims of these proposed rules to facilitate timely rendering of payment determinations and to improve the functioning of the Federal IDR process, in which a participant, beneficiary, or enrollee cannot participate as a party. Therefore, the requirement to use CARCs and RARCs under these proposed rules would not apply for out-of-network items and services for which the plan or issuer makes payment directly to the participant, beneficiary, or enrollee. The Departments seek comment on whether a plan or issuer should generate a remittance advice that can be obtained upon request by the provider, facility, or provider of air ambulance services when the plan or issuer makes a payment directly to a participant, beneficiary, or enrollee, and whether the requirement to use CARCs and RARCs to convey No Surprises Act-specific information as proposed in these rules should apply in these circumstances.

While the proposal refers to any paper or electronic remittance advice,[103] the Departments seek comment on whether a more general term, such as "any remittance advice," would be helpful in characterizing the types of communications accompanying payments for items and services. The Departments also seek comment on this proposal generally.

C. Information to be Shared About the QPA

As described in sections I.B. and I.E. of this preamble, the July 2021 interim final rules and August 2022 final rules provide that if the recognized amount with respect to an item or service is the QPA, plans and issuers must make certain disclosures about the QPA with each initial payment or notice of denial of payment and must also provide certain additional information upon request.[104] This information must be provided in writing, either on paper or electronically, to a provider, facility, or provider of air ambulance services, as applicable.[105]

While these requirements were intended to ensure the disclosure of information about the QPA in any instance in which an item or service would be eligible for the Federal IDR process, the text of the current regulation directs plans and issuers to make these disclosures only if the recognized amount with respect to an item or service furnished by a provider, facility, or provider of air ambulance services is the QPA. The Departments propose a change to reflect that the term "recognized amount" is not used in the statute or regulations for purposes of determining cost sharing with respect to air ambulance services furnished by nonparticipating providers of air ambulance services. Rather, under the July 2021 interim final rules, plans and issuers must calculate the cost-sharing amount for air ambulance services furnished by a nonparticipating provider of air ambulance services as if the total amount that would have been charged were equal to the lesser of the QPA or the billed amount for the services.[106] Therefore,

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[103] The Departments are aware that different terms are sometimes used, such as paper remittance advice or explanation of payment, when referring to the paper communication that accompanies a payment or notice of denial of payment to a provider or facility for a claim and provides additional information about the adjudication of the claim for which payment is being made.
[104] 86 FR 36898; 87 FR 52633.
[105] 26 CFR 54.9816-6T(d) and 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d).
[106] 86 FR 36884.

the Departments propose to amend the regulations to specify that plans and issuers must, in the case of air ambulance services, disclose the QPA and certain information about the QPA when cost sharing is calculated using the QPA. In addition, the Departments propose to require plans and issuers to make the same disclosures when the recognized amount (or with respect to air ambulance services, the amount on which cost sharing is based) is the amount billed by the provider, facility, or provider of air ambulance services, and not only when the recognized amount (or with respect to air ambulance services, the amount on which cost sharing is based) is the QPA, as these items and services would also be eligible for the Federal IDR process (provided all other eligibility criteria are satisfied).

Under 26 CFR 54.9816-6T(d)(1)(iv), 29 CFR 2590.716-6(d)(1)(iv), and 45 CFR 149.140(d)(1)(iv), a plan or issuer making disclosures about the QPA must include a statement that if the provider or facility wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and if the 30-day open negotiation period does not result in a determination, generally the provider or facility may initiate the Federal IDR process 4 days after the end of the open negotiation period. Under 26 CFR 54.9816-6T(d)(2), 29 CFR 2590.716-6(d)(2), and 45 CFR 149.140(d)(2), plans and issuers are required to disclose additional information in a timely manner upon the request of the provider or facility.

The Departments propose technical and conforming amendments to align these requirements with the October 2021 interim final rules[107] and current practice. First, the Departments acknowledge that 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) do not consistently include references to providers of air ambulances services when referring to providers and facilities, and propose amendments to clarify that these disclosure requirements apply with respect to providers of air ambulance services (in addition to providers and facilities). Specifically, in 26 CFR 54.9816-6T, 29 CFR 2590.716-6, and 45 CFR 149.140,

[107] 86 FR 55980.

the Departments propose to amend the introductory language in paragraph (d), paragraph (d)(1)(iv), and the introductory language of paragraph (d)(2) to clarify the applicability with respect to disclosures to providers of air ambulance services.[108] Second, the Departments propose to align the timeframes described in the disclosure with the timeframes established in the October 2021 interim final rules,[109] by specifying that days are counted using business days (rather than calendar days), where applicable. The Departments also propose an amendment to align the language in 26 CFR 54.9816-6T(d)(1)(iv), 29 CFR 2590.716-6(d)(1)(iv), and 45 CFR 149.140(d)(1)(iv) with the same requirements established in the October 2021 interim final rules by replacing the phrase "amount of total payment" with the term "out-of-network rate," as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30, and by describing an unsuccessful open negotiation period as not resulting in an "agreement on the amount of payment" rather than a "determination."

The Departments further propose to require that the statement also explain that the provider, facility, or provider of air ambulance services must notify the Departments as described under proposed 26 CFR 54.9816-8(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510(b)(1)(i), as applicable, to initiate open negotiation.[110] The Departments propose that plans and issuers include this explanation as part of the disclosure once the open negotiation notice can be submitted through the Federal IDR portal.

As stated in the preamble to the July 2021 interim final rules[111] and the August 2022 final rules,[112] the Departments seek to ensure transparent and meaningful disclosure of information relating to the calculation of the QPA for providers, facilities, and providers of air ambulance services, while at the same time minimizing administrative burdens on plans and issuers and on

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[108] The Departments anticipate finalizing additional corrections to address this issue when finalizing the remainder of the July 2021 interim final rules.
[109] 26 CFR 54.9816-8T(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510(b)(1)(i).
[110] For a discussion of the proposed requirement to notify the Departments when initiating open negotiation, *see* section II.D.1.c. of this preamble.
[111] 86 FR 36898.
[112] 87 FR 52625.

the Federal IDR process. The Departments are now of the view that additional disclosure of information with the QPA is critical to ensuring that all parties have the information necessary to determine whether a payment dispute is eligible for the Federal IDR process. The Departments therefore propose to amend 26 CFR 54.9816-6T, 29 CFR 2590.716-6, and 45 CFR 149.140 by re-designating paragraph (d)(1)(v) as (d)(1)(vi) and adding a new paragraph (d)(1)(v) that would require plans and issuers to disclose the legal business name of the plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the registration number assigned under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, or 45 CFR 149.530, as applicable, if the plan or issuer is registered with the Federal IDR registry.[113] The Departments seek comment on the specific technical and operational steps that would be necessary for plans and issuers to disclose this additional information when providing an initial payment or notice of denial of payment. Further, the Departments are seeking comment on the appropriate implementation period that would allow plans and issuers to complete these steps to comply with these proposed rules, if finalized. As noted in section II.B. of this preamble, the Departments are also seeking comment on whether any of the additional proposed disclosures should be required to be communicated using a CARC or RARC specified in guidance issued by the Departments.

D. Open Negotiation and Initiation of the Federal IDR Process

Section 9816(c)(1)(A) of the Code, section 716(c)(1)(A) of ERISA, section 2799A-1(c)(1)(A) of the PHS Act, and the October 2021 interim final rules establish that, when the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified State law as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30, the plan or issuer or provider or facility may engage in open negotiations to determine the total out-of-network rate (inclusive of any cost sharing).[114] If the parties fail to reach an agreement through open negotiation, they may initiate the Federal IDR

[113] For a discussion of the proposal to establish a Federal IDR registry and assign a registration number to each plan and issuer, *see* section II.F. of this preamble.
[114] 86 FR 55990.

process. Section 9817(b) of the Code, section 717(b) of ERISA, and section 2799A-2(b) of the PHS Act provide that out-of-network rates for air ambulance services may be determined through open negotiation or an IDR process that is largely identical to the process provided for in section 9816(c) of the Code, section 716(c) of ERISA, and section 2799A-1(c) of the PHS Act. Thus, the preamble and regulatory text describing open negotiations and the Federal IDR process generally apply to providers of air ambulance services, unless otherwise specified.

1. Open Negotiation

The Departments propose to amend the open negotiation provisions of 26 CFR 54.9816-8T(b)(1)(i) and (ii), 29 CFR 2590.716-8(b)(1)(i) and (ii), and 45 CFR 149.510(b)(1)(i) and (ii) to establish additional requirements for initiating open negotiation and to revise the open negotiation period start date. In addition, the Departments propose to add a new paragraph at 26 CFR 54.9816-8(b)(1)(iii), 29 CFR 2590.716-8(b)(1)(iii), and 45 CFR 149.510(b)(1)(iii) that would establish a requirement that in response to a party's written notice of its intent to negotiate (open negotiation notice), the party in receipt of the notice must provide a written open negotiation response notice. In these proposed rules, the Departments propose amendments to the content requirements for the open negotiation notice. The Departments also propose to require an open negotiation response notice from non-initiating parties, including specific content requirements.

Section 9816(c)(1)(A) of the Code, section 716(c)(1)(A) of ERISA, section 2799A-1(c)(1)(A) of the PHS Act, and the October 2021 interim final rules establish that the open negotiation period may be initiated by either party during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives either an initial payment or a notice of denial of payment for an item or service.[115] The October 2021 interim final rules provide that in order for a plan, issuer, provider, facility, or provider of air ambulance

[115] As clarified in the July 2021 interim final rules, the initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances, prior to the beginning of any open negotiations or initiation of the Federal IDR process. (86 FR 36900 through 36901).

services to know when it is a party to an open negotiation period and the item or service for which the payment is the subject of open negotiation, the party initiating open negotiation must provide to the other party a written open negotiation notice.[116] Under 26 CFR 54.9816-8T(b)(1)(ii)(A), 29 CFR 2590.716-8(b)(1)(ii)(A), and 45 CFR 149.510(b)(1)(ii)(A), an open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and the initial amount, if applicable, an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice). The day on which the open negotiation notice is first sent by the party is the date that the 30-business-day open negotiation period begins. Consistent with the October 2021 interim final rules, negotiation during the open negotiation period occurs without the involvement of the Departments or a certified IDR entity.[117] Furthermore, the requirement to complete a 30-business-day open negotiation period before initiating the Federal IDR process does not preclude the parties from reaching an agreement in fewer than 30 business days. However, in the event the parties do not reach an agreement, they still must exhaust the 30-business-day open negotiation period before either party may initiate the Federal IDR process. The Departments encourage disputing parties to negotiate in good faith during this time period to reach an agreement on the out-of-network rate. The Departments expect parties to make a genuine effort to exchange information with one another at reasonable times and intervals with the goal of reaching a solution satisfactory to both parties. To the extent parties reach an agreement during the open negotiation period, they can avoid the administrative fee and other costs associated with the Federal IDR process.

The preamble to the October 2021 interim final rules explained that, given that the parties already would have made initial contact (namely, the provider, facility, or provider of air ambulance services transmitted a bill to the plan or issuer, and the plan or issuer sent an initial

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[116] 86 FR 55990.
[117] *See* 86 FR 55991.

payment or notice of denial of payment to the provider, facility, or provider of air ambulance services), the Departments expected the parties to provide effective notice and encouraged the parties to take reasonable measures to confirm the other party's contact information and confirm electronic receipt through approaches such as read receipts, especially if a party does not initially respond to an open negotiation notice.[118] Further, the Departments contemplated that issues related to eligibility and jurisdiction would be resolved through the disclosures that plans and issuers are required to provide with their initial payment or notice of denial of payment or, through the required 30-business-day open negotiation period. However, disputing parties and certified IDR entities have reported that disputing parties are sometimes not actively negotiating with each other during the required period as expected by the Departments. In addition, non-initiating parties and certified IDR entities continue to express concern that initiating parties sometimes do not properly initiate or complete the open negotiation period before initiating the Federal IDR process. Plans and issuers also have expressed concern with the Departments and the certified IDR entities, that providers, facilities, and providers of air ambulance services overwhelm them with requests to negotiate items or services that are ineligible for the Federal IDR process. At the same time, providers, facilities, and providers of air ambulance services assert that plans and issuers rarely respond to their notices initiating open negotiation or provide inadequate information to determine whether the Federal IDR process applies during the open negotiation period.

a. Determination of Payment Amount Through Open Negotiation

To improve communication and information exchange between disputing parties and promote efficiencies in the Federal IDR process, the Departments propose to amend the open negotiation provisions of 26 CFR 54.9816-8(b), 29 CFR 2590.716-8(b), and 45 CFR 149.510(b)(1) to impose new information exchange requirements and processes and to establish

[118] 86 FR 55990.

a process for tracking open negotiations through the Federal IDR portal in anticipation of initiation of a Federal IDR dispute.

First, the Departments propose to amend paragraph 26 CFR 9816-8(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510(b)(1)(i) to establish a requirement that a party must provide a written open negotiation notice to the other party and to the Departments through the Federal IDR portal to initiate the open negotiation period.[119] Requiring a party to submit the open negotiation notice to the Departments in addition to the other party would provide a record of whether and when the open negotiation period was properly initiated, which is essential in determining eligibility for the Federal IDR process, and would create greater transparency among parties engaged in open negotiation, the Departments, and certified IDR entities.

Second, the Departments propose to amend 26 CFR 54.9816-8(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510(b)(1)(i) to specify that the 30-business-day open negotiation period begins on the day a party first submits the open negotiation notice and a copy of the initial payment, notice of denial of payment, or other remittance advice, as specified at proposed 26 CFR 54.9816-8(b)(1)(ii)(A)(*12*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*12*), and 45 CFR 149.510(b)(1)(ii)(A)(*12*), to the other party and the Departments through the Federal IDR portal. This amendment would not change the timeframe for engaging in open negotiations but would provide greater clarity for parties engaged in open negotiation and improve the shared understanding of deadlines related to the open negotiation period. The Departments seek comment on these proposed amendments.

b. Open Negotiation Response Notice

To have a meaningful open negotiation, the Departments are of the view that both parties must be active and responsive participants. The Departments' experience and feedback from disputing parties and certified IDR entities indicate that the Federal IDR process is less efficient overall when disputing parties are not engaging with each other during the open negotiation

[119] 26 CFR 9816-8T(b)(3), 29 CFR 2590.716-8(b)(3), and 45 CFR 149.510(b)(3).

period. Therefore, the Departments propose at 26 CFR 54.9816-8(b)(1)(iii), 29 CFR 2590.716-8(b)(1)(iii), and 45 CFR 149.510(b)(1)(iii) to require that the party in receipt of the open negotiation notice provide a written notice and supporting documentation in response to the open negotiation notice (open negotiation response notice) to the other party and the Departments through the Federal IDR portal as soon as practicable, but no later than the 15th business day of the 30-business-day open negotiation period. Requiring the party in receipt of the open negotiation notice to submit an open negotiation response notice to both the other party and the Departments through the Federal IDR portal would help ensure that parties are responding to open negotiation notices and engaging with one another during the open negotiation period. To better inform the parties' negotiations, the Departments are proposing this 15-business-day timeframe to give the party in receipt of the open negotiation notice sufficient time to review and respond to the open negotiation notice. This would also allow the party that submitted the open negotiation notice to consider, at its discretion, the information included in the open negotiation response notice during (at a minimum) the remaining 15 business days in the 30-business-day open negotiation period.

These deadlines are intended to encourage meaningful participation in open negotiations and allow both parties time to consider offers and raise eligibility concerns prior to initiating the Federal IDR process. If a party were to fail to furnish an open negotiation response notice containing all required information to the other party and the Departments, the Departments would review and determine whether enforcement actions may be appropriate. However, failure to timely furnish an open negotiation response notice in any specific open negotiation would not extend the open negotiation period, delay the timeframe for initiation of the Federal IDR process, or affect either party's ability to initiate the Federal IDR process.

The Departments solicit comment on the proposed modifications to the requirements for submitting the open negotiation notice and the newly proposed open negotiation response notice. Specifically, the Departments seek comment on whether the party in receipt of the open

negotiation notice should be required to furnish the open negotiation response notice to the other party and the Departments earlier than proposed to allow additional time for the party submitting the open negotiation notice to review the open negotiation response notice. The Departments also seek comment on imposing a deadline for the open negotiation response notice later than the proposed deadline, including by the 20th business day or up to the last day of the 30-business-day open negotiation period. A longer response timeframe may be necessary for a party in receipt of open negotiation notice to review and respond if the party receives a high number of open negotiation notices within a short time period. However, submission of the open negotiation response notice at the end of the open negotiation period would not provide the party that submitted the open negotiation notice sufficient time to review, consider, and engage with the party submitting the open negotiation response notice in a meaningful manner prior to the deadline for initiation of the Federal IDR process. Additionally, the Departments seek comment on allowing the certified IDR entities, as a means of incentivizing participation in the proposed exchange of notices, to take into consideration a party's compliance with the 15-business-day deadline for the open negotiation response notice when making their payment determinations.

c. Open Negotiation Notice Content

The Departments propose to amend 26 CFR 54.9816-8(b)(1)(ii)(A), 29 CFR 2590.716-8(b)(1)(ii)(A), and 45 CFR 149.510(b)(1)(ii)(A) and add 26 CFR 54.9816-8(b)(1)(ii)(A)(*1*) through (*12*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*1*) through (*12*), and 45 CFR 149.510(b)(1)(ii)(A)(*1*) through (*12*) to require that the open negotiation notice include additional information regarding the item or service under dispute and the party sending the open negotiation notice. The proposed amendments would add new elements and expand the information required on the open negotiation notice.

Under these proposed rules, the content elements to identify the item or service on the open negotiation notice would align with those that the Departments propose to require in the notice of IDR initiation to identify an item or service under dispute as specified in 26 CFR

54.9816-8(b)(2)(iii)(A), 29 CFR 2590.716-8(b)(2)(iii)(A), and 45 CFR 149.510(b)(2)(iii)(A) and would encourage consistency between open negotiation and the Federal IDR process. The Departments are of the view that requiring the additional elements as part of the open negotiation notice would help parties identify the item or service, the reasons for the denial of payment or initial payment amount, and whether the Federal IDR process applies. Each proposed new or amended element on the open negotiation notice is described in this section, and the Departments' reasoning for the proposed change is explained.

Under current rules, the open negotiation notice must include contact information for the party sending the notice. At proposed paragraphs 26 CFR 54.9816-8(b)(2)(iii)(A)(*1*) through (3), 29 CFR 2590.716-8(b)(2)(iii)(A)(*1*) through (3), and 45 CFR 149.510(b)(1)(ii)(A)(*1*) through (3), the Departments would require specific contact information sufficient to identify the provider, facility, or provider of air ambulance services, the plan or issuer, and any third party representing the parties in the open negotiation. This contact information would include legal business name, email address, phone number, and mailing address, as provided with the claim form submitted by the provider, facility, or air ambulance provider to the plan or issuer, which would encourage open negotiation initiation between the correct parties and effective communication of the required information.

In addition to the proposed standard contact information elements, parties would also be required to include the National Provider Identification (NPI) number to identify the provider, facility, or provider of air ambulance services and the IDR registration number, assigned under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, to identify the plan or issuer (described further in section II.F. of this preamble).

Providers, facilities, and providers of air ambulance services would obtain the IDR registration number from the plan or issuer when the plan or issuer provides it with the initial payment or notice of denial of payment. The proposed registration number would help the provider, facility, or provider of air ambulance services to accurately identify the plan and issuer

with which to initiate open negotiation, and the contact and plan information necessary to initiate open negotiation, particularly if the plan or issuer fails to clearly disclose such information. Including this element on the open negotiation notice would streamline the process of submitting the open negotiation notice by providing a validated source of plan and issuer business and contact information, which providers, facilities, and providers of air ambulance services often struggle to identify on documentation provided with the initial payment or the notice of denial of payment and would promote greater consistency and accuracy in initiating open negotiation with the correct plan or issuer.

The Departments acknowledge, as described in section II.F. of this preamble, that the plan or issuer may not be registered in the IDR registry at the time the provider, facility, or provider of air ambulance services initiates the open negotiation period. In these circumstances, the party submitting the open negotiation notice would attest that the party receiving the open negotiation notice was not registered prior to the date the party submitted its open negotiation notice and the registration number would not be required to be included in the notice. The submitting party would use the contact information currently required by the disclosure requirements established in sections 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1) with the initial payment or notice of denial of payment to complete the open negotiation notice. Finally, if the party submitting the open negotiation notice is a plan or issuer, the plan or issuer would be required to include the plan type. It is the Departments' view that the plan or issuer is best positioned to provide this information and that this information is necessary in assessing applicability of the Federal IDR process. If the plan or issuer is not the party initiating open negotiation, the plan or issuer would be required to include this information on the open negotiation response notice form, as discussed in section II.D.1.d. of this preamble.

Under the current regulations, the open negotiation notice must include information sufficient to identify the item(s) and service(s) furnished by the provider, facility, or provider of air ambulance services. These include the date(s) the item(s) or service(s) were furnished, the

service code, and initial payment amount, if applicable, an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice. If finalized, these proposed rules would add to this list of elements considered information sufficient to identify the item or service and, therefore, required to be included in the open negotiation notice at proposed paragraphs 26 CFR 54.9816-8(b)(1)(ii)(A)(*4*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*4*), and 45 CFR 149.510(b)(1)(ii)(A)(*4*). The proposed additions include information to identify the location where the item or service was furnished (such as place of service code or bill type code[120]), type of item or service, the State where the item or service was furnished, and the claim number. The place of service code is a two-digit code on health care professional claims that indicates the setting in which a service was furnished.[121] Place of service code information is often needed to determine the acceptability of direct billing of Medicare, Medicaid, and private insurance services furnished by a given provider.[122] Further, these proposed rules would require the open negotiation notice to include the type of item or service, including whether the item or service is an emergency service or a non-emergency service; whether the item or service is an air ambulance service as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716-3, and 45 CFR 149.30; and whether any service is a professional service or a facility-based service. Parties engaged in open negotiations may use place of service code and information on the type of item or service to analyze the appropriateness of the payment for the item or service and the applicability of the Federal IDR process. The place of service code and type of item or service along with the proposed requirement to include the State where the item or service was furnished would help the parties assess whether a specified State law or an All-Payer Model Agreement might apply. In some States, a specified State law or All-Payer Model Agreement may apply only to certain

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[120] Bill type code is the code relevant for billing by facilities (as opposed to place of service code for providers).
[121] *See* Centers for Medicare & Medicaid Services. (December 1, 2021). *Place of Service Codes*. *https://www.cms.gov/Medicare/Coding/place-of-service-codes#:~:text=Place%20of%20Service%20Codes%20are,throughout%20the%20health%20care%20industry*.
[122] *Id*.

items or services or with respect to services furnished by certain out-of-network providers or at certain locations ("bifurcated States").[123]

The combination of these requirements would help parties identify whether the Federal IDR process applies or whether an applicable specified State law or All-Payer Model Agreement governs the out-of-network payment amount. The Departments are of the view that requiring parties to provide this information on the open negotiation notice would improve communication between parties and help identify and resolve differences in their understanding of the items or services that are the subject of open negotiation. Further, the Departments expect that as the Federal IDR portal continues to evolve, this information may also be helpful in providing automatic verifications upon a party's initiation of the open negotiation period of eligibility for the Federal IDR process, which may result in a reduction in submission of ineligible items and services.[124]

Plans and issuers have expressed concern that it is often difficult to identify the item or service subject to the dispute within their billing systems without the associated claim number provided by the provider, facility, or provider of air ambulance services. Therefore, the Departments amended the standard open negotiation notice to include the claim number, as it is necessary to identify the item or service that is subject of the dispute.[125] Under these proposed rules, the Departments are proposing to codify the requirement to include the associated claim number in the open negotiation notice.

At proposed paragraph 26 CFR 54.9816-8(b)(1)(ii)(A)(*5*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*5*), and 45 CFR 149.510(b)(1)(ii)(A)(*5*), the Departments would specify that the

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[123] There are currently 21 bifurcated States: California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Maine, Maryland, Michigan, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Texas, Virginia, and Washington. *See https://www.cms.gov/files/document/applicability-federal-idr-bifurcated-states.pdf.*

[124] The Departments note that while this information may assist parties in preliminarily assessing eligibility based on the location of service, it would not eliminate the need for the certified IDR entity or the Departments to determine whether a specified State law applies to the specific item or service and provider at issue.

[125] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of Treasury. (expiration Nov. 30, 2025). *Open Negotiation Notice*. (OMB Control No. 1210-0169). *https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-2.pdf.*

open negotiation notice must include the initial payment amount (including $0 if, for example, the payment is denied) of the item or service subject to the open negotiation. The initial payment amount is an existing requirement of the open negotiation notice, and this proposed amendment relocates it to 26 CFR 54.9816-8(b)(1)(ii)(A)(*5*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*5*), and 45 CFR 149.510(b)(1)(ii)(A)(*5*) in the regulatory text and clarifies that the plan or issuer must specify $0 if payment is denied.

The Departments propose to add paragraph 26 CFR 54.9816-8(b)(1)(ii)(A)(*6*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*6*), and 45 CFR 149.510(b)(1)(ii)(A)(*6*) to require a party initiating open negotiations to provide the QPA for the item or service that is the subject of the negotiation if it has been provided on the initial payment or notice of denial of payment or if the party submitting the open negotiation notice is a plan or issuer. Similarly, by requiring the QPA to be disclosed on the open negotiation notice, the Departments intend to facilitate better communication between parties in identifying whether there may be a mistake in the identified QPA, such as a typographical error or the incorrect use of the cost sharing amount rather than the QPA, so the information can be rectified before initiating the Federal IDR process, if applicable.

At proposed paragraph 26 CFR 54.9816-8(b)(1)(ii)(A)(*7*), 29 CFR 2590.716-*8*(b)(1)(ii)(A)(*7*), and 45 CFR 149.510(b)(1)(ii)(A)(*7*) the Departments would specify that the open negotiation notice must include an offer of an out-of-network rate for each item or service that is the subject of the open negotiation. The offer of an out-of-network-rate is an existing requirement of the open negotiation notice, and this proposed amendment relocates it to new paragraph (b)(1)(ii)(A)(*7*) in the regulatory text.

Under proposed 26 CFR 54.9816-8(b)(1)(ii)(A)(*8*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*8*), and 45 CFR 149.510(b)(1)(ii)(A)(*8*) the Departments propose to require that if the party submitting the open negotiation notice is a plan or issuer, it must include the amount of cost sharing imposed for the item or service, if any. The Departments are of the view that the plan or issuer is in the best position to provide this information since non-participating providers,

facilities, or providers of air ambulance services generally would not have access to this information. Because the amount of cost sharing for a qualified IDR item or service would be determined by the QPA amount, requiring the amount of cost sharing paid or owed by the participant, beneficiary, or enrollee could help parties better inform their offers while negotiating. The amount of cost sharing paid or owed by the participant, beneficiary, or enrollee would be used, along with the prevailing offer to calculate the final payment amount, should a party choose to initiate the Federal IDR process for the item or service in question. Having a shared understanding of this value and its impact on payment during open negotiations would support the parties' ability to negotiate with one another in good faith.

A non-emergency item or service is ineligible for the Federal IDR process if the patient was properly provided notice and consented to waive their protections from balance billing under the No Surprises Act.[126] To reduce the number of Federal IDR process disputes initiated for items or services that are ineligible for this reason, the Departments propose to require at new 26 CFR 54.9816-8(b)(1)(ii)(A)(*9*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*9*), and 45 CFR 149.510(b)(1)(ii)(A)(*9*) that if the party submitting the open negotiation notice is a provider or facility, that party must provide a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i), either because the items and services are subject to the prohibition on balance billing without exception or because the provider or facility did not provide notice and receive consent.

To further reduce the number of Federal IDR disputes initiated for ineligible items or services, the Departments propose at 26 CFR 54.9816-8(b)(1)(ii)(A)(*10*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*10*), and 45 CFR 149.510(b)(1)(ii)(A)(*10*) to require that the party submitting the

[126] The notice and consent exception does not apply to ancillary services, which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether furnished by a physician or non-physician practitioner; items and services furnished by assistant surgeons, hospitalists, and intensivists; diagnostic services, including radiology and laboratory services; and items and services furnished by a nonparticipating provider, if there is no participating provider who can furnish such item or service at such facility. Additionally, as specified in PHS Act section 2799B–2(c), the notice and consent exception does not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished for which a nonparticipating provider satisfied the notice and consent criteria.

open negotiation notice provide a statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, facility, or provider of air ambulance services on the date the item or service was furnished. Identification of this eligibility factor at open negotiation may decrease the number of ineligible disputes initiated by drawing the attention of the parties to the statutory eligibility standards underlying the Federal IDR process.

Currently, the standard form[127] for the open negotiation notice provided by the Departments contains general information including a description of the open negotiation period, what happens at the end of the open negotiation period, and the Federal IDR process. The Departments propose at 26 CFR 54.9816-8(b)(1)(ii)(A)(*11*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*11*), and 45 CFR 149.510(b)(1)(ii)(A)(*11*) to align the general information requirements for the open negotiation notice with existing requirements under the October 2021 interim final rules regarding the notice of IDR initiation, which specify that the notice of IDR initiation must include a statement describing the Federal IDR process and general information to help ensure that the non-initiating party is informed about the process and is familiar with the next steps.[128]

To support the identification of items or services ineligible for the Federal IDR process, the Departments propose to require the party submitting the open negotiation notice to provide a copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the proposed CARC and RARC disclosures described in section II.B. of this preamble at proposed 26 CFR 54.9816-8(b)(1)(ii)(A)(*12*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*12*), and 45 CFR 149.510(b)(1)(ii)(A)(*12*). The remittance advice containing the proposed CARC and RARC disclosures would provide information as to whether the plan or issuer believes the claim is eligible for the Federal IDR process and ensure that a provider initiating open negotiation

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[127] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. (expiration Nov. 30, 2025). *Open Negotiation Notice*. (OMB Control No. 1210-0169). *https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-2.pdf.*

[128] 86 FR 55991.

understands the position of the plan or issuer regarding the eligibility of an item or service, even in situations in which a plan or issuer in receipt of an open negotiation notice is not otherwise responsive.

The Departments seek comment on the addition of these proposed required elements to the open negotiation notice. The Departments also solicit comment on whether the party submitting the open negotiation notice should be required to provide a statement describing why the party is initiating the open negotiation period, including any considerations that serve as the basis for the initiation of open negotiation for the item or service, such as any of the considerations currently described in 26 CFR 54.9816-8T(c)(4)(iii) and 54.9817-2T(b)(2), 29 CFR 2590.716-8(c)(4)(iii) and 2590.717-2(b)(2), and 45 CFR 149.510(c)(4)(iii) and 149.520(b)(2).

d. Open Negotiation Response Notice Content

The Departments propose to establish requirements for an open negotiation response notice at 26 CFR 54.9816–8(b)(1)(iii)(A), 29 CFR 2590.716–8(b)(1)(iii)(A), and 45 CFR 149.510(b)(1)(iii)(A). Specifically, the Departments propose to require that the party receiving an open negotiation notice must provide a response to the open negotiation notice, which would include the same information specified in proposed 26 CFR 54.9816–8(b)(1)(ii)(A)(*1*) through (*3*), 29 CFR 2590.716–8(b)(1)(ii)(A)(*1*) through (*3*), and 45 CFR 149.510(b)(1)(ii)(A)(*1*) through (*3*) related to the requirements to provide contact information sufficient to identify the provider, facility, or provider of air ambulance services, the plan or issuer that are parties to the open negotiation, and any third party representing a party in the open negotiation. The Departments further propose that the open negotiation response notice would include the following additional information under proposed 26 CFR 54.9816–8(b)(1)(iii)(A)(*4*) through (*11*), 29 CFR 2590.716–8(b)(1)(iii)(A)(*4*) through (*11*), and 45 CFR 149.510(b)(1)(iii)(A)(*4*) through (*11*): (*4*) information sufficient to identify the item or service included in the open negotiation notice, including the date(s) the item or service was furnished, the claim number, and if the party in

receipt of the open negotiation notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer; (*5*) if the party in receipt of the open negotiation notice is a plan or issuer, a statement as to whether it agrees that the initial payment amount (including $0 if, for example, payment is denied) and the QPA reflected in the open negotiation notice accurately reflects the initial payment amount and QPA disclosed with the initial payment for the item or service, and if not, the initial payment amount (including $0 if, for example, payment is denied) and/or the QPA it believes to be correct and documentation to support the statement (for example, the remittance advice confirming the QPA amount); (*6*) if the party in receipt of the open negotiation notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any; (*7*) a counteroffer of an out-of-network rate for each item or service or an acceptance of the other party's offer; (*8*) if the party in receipt of the open negotiation notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i); (*9*) with respect to each item or service, a statement and supporting documentation that explains why the item or service is ineligible for the Federal IDR process or a statement agreeing that the item or service is eligible for the Federal IDR process; (*10*) a statement as to whether any of the information provided in the open negotiation notice is inaccurate and the basis for the statement, as well as supporting documentation; and (*11*) a statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the party submitting the open negotiation notice is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service.

Based on feedback from the certified IDR entities, non-initiating parties often do not object to the applicability of the Federal IDR process or to the accuracy of the QPA until after the certified IDR entity has been selected, including at the time of offer submission. Also, at times, disputing parties disagree about the accuracy of information relevant to the claim under dispute. In these cases, the initiating party is unaware of the non-initiating party's statement because this information is sent to the certified IDR entity and not to the initiating party well after the open negotiation period has ended. This significantly slows down the processing of disputes, as the certified IDR entity then must contact both parties to determine the appropriate QPA or solicit information necessary to confirm the Federal IDR process applies. To implement an efficient Federal IDR process, both parties must be active participants in the process. For this reason, and to minimize communication challenges between parties, the Departments are of the view that the party in receipt of the open negotiation notice should provide the proposed content elements to the party sending the open negotiation notice and to the Departments. All of the proposed open negotiation response notice content requirements are also included in the proposed open negotiation notice content requirements, except for: (1) a statement that explains why the item or service is not subject to the Federal IDR process or a statement agreeing that the item or service is subject to the Federal IDR process; (2) a statement as to whether the QPA reflected in the open negotiation notice is accurate for the item or service, and if not, a statement providing the QPA it believes to be correct and documentation to support the statement (for example, the remittance advice confirming the QPA amount); and (3) a statement confirming the accuracy of the initial payment, notice of denial of payment, or other remittance advice provided by the party submitting the open negotiation notice, and a copy of an accurate initial payment, notice of denial of payment or other remittance advice if inaccurate. By restating information on both the open negotiation notice and open negotiation response notice, parties would have an opportunity to confirm or update information necessary to negotiate and identify any information discrepancies which could impact eligibility and decisions to negotiate or participate in the

Federal IDR process. With respect to the three proposed open negotiation response notice content requirements not included in the open negotiation notice, this proposal, if finalized, would make the party submitting the open negotiation notice aware of any objection that the party in receipt of the open negotiation notice has to the dispute's eligibility for the Federal IDR process or its objection to the QPA or remittance advice accuracy. Additionally, this proposal would require the party in receipt of the open negotiation notice to provide an explanation and documentation to support its statement(s).

The Departments are of the view that this proposed method of exchanging information would facilitate communication and understanding between the parties as to the eligibility of an item or service for the Federal IDR process. The Departments seek comment on the content elements of the open negotiation response notice. The Departments also seek comment on the requirement to submit a counteroffer for an out-of-network rate for the item or service or a statement accepting the other party's offer on the open negotiation response notice. Specifically, the Departments seek comment on whether it would hinder meaningful negotiation between the parties outside the Federal IDR portal, or whether it would promote negotiation among parties that might otherwise not negotiate.

e. Technical Amendments

The Departments propose several technical amendments to the open negotiation regulatory text. These proposed changes correct or remove regulatory text that is being updated by the open negotiation proposals in these proposed rules. First, the Departments propose a technical correction for the cross reference at 26 CFR 54.9816-8T(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510(b)(1)(i) which directs readers to the definition of a qualified IDR item or service at paragraph (a)(2)(xii)(A), but should instead reference paragraph (a)(2)(xi)(A) for the appropriate cross reference to the definition of a qualified IDR item or service.

Second, the Departments propose to remove the current regulatory text that describes the manner in which the open negotiation notice must be provided. The requirements for submitting

the open negotiation notice described in paragraphs 26 CFR 54.9816-8T(b)(1)(ii)(B), 29 CFR 2590.716-8(b)(1)(ii)(B), and 45 CFR 149.510(b)(1)(ii)(B) would be removed because they would no longer apply under the proposed changes to the open negotiation notice, and the removal of this paragraph aligns with the proposal described at section II.D.3. of this preamble, which would establish uniform standards for submitting notices for both open negotiations and the IDR initiation through the Federal IDR portal.

f. Implementation of Open Negotiation through the Federal IDR Portal

As discussed in section II.D.3. of this preamble, to implement the proposed modifications to the requirements for submitting the open negotiation notice and the newly proposed open negotiation response notice, the Departments would need to modify the Federal IDR portal to allow parties to send the open negotiation notice and open negotiation response notice to the other party and the Departments through the Federal IDR portal. While some plans or issuers have created their own proprietary portals to facilitate open negotiations, providers, facilities, and providers of air ambulance services are not required to use them. Accordingly, providers and facilities are not considered to have failed to provide an open negotiation notice or open negotiation response notice solely because they did not use a plan's or issuer's proprietary portal. The Departments are of the view that having one central location where plans, issuers, providers, facilities, and providers of air ambulance services could initiate open negotiations would increase efficiency. Plans, issuers, providers, facilities, providers of air ambulance services, and certified IDR entities have also requested that the Departments amend the rules to require parties to send the open negotiation notice through the Federal IDR portal to streamline the process and create a centralized platform where parties can better track their open disputes. The Departments note that though these rules propose to require the open negotiation notice and the open negotiation response notice to be submitted through the Federal IDR portal, parties would not be required to conduct negotiations within the Federal IDR portal.

The Federal IDR portal would facilitate transmittal of the open negotiation notice to the appropriate party. Specifically, if the party receiving the open negotiation notice is a provider, facility, or provider of air ambulance services, the Federal IDR portal would transmit the notice to the party based on the contact information provided in the open negotiation notice. However, if the party in receipt of the open negotiation notice is a plan or issuer, the Federal IDR portal would transmit the notice to the party based on the contact information provided through the IDR registry. As discussed in sections II.D.1.c. and II.F. of these proposed rules, it is possible that a plan or issuer would not have submitted their information to the registry by the time a party submits an open negotiation notice to them. If, at the time the open negotiation notice is submitted there is not a registration number for the plan or issuer, the Federal IDR portal would transmit the notice to the party based on the contact information provided in the open negotiation notice.

The Departments seek comment on whether the disputing parties should be required to use the Federal IDR portal for further communication related to open negotiations beyond the initiation of open negotiation and the submission of the open negotiation response notice. The Departments seek comment on what modes of correspondence might be useful to the parties during the open negotiation period (for example, the submission of additional documentation to the other party, live chat, or message exchange, etc.) and if the content of those communications should be accessible to the certified IDR entities if a dispute is initiated on the relevant item or service. Lastly, the Departments solicit comment on whether there are any additional challenges preventing the parties from, or clarifications needed to assist the parties in, fully engaging in meaningful negotiations during the open negotiation period.

2. Changes to the Initiation of the Federal IDR Process

Section 9816(c)(1)(B) of the Code, section 716(c)(1)(B) of ERISA, section 2799A-1(c)(1)(B) of the PHS Act, and the October 2021 interim final rules establish that, with respect to items or services that are the subject of an open negotiation period, if the parties have not agreed

upon an amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.[129]

a. Notice of IDR initiation

As discussed in section II.D.1. of this preamble, an efficient and transparent Federal IDR process requires both parties to be active participants. Therefore, the Departments propose to amend the IDR initiation provisions of 26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2) to improve communication between parties, accelerate dispute processing, and reduce the burden on certified IDR entities when determining whether a case is eligible for the Federal IDR process. Specifically, these proposed rules would require the initiating party to include additional information in the notice of IDR initiation and would require non-initiating parties to provide a response to the notice of IDR initiation (notice of IDR initiation response) to the Departments and to the initiating party through the Federal IDR portal within 3 business days of receipt of the notice of IDR initiation. Section II.D.3. of this preamble describes how the parties would provide both the notice of IDR initiation and notice of IDR initiation response to the other party and the Departments.

The Departments propose to amend the content of the notice of IDR initiation and redesignate proposed 26 CFR 54.9816–8(b)(2)(iii)(A), 29 CFR 2590.716–8(b)(2)(iii)(A), and 45 CFR 149.510(b)(2)(iii)(A) as 26 CFR 54.9816–8(b)(2)(ii)(A), 29 CFR 2590.716–8(b)(2)(ii)(A), and 45 CFR 149.510(b)(2)(ii)(A). As described in section II.D.1.c. of this preamble, under these proposed rules several of the content elements in the notice of IDR initiation would be required in the open negotiation notice and open negotiation response notice.[130] As discussed in section II.D.1.d. of this preamble, by restating information on the notices, parties would have an

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[129] 86 FR 55991.

[130] *See* proposed regulations for the open negotiation notice content at: 26 CFR 54.9816–8(b)(1)(ii)(A)(*1*)-(*6*) and (*9*)-(*12*); 29 CFR 2590.716–8(b)(1)(ii)(A)(*1*)-(*6*) and (*9*)-(*12*); and 45 CFR 149.510(b)(1)(ii)(A)(*1*)-(*6*) and (*9*)-(*12*). *See* proposed regulations for the open negotiation response content at: 26 CFR 54.9816–8(b)(1)(iii)(A)(*1*)-(*4*), (*8*), and (*11*); 29 CFR 2590.716–8(b)(1)(iii)(A)(*1*)-(*4*), (*8*), and (*11*); and 45 CFR 149.510(b)(1)(iii)(A)(*1*)-(*4*), (*8*) and (*11*).

opportunity to confirm or update information necessary to continue negotiations and identify any information discrepancies that could impact eligibility for the Federal IDR process. Further, the open negotiation notice and notice of IDR initiation would often not be identical since disputing parties do not always decide to initiate the Federal IDR process for all items and services included in the open negotiation notice. The Departments anticipate that the Federal IDR portal would be able to prepopulate information included in the open negotiation notices and open negotiation response notices, which would mitigate additional burden on the disputing parties and would provide the certified IDR entity (or the Departments in the event the departmental eligibility review applies as described in section II.E.1.b.ii. of these proposed rules) sufficient information with respect to the item or service and dispute in a single document.

Under current rules, the notice of IDR initiation must include contact information for the parties to the dispute. The proposed rules under 26 CFR 54.9816–8(b)(2)(ii)(A)(*1*) through (*3*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*1*) through (*3*), and 45 CFR 149.510(b)(2)(ii)(A)(*1*) through (*3*), would require specific contact information depending on whether the initiating party is a provider, facility, or provider of air ambulance services, or the plan or issuer, as well as any third party representing the initiating party in the dispute. This contact information would include the legal business name, email address, phone number, mailing address, and Tax Identification Number (TIN). The initiating party would also be required to include the NPI to identify the provider, facility, or provider of air ambulance services and the plan or issuer IDR registration number, assigned under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 to identify the plan or issuer, if the plan or issuer is registered, or an attestation from the initiating party that the plan or issuer was not registered prior to the date of the notice (described further in section II.F. of this preamble). Further, if there is any third party representing the initiating party,

the notice of IDR initiation would be required to include an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process.[131]

Under current rules, the notice of IDR initiation must also include information sufficient to identify the items or services that are the subject of the dispute. These proposed rules would amend these requirements to include whether the dispute being initiated includes batched or bundled qualified IDR items or services[132] (described in section II.E.2. of this preamble); the date(s) the qualified IDR item or service was furnished; if the initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer; the date the open negotiation period began; the type of item or service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location the item or service was furnished (including the place of service code or bill type code).[133] The proposed rule requiring plans and issuers to provide the claim number in the notice of IDR initiation would codify existing content requirements in the notice of IDR initiation. The claim number is an element on the notice of IDR initiation that is currently approved for use by the initiating party, as it is information that is necessary to identify the item or service under dispute, as currently required by 26 CFR 54.9816-8T(b)(2)(iii)(A)(1), 29 CFR 2590.716-8(b)(2)(iii)(A)(1), and 45 CFR 149.510(b)(2)(iii)(A)(1). The Departments also propose requiring the initiating party to submit its TIN in the notice of IDR initiation in order to facilitate the Departments' ability to collect the administrative fees directly, as described in section II.E.3.d. of this preamble.[134] The TIN would also facilitate debt

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[131] Proposed 26 CFR 54.9816–8(b)(2)(ii)(A)(*3*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*3*), and 45 CFR 149.510(b)(2)(ii)(A)(*3*).
[132] Proposed 26 CFR 54.9816– 8(b)(2)(ii)(A)(*4*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*4*), and 45 CFR 149.510(b)(2)(ii)(A)(*4*).
[133] Proposed 26 CFR 54.9816– 8(b)(2)(ii)(A)(*5*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*5*), and 45 CFR 149.510(b)(2)(ii)(A)(*5*).
[134] Currently, the administrative fee is paid to the selected certified IDR entity and then remitted to the Departments. 26 CFR 54.9816–8T(d)(2)(i) and (e)(2)(ix), 29 CFR 2590.716–8(d)(2)(i) and (e)(2)(ix), and 45 CFR 149.510(d)(2)(i) and (e)(2)(ix).

collection from parties that fail to pay their administrative fees and generally streamline the collection process by serving as a unique identifier for disputing parties.

Under current rules, the notice of IDR initiation requires the initiating party to provide the initial payment amount, the QPA, and if the initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i). This information would still be required under these proposed rules at paragraphs 26 CFR 54.9816–8(b)(2)(ii)(A)(*6*) through (*8*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*6*) through (*8*), and 45 CFR 149.510(b)(2)(ii)(A)(*6*) through (*8*), but would require the QPA only if provided with the initial payment of notice of denial or payment or if the initiating party is a plan or issuer. These proposed rules would also require that the initiating party provide the initial payment amount, including $0, if the payment was denied.

Further, these proposed rules would require a statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished.[135] As discussed in section II.D.1.c. of this preamble, identification of this eligibility factor at the time of initiating the Federal IDR process may decrease the number of ineligible disputes initiated by drawing the attention of the parties to the statutory eligibility standards underlying the Federal IDR process.

Under current rules, the notice of IDR initiation requires the initiating party to provide an attestation that the item or service under dispute is a qualified IDR item or service, and the basis for the attestation; general information listed in the standard notice of IDR initiation developed by the Departments describing the Federal IDR process (including a description of the purpose of the Federal IDR process and key deadlines in the Federal IDR process); and the preferred

[135] Proposed 26 CFR 54.9816–8(b)(2)(ii)(A)(*9*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*9*), and 45 CFR 149.510(b)(2)(ii)(A)(*9*).

certified IDR entity. Each of these content requirements would still be required under these proposed rules.[136]

To improve communications between the parties to a dispute, these proposed rules would also require the initiating party to include a copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service;[137] and a statement describing the key aspects of the claim discussed by the parties during open negotiation that relate to the payment for the disputed claim, whether the reasons for initiating the Federal IDR process are different from those aspects discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process, including any of the considerations currently described in 26 CFR 54.9816-8(c)(4)(iii) and 54.9817-2(b)(2), 29 CFR 2590.716-8(c)(4)(iii) and 2590.717-2(b)(2), and 45 CFR 149.510(c)(4)(iii) and 149.520(b)(2) that serve as the party's basis for initiating the Federal IDR process.[138] The Departments have received feedback that plans and issuers are often unaware of the reasons why the provider, facility, or provider of air ambulance services is initiating the Federal IDR process, despite engaging in the 30-business-day open negotiation period. Further, plans and issuers have stated that providers, facilities, and providers of air ambulance services often raise different reasons in the notice of offer submission than the reasons they presented during the open negotiation period. Plans and issuers have also stated that if they knew earlier of a provider's, facility's, or provider of air ambulance services' reasoning for initiating the Federal IDR process, they may have a more accurate basis for making an alternative out-of-network payment amount that may better align with the provider's, facility's, or provider of air ambulance services' requested total payment amount. Thus, the Departments

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[136] Proposed 26 CFR 54.9816–8(b)(2)(ii)(A)(*10*) through (*11*) and (*13*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*10*) through (*11*) and (*13*), and 45 CFR 149.510(b)(2)(ii)(A)(*10*) through (*11*) and (*13*).
[137] Proposed 26 CFR 54.9816–8(b)(2)(ii)(A)(*12*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*12*), and 45 CFR 149.510(b)(2)(ii)(A)(*12*).
[138] Proposed 26 CFR 54.9816– 8(b)(2)(ii)(A)(*14*), 29 CFR 2590.716–8(b)(2)(ii)(A)(*14*), and 45 CFR 149.510(b)(2)(ii)(A)(*14*).

are of the view that requiring this information would result in the non-initiating party providing a more informed offer or help the disputing parties reach a settlement before the certified IDR entity makes a payment determination.

Requiring the initiating party to attest that the item or service under dispute is a qualified IDR item or service and to identify the basis for the attestation may reduce the number of ineligible disputes submitted because it would require the initiating party to actively evaluate eligibility before initiating the Federal IDR process. This would help reduce the time certified IDR entities spend conducting outreach to confirm whether the item or service is eligible for the Federal IDR process.

Lastly, the Departments propose to remove paragraphs 26 CFR 54.9816-8T(b)(2)(iii)(B) and (C), 29 CFR 2590.716-8(b)(2)(iii)(B) and (C), and 45 CFR 149.510(b)(2)(iii)(B) and (C), which specify the manner in which the notice of IDR initiation must be provided to the other party and the Departments. The Departments propose to establish paragraphs 26 CFR 54.9816-8(b)(3), 29 CFR 2590.716-8(b)(3), and 45 CFR 149.510(b)(3) to require use of the Federal IDR portal for transmission of notices of IDR initiation in the same manner as would be required for the transmission of notices related to open negotiation discussed in section II.D.3. of this preamble.

The Departments seek comment on these proposals. Specifically, the Departments seek comment on the new content elements for the notice of IDR initiation and whether additional elements should be required to facilitate the exchange of information necessary to initiate the Federal IDR process. Further, the Departments solicit comment on the proposed requirement for the initiating party to include in the notice of IDR initiation a statement describing any key aspects of the claim discussed by the parties during open negotiation, whether the considerations for initiating the Federal IDR process are different from the key aspects of the claim discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process, including any of the permissible considerations described at 26 CFR 54.9816-

8(c)(4)(iii) and 54.9817-2(b)(2), 29 CFR 2590.716-8(c)(4)(iii) and 2590.717-2(b)(2), and 45 CFR 149.510(c)(4)(iii) and 149.520(b)(2).

b. Notice of IDR Initiation Response

The Departments propose to amend 26 CFR 54.9816-8(b)(2)(i), 29 CFR 2590.716-8(b)(2)(i), and 45 CFR 149.510(b)(2)(i) to require that the non-initiating party provide a written notice and supporting documentation in response to the notice of IDR initiation to the initiating party and the Departments within 3 business days after the date of IDR initiation. As described in section II.D.2.a. of this preamble, the initiating party must submit the notice of IDR initiation through the Federal IDR portal. Upon proper submission of the notice of IDR initiation by the initiating party, the Federal IDR portal would facilitate transmittal of the notice of IDR initiation to the non-initiating party. The non-initiating party would also receive the notice of IDR initiation response form from the Federal IDR portal on the date of IDR initiation, which is the date the Departments receive the notice of IDR initiation. The Departments are of the view that it is critical to require the non-initiating party to provide a response to the notice of IDR initiation (including any objections regarding preferred certified IDR entity selection and notice of any objection to Federal IDR process eligibility) in order to increase transparency and improve efficiencies in the Federal IDR process.

The Departments propose to add 26 CFR 54.9816-8(b)(2)(iii)(A), 29 CFR 2590.716-8(b)(2)(iii)(A), and 45 CFR 149.510(b)(2)(iii)(A), to provide that the notice of IDR initiation response must include information sufficient to identify the non-initiating party. Under the proposed rules, the notice of IDR initiation response must include the legal business name, email address, phone number, mailing address, the TIN, the NPI, and the plan's or issuer's registration number, as required under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530. These proposed rules would also require the notice to include the name and contact information (including the legal business name, email address, phone number, and mailing

address) for any third party representing the non-initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process.

The Departments also propose that the notice must include information sufficient to identify each item or service included in the notice of IDR initiation (including the date(s) the item or service was furnished. If the non-initiating party is a provider, facility, or provider of air ambulance services, the notice must include the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer and the claim number). If the non-initiating party is a plan or issuer, the proposed rules would require a statement as to whether the non-initiating party agrees that the initial payment (including $0 if, for example, payment is denied) and the QPA reflected in the notice of IDR initiation was the initial payment amount and/or the QPA disclosed with the initial payment or notice of denial of payment for the item or service that is the subject of the dispute, and if not, the initial payment amount (including $0 if, for example, payment is denied) and/or QPA it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the QPA). If the non-initiating party is a plan or issuer, the notice must include the amount of cost sharing imposed for the item or service, if any. If the non-initiating party is a provider or facility, the notice must include a statement that the items and services do not qualify for the notice and consent exception described at § 149.410(b) or § 149.420(c) through (i).

With respect to each item or service that is the subject of the dispute, the notice must also include an attestation that the item or service is a qualified IDR item or service, or for each item or service that the non-initiating party asserts is not a qualified IDR item or service, an explanation and documentation to support the statement; a statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the initiating party under paragraph (b)(2)(ii)(A)(*12*) is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of payment or other remittance advice required to include the

disclosures under 26 CFR 54.9816-6T(d)(1), 26 CFR 54.9816-6(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service; a statement as to whether any of the information provided in the notice of IDR initiation is inaccurate, the basis for the statement, and any supporting documentation; and a statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity. If the non-initiating party objects to the initiating party's preferred certified IDR entity, the notice of IDR initiation response must include the name of an alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the initiating party's preferred certified IDR entity.

Most of the proposed notice of IDR initiation response content requirements are included in the proposed open negotiation notice, open negotiation response notice, and notice of IDR initiation content requirements.[139] As discussed in sections II.D.1.d. and II.D.2.a., by restating information on the notices, parties would have an opportunity to confirm or update information necessary to continue negotiations and identify any information discrepancies which could impact eligibility. Further, by requiring this information at IDR initiation, it would reduce the likelihood that additional outreach would be necessary to make eligibility determinations, improving IDR dispute processing. As discussed in section II.D.2.a. of this preamble, the Departments anticipate that the Federal IDR portal would be able to prepopulate information included in the open negotiation notice, open negotiation response notice, and the notice of IDR initiation notice, which would mitigate additional burden on the disputing parties.

The proposed rules also include additional content requirements for the notice of IDR initiation response that require a statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity and, if the non-initiating party objects to the

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[139] *See* proposed regulations for the open negotiation notice content at: 26 CFR 54.9816–8(b)(1)(ii)(A)(*1*)-(*6*), (*8*)-(*9*), and (*12*); 29 CFR 2590.716–8(b)(1)(ii)(A)(*1*)-(*6*), (*8*)-(*9*), and (*12*); and 45 CFR 149.510(b)(1)(ii)(A)(*1*)-(*6*), (*8*)-(*9*), and (*12*). *See* proposed regulations for the open negotiation response content at: 26 CFR 54.9816–8(b)(1)(iii)(A)(*1*)-(*6*), (*8*)-(*9*), and (*11*); 29 CFR 2590.716–8(b)(1)(iii)(A)(*1*)-(*6*), (*8*)-(*9*), and (*11*); and 45 CFR 149.510(b)(1)(iii)(A)(*1*)-(*6*), (*8*)-(*9*), and (*11*). *See* proposed regulations for the notice of IDR initiation content at: 26 CFR 54.9816–8(b)(2)(ii)(A)(*1*)-(*3*), (*5*)-(*8*), (*10*), and (*12*); 29 CFR 2590.716–8(b)(2)(ii)(A)(*1*)-(*3*), (*5*)-(*8*), (*10*), and (*12*); and 45 CFR 149.510(b)(2)(ii)(A)(*1*)-(*3*), (*5*)-(*8*), (*10*) and (*12*).

initiating party's preferred certified IDR entity, the name of an alternative preferred certified IDR entity. This proposed requirement is to meet the statutory requirement under Code section 9816(c)(4)(F), ERISA section 716(c)(4)(F), and PHS Act section 2799A-1(c)(4)(F) that the Departments must provide a method for the plan or issuer and the provider, facility, or provider of air ambulance services that are parties to a determination subject to the Federal IDR process to jointly select a certified IDR entity no later than 3 business days following the date of the IDR initiation. Section II.E.1.a. of this preamble further describes the selection of the certified IDR entity process and the proposed amendments to the certified IDR entity selection process.

The Departments anticipate updating the Federal IDR portal to create parameters to ensure information is submitted for each of the required fields for the notice of IDR initiation and notice of IDR initiation response. However, failure to timely furnish a notice of IDR initiation response would not delay the timeframe for initiation of the Federal IDR process (because the Federal IDR process has been initiated once a notice of IDR initiation has timely been submitted to the non-initiating party and the Departments) or delay any subsequent timeframes under the Federal IDR process. As discussed in section II.D.1.b. of this preamble, if a party were to fail to furnish a notice of IDR initiation response to the other party and the Departments or fail to fill out all of the required information in good faith (for example, intentional omission of detail with the intent to advance the process without providing sufficient content), the Departments would review and determine whether enforcement actions may be warranted.

The Departments seek comment on these proposals, including any administrative burden associated with the additional disclosure requirements.

3. Manner of Notices

The October 2021 interim final rules generally require a party to initiate open negotiations and initiate the Federal IDR process by providing written notice to the other party.[140] The party initiating the Federal IDR process must also furnish the notice of IDR

[140] 86 FR 55990.

initiation to the Departments through the Federal IDR portal. In both cases, notice to the other party may be provided electronically if the following two conditions are satisfied: (1) the party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and (2) the notice is provided in paper form free of charge upon request.[141] As mentioned in section II.D.1. and II.D.2. of this preamble, the Departments are proposing to remove the regulatory text at 26 CFR 54.9816-8T(b)(1)(ii)(B), (b)(2)(iii)(B), and (b)(2)(iii)(C), 29 CFR 2590.716-8(b)(1)(ii)(B), (b)(2)(iii)(B), and (b)(2)(iii)(C), and 45 CFR 149.510(b)(1)(ii)(B), (b)(2)(iii)(B), and (b)(2)(iii)(C) and instead include new requirements related to the manner of submission of open negotiation notices and notices of IDR initiation to the Departments and the other party at 26 CFR 54.9816-8(b)(3), 29 CFR 2590.716-8(b)(3), and 45 CFR 149.510(b)(3). The Departments propose that these new requirements would also apply to the open negotiation response notice and the notice of IDR initiation response. Specifically, the Departments propose that a party must furnish to the other party and the Departments the notices and supporting documentation described in proposed paragraphs (b)(1)(ii) (open negotiation notice), (b)(1)(iii) (open negotiation response notice), (b)(2)(ii) (notice of IDR initiation), and (b)(2)(iii) (notice of IDR initiation response) through the Federal IDR portal, using the standard forms developed by the Departments.

Under the current regulations, the open negotiation notice between parties has taken place outside of the Federal IDR portal and has led to challenges for the Departments and certified IDR entities to confirm that all requirements related to the open negotiation notice and open negotiation period have been satisfied for each initiated dispute. Requiring a party to submit the open negotiation notice to the Departments and the other party through the Federal IDR portal would provide a record of whether and when the initiating party began open negotiations, which would help inform whether the item or service that is the subject of negotiation is eligible for the

[141] 26 CFR 54.9816-8T(b)(1)(ii)(B), (b)(2)(iii)(B), and (b)(2)(iii)(C), 29 CFR 2590.716-8(b)(1)(ii)(B), (b)(2)(iii)(B), and (b)(2)(iii)(C), and 45 CFR 149.510(b)(1)(ii)(B), (b)(2)(iii)(B) and (b)(2)(iii)(C).

Federal IDR process. The Departments expect that this would decrease the amount of time and resources the Departments and certified IDR entities spend seeking information from the disputing parties to determine whether the open negotiation period was initiated and exhausted, which would ultimately provide certified IDR entities more time to review eligible disputes.

As specified in the October 2021 interim final rules and set forth in these proposed rules, the Departments are of the view that it is important for a party receiving a notice to be furnished the notice on the same day as it is submitted to the Departments, because many of the timeframes required in the October 2021 interim final rules and proposed in these proposed rules are triggered upon receipt of a notice.[142] Currently, when an initiating party submits the notice of IDR initiation to the Federal IDR portal, the non-initiating party receives a notice from the Departments on the same day the Departments receive the notice of IDR initiation. This notice from the Departments to the non-initiating party provides information contained in the notice of IDR initiation. However, it does not include any of the supporting documentation that the initiating party may have provided with the notice of IDR initiation. While the initiating party is required to directly furnish the notice of IDR initiation to the other party, non-initiating parties report that, at times, the initiating party provides the notice after the period for IDR initiation has expired, although it submits the notice to the Departments within the applicable notice period.

If these proposed rules are finalized, the Departments would enhance the Federal IDR portal to allow the parties to transmit notices, including supporting documentation, through the Federal IDR portal so that the party sending the notice can notify the Departments and the other party at the same time. Further, as discussed in sections II.D.1.c. and II.D.2.a. of this preamble, the Departments are proposing to require similar content requirements in the open negotiation notice and notice of IDR initiation. By streamlining the submission of these notices, the Departments would be able to use information that was submitted for one notice to pre-populate subsequent notices, reducing the burden of providing duplicative information. For instance, if a

[142] 86 FR 55990 through 55991.

party decides to initiate the Federal IDR process after submitting the open negotiation notice through the Federal IDR portal and completing the 30-business-day open negotiation period, the Departments intend that the Federal IDR portal would pre-populate the fields in the notice of IDR initiation and notice of IDR initiation response with the same information that was provided in the open negotiation notice and open negotiation response notice, as applicable. The Departments solicit comment on these proposals.

E. Federal IDR Process Following Initiation

1. Certified IDR Entity Selection and Eligibility Determinations

a. Certified IDR Entity Selection

Section 9816(c)(4)(F) of the Code, section 716(c)(4)(F) of ERISA, section 2799A-1(c)(4)(F) of the PHS Act, and the October 2021 interim final rules[143] provide parties to a dispute 3 business days after the initiation date of the Federal IDR process to jointly select a certified IDR entity. If parties to a dispute fail to jointly agree and select a certified IDR entity within the required timeframe, the Departments must select the certified IDR entity no later than 6 business days after the initiation date of the Federal IDR process. More specifically, under the current rules, the non-initiating party may agree or object to the preferred certified IDR entity that the initiating party identifies in its notice of IDR initiation. If the non-initiating party fails to object within 3 business days after the date of IDR initiation, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties. In this case, the initiating party's preferred certified IDR entity becomes the certified IDR entity for the dispute, provided that the certified IDR entity does not have a conflict of interest. If the non-initiating party objects to the initiating party's preferred certified IDR entity, it must notify the initiating party of the objection and propose an alternative preferred certified IDR entity within 3 business days after the date of IDR initiation. The initiating party must then agree or object to the alternative preferred certified IDR entity within 3 business days

[143] 87 FR 55991 through 55992.

after the date of IDR initiation. If the initiating party fails to agree or object to the alternative preferred certified IDR entity within that timeframe, the alternative preferred certified IDR entity selected by the non-initiating party will be selected and will be treated as jointly agreed to by the parties. If the parties fail to jointly agree on a certified IDR entity within 3 business days after the date of IDR initiation, the Departments select a certified IDR entity through random selection.[144]

Further, under the current rules, upon the joint selection of a certified IDR entity the initiating party must provide a notice of certified IDR entity selection to the Departments indicating whether the parties have jointly agreed or failed to agree on the selection of a certified IDR entity, as soon as practicable but no later than 1 business day after selection.[145] The notification must include an attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity does not have a conflict of interest as specified in 26 CFR 54.9816-8(c)(1)(ii), 29 CFR 2590.716-8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii).[146] Under the current rules, after the selection of the certified IDR entity by the parties (including when the initiating party selects a certified IDR entity and the non-initiating party does not object), or by the Departments when the parties fail to select a certified IDR entity, the certified IDR entity must review the selection and attest that it meets these conflict-of-interest requirements.[147] If the certified IDR entity is unable to attest that it meets the conflict-of-interest requirements within 3 business days of selection, the parties, upon notification, must select another certified IDR entity. In such circumstances, the date of the notification sent by the certified IDR entity informing the parties that it cannot attest that it meets the conflict-of-interest requirements is treated as the date of IDR initiation for the purposes of selecting a new certified IDR entity.

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[144] 26 CFR 54.9816-8T(c)(1)(iv), 29 CFR 2590.716-8(c)(1)(iv), and 45 CFR 149.510(c)(1)(iv).
[145] 26 CFR 54.9816-8T(c)(1)(iii)-(iv), 29 CFR 2590.716-8(c)(1)(iii)-(iv), and 45 CFR 149.510(c)(1)(iii)-(iv).
[146] 26 CFR 54.9816-8T(c)(1)(iii)(A)(*3*), 29 CFR 2590.716-8(c)(1)(iii)(A)(*3*), and 45 CFR 149.510(c)(1)(iii)(A)(*3*).
[147] 26 CFR 54.9816-8T(c)(1)(v), 29 CFR 2590.716-8(c)(1)(v), and 45 CFR 149.510(c)(1)(v).

Since implementation of the Federal IDR process, the Departments have identified potential areas to improve upon and provide additional clarity with respect to the process for selecting a certified IDR entity. First, in the Departments' experience implementing these rules, when a non-initiating party waits until the third business day after the date of IDR initiation to select an alternative preferred certified IDR entity, the initiating party lacks sufficient time to agree or object to the alternative preferred certified IDR entity. As a result, the alternative preferred certified IDR entity will be "jointly" selected by default. The Departments are of the view that in order for a certified IDR entity to be "jointly" selected, the parties must agree on, or be given the opportunity to object to that certified IDR entity. Therefore, the Departments propose to amend the process for selecting a certified IDR entity when the parties fail to jointly agree on a certified IDR entity under section 9816(c)(4)(F)(i) of the Code, section 716(c)(4)(F)(i) of ERISA, and section 2799A-1(c)(4)(F)(i) of the PHS Act.

Second, as part of the current operations, the Federal IDR portal automates the process for selecting the certified IDR entity such that the initiating party and the non-initiating party communicate directly through the Federal IDR portal when selecting, agreeing to, or objecting to a certified IDR entity. Therefore, the Departments are notified automatically through the Federal IDR portal if both parties have jointly agreed on a certified IDR entity. Similarly, when the Departments select a certified IDR entity, the disputing parties are notified automatically, provided the selected certified IDR entity attests to having no conflicts of interest. As described in section II.D. of this preamble, if finalized, these proposed rules would collect information regarding the applicability of the Federal IDR process from both parties as part of the proposed notice of IDR initiation and notice of IDR initiation response requirements. Because this information is automated through the Federal IDR portal or would be collected at other points of the IDR initiation process, the Departments propose to amend the notice of certified IDR entity selection requirements of 26 CFR 54.9816-8(c)(1)(iii), 29 CFR 2590.716-8(c)(1)(iii), and 45 CFR 149.510(c)(1)(iii) and establish at 26 CFR 54.9816-8(c)(1)(i)(D), 29 CFR 2590.716-

8(c)(1)(i)(D), and 45 CFR 149.510(c)(1)(i)(D) the mechanism for parties to agree or object and select another alternative preferred certified IDR entity after the non-initiating party submits the notice of IDR initiation response form and before the deadline for parties to jointly select a certified IDR entity, which is within 3 business days after the date of IDR initiation.

Lastly, to provide clarity on the Federal IDR process timeframes, in *the Federal IDR Process Guidance for Certified IDR Entities* and *the Federal IDR Process Guidance for Disputing Parties*, the Departments clarified that the certified IDR entity is "preliminarily" selected until it attests that it does not have a conflict of interest and determines whether the Federal IDR Process is applicable, thereby finalizing the selection.[148] The guidance further clarifies that the certified IDR entities must submit their conflict-of-interest attestation within 3 business days of being contingently selected, and that the parties must submit their offers for an out-of-network payment amount, as specified in 26 CFR 54.9816-8(c)(4)(i), 29 CFR 2590.716-8(c)(4)(i), and 45 CFR 149.510(c)(4)(i) no later than 10 business days after final selection of the certified IDR entity. To provide further clarity and to codify the process and timeframes for selecting a certified IDR entity, the certified IDR entity's conflict-of-interest review, and the date the certified IDR entity selection is considered finally selected, the Departments propose to amend 26 CFR 54.9816-8(c)(1), 29 CFR 2590.716-8(c)(1), and 45 CFR 149.510(c)(1) to establish a process that includes both preliminary selection of the certified IDR entity and final selection of the certified IDR entity.

i. Preliminary Selection of the Certified IDR Entity

The Departments propose to amend 26 CFR 54.9816-8T(c)(1)(i), 29 CFR 2590.716-8(c)(1)(i), and 45 CFR 149.510(c)(1)(i) to establish the preliminary selection of the certified IDR entity in accordance with the statutory requirement at section 9816(c)(4)(F) of the Code, section 716(c)(4)(F) of ERISA, and section 2799A-1(c)(4)(F) of the PHS Act. Under the process for

[148] *See https://www.cms.gov/files/document/federal-idr-guidance-idr-entities-march-2023.pdf* and *https://www.cms.gov/files/document/federal-idr-guidance-disputing-parties-march-2023.pdf.*

preliminary selection of the certified IDR entity proposed in these rules, the non-initiating party would be required to agree or object to the preferred certified IDR entity in the notice of IDR initiation response within 3 business days after the date of IDR initiation as discussed in section II.D.2.b of this preamble. Under these proposed rules, if the non-initiating party agrees, or fails to object, to the selection of the initiating party's preferred certified IDR entity in the notice of IDR initiation response within the 3-business-day timeframe after the date of IDR initiation, the initiating party's preferred certified IDR entity would be considered jointly selected by the parties on the third business day after the date of IDR initiation. If the non-initiating party objects to the selection of the initiating party's preferred certified IDR entity by designating an alternative preferred certified IDR entity in the notice of IDR initiation response within the 3-business-day timeframe after the date of IDR initiation, the initiating party would be required to agree or object to the alternative preferred certified IDR entity using the notice of certified IDR entity selection. Under these proposed rules, if the initiating party agrees to the alternative preferred certified IDR entity within 3 business days after the date of IDR initiation, or if the non-initiating party submits the notice of IDR initiation response on or before the second business day after the date of IDR initiation and the initiating party fails to respond within 3 business days after the date of IDR initiation, the alternative preferred certified IDR entity would be considered jointly selected by the parties. If the non-initiating party submits the notice of IDR initiation response on the third business day after the date of IDR initiation and the initiating party does not agree on the same day, the parties would have failed to jointly select a certified IDR entity.

Additionally, these proposed rules would amend the process for the initiating and non-initiating parties to go back-and-forth in selecting and responding to a selection of an alternative preferred certified IDR entity after the non-initiating party submits a notice of IDR initiation response within the 3-business-day period after IDR initiation. Specifically, if a certified IDR entity is not jointly selected because the initiating party submits a notice of certified IDR entity

selection objecting to the non-initiating party's alternative preferred certified IDR entity reflected in the notice of IDR initiation response, the non-initiating party may agree to the alternative preferred certified IDR entity selected in the initiating party's notice of certified IDR entity selection or select another alternative preferred certified IDR entity by submitting a notice of certified IDR entity selection to the initiating party and to the Departments. This back-and-forth may continue until the earlier of the date that the parties agree on an alternative preferred certified IDR entity or the deadline for joint selection, which is 3 business days after the date of IDR initiation. However, if either the notice of IDR initiation response or the notice of certified IDR entity selection is submitted on the third business day after the date of IDR initiation, the party last in receipt of the applicable notice would not be allowed to select another alternative preferred certified IDR entity, as discussed later in this section of the preamble. Once a party submits a notice of certified IDR entity selection, it may not submit another notice of IDR entity selection until after it receives a responding notice of certified IDR entity selection from the other party.

If a party submits a notice of certified IDR entity selection to the other party on the first or second day after the date of IDR initiation and the party in receipt of the notice agrees or fails to object to the alternative preferred certified IDR entity by the third business day after the date of IDR initiation, the alternative preferred certified IDR entity would be considered jointly selected by the parties. If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice agrees to the alternative preferred certified IDR entity on the same day, the alternative preferred certified IDR entity will be considered jointly selected by the parties. If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice does not agree to the alternative preferred certified IDR entity on the same day, the parties would have failed to jointly select a certified IDR entity.

Under these proposed rules at 26 CFR 54.9816-8(c)(1)(i)(D), 29 CFR 2590.716-8(c)(1)(i)(D), and 45 CFR 149.510(c)(1)(i)(D), to notify the Departments and the other party of any subsequent agreement or objection to an alternative preferred certified IDR entity after the non-initiating party submits the notice of IDR initiation response, a party must submit a notice of certified IDR entity selection. The party must furnish the notice of certified IDR entity selection using the standard form developed by the Departments through the Federal IDR portal within 3 business days after the date of IDR initiation.

The Departments propose to amend the existing content of the notice of certified IDR entity selection and specify that the notice must include a statement indicating the party's agreement with or objection to the other party's alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the other party's alternative preferred certified IDR entity. If the party in receipt of a notice of certified IDR entity selection objects to the other party's alternative preferred certified IDR entity and the party submits a notice of certified IDR entity selection by the end of the third business day after the date of IDR initiation, that party's notice of certified IDR entity selection reflecting the objection must include the name of another alternative preferred certified IDR entity.

The Departments propose to amend 26 CFR 54.9816-8(c)(1)(iv), 29 CFR 2590.716-8(c)(1)(iv), and 45 CFR 149.510(c)(1)(iv), which describe the certified IDR entity selection process when the disputing parties fail to jointly select a certified IDR entity, and redesignate the paragraphs as amended 26 CFR 54.9816-8(c)(1)(ii), 29 CFR 2590.716-8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii). If the parties fail to jointly select a certified IDR entity within 3 business days after the date of IDR initiation, the Departments would select a certified IDR entity. The parties would have failed to jointly select a certified IDR entity if, by the end of the third business day after the date of IDR initiation, the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection has objected to the other party's alternative preferred certified IDR entity, or if the notice of IDR initiation response or the notice of certified IDR

entity selection is submitted to the other party on the third business day after the date of IDR initiation and the party in receipt of the notice does not agree to the alternative preferred certified IDR entity within 3 business days after the date of IDR initiation.

As part of the Departments' process to select a certified IDR entity when the parties do not jointly select one,[149] under these proposed rules, the Departments would first confirm whether a party submitted the notice of IDR initiation response or notice of certified IDR entity selection with an alternative preferred certified IDR entity on the third business day after the date of IDR initiation without the other party's agreement to the selection. If either notice was provided on the third business day after the date of IDR initiation without the other party's agreement to the alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Departments would provide the party last in receipt of the applicable notice 2 additional business days to either agree or object to the other party's alternative preferred certified IDR entity selection. In these circumstances, under these proposed rules, if a party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection agrees with the other party's alternative preferred certified IDR entity and notifies the Departments of the agreement or fails to notify the Departments of its objection in the Federal IDR portal by the fifth business day after the date of IDR initiation, the Departments would select the final alternative preferred certified IDR entity selected in the applicable notice. In disputes where the applicable notice was submitted on the third business day after the date of IDR initiation, the party last in receipt of the notice would not be allowed to select another alternative preferred certified IDR entity. If the party last in receipt of the notice notifies the Departments of its objection to the alternative preferred certified IDR entity by the fifth business day after the date of IDR initiation, the Departments would proceed with the random selection of the certified IDR entity from among the certified IDR entities (other than the preferred certified

[149] Section 9816(c)(4)(F)(ii) of the Code, section 716(c)(4)(F)(ii) of ERISA, and section 2799A-1(c)(4)(F)(ii) of the PHS Act.

IDR entity and any alternative preferred certified IDR entity previously selected in such dispute by a party, unless there is no other certified IDR entity available to select) that charge a fee within the allowed range of certified IDR entity fees on the sixth business day after the date of IDR initiation. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Departments would select a certified IDR entity that has received approval, as described in paragraph 26 CFR 54.9816-8T(e)(2)(vii)(B), 29 CFR 2590.716-8(e)(2)(vii)(B), and 45 CFR 149.510(e)(2)(vii)(B), to charge a fee outside of the allowed range of certified IDR entity fees. In either case, the Departments would notify the parties of the preliminarily selected certified IDR entity not later than 6 business days after the date of IDR initiation. The Departments are of the view that this proposed requirement would give each party a reasonable opportunity to review the other party's alternative preferred selected certified IDR entity and to notify the other party and the Departments whether the party agrees or disagrees with the selection. Consistent with section 9816(c)(4)(F) of the Code, section 716(c)(4)(F) of ERISA, and section 2799A-1(c)(4)(F) of the PHS Act, these requirements would ensure that the certified IDR entity selection timeframe occurs within 6 business days after the date of Federal IDR initiation, when the parties do not jointly select the certified IDR entity.

The Departments also propose to amend 26 CFR 54.9816-8T(c)(1)(iii), 29 CFR 2590.716-8(c)(1)(iii), and 45 CFR 149.510(c)(1)(iii) to provide that the date of preliminary selection of the certified IDR entity is 3 business days after the date of IDR initiation if the parties jointly selected a certified IDR entity, or 6 business days after the date of IDR initiation if the parties fail to jointly select a certified IDR entity and the Departments instead select the certified IDR entity.

The Departments seek comment on these proposals.

ii. Final Selection of the Certified IDR Entity and Certified IDR Entity Conflict-of-Interest Review

The Departments propose to add 26 CFR 54.9816-8(c)(1)(iv), 29 CFR 2590.716-8(c)(1)(iv), and 45 CFR 149.510(c)(1)(iv) to establish the process for finalizing certified IDR entity selection. Under the proposed rules, the date of final selection of the certified IDR entity would be the date that triggers the timeframes for the requirement to issue payment determinations (not later than 30 business days after the date of final selection of the certified IDR entity) and the submission of offers from both parties (not later than 10 business days after the date of final selection of the certified IDR entity) under section 9816(c)(5)(A) and (B) of the Code, section 716(c)(5)(A) and (B) of ERISA, and section 2799A-1(c)(5)(A) and (B) of the PHS Act.

The statute provides that a certified IDR entity must meet certain conflict-of-interest standards before being selected as a certified IDR entity assigned to make a payment determination. However, the statute is silent on the specific timeframe or process for the selected certified IDR entity to review the parties' (or the Departments') selection to ensure that a conflict of interest does not exist. Based on feedback from interested parties and the Departments' experience with implementation of the Federal IDR process, the Departments are of the view that it is important to implement a timeframe that permits a meaningful opportunity for conflict-of-interest review by the certified IDR entity while ensuring that it does not limit the time periods for either disputing parties to submit their offers or for the certified IDR entity to make a payment determination. To streamline this process, the Departments are of the view that permitting the certified IDR entity to be considered preliminarily selected until the certified IDR entity confirms that it has no conflict of interest with either party, would increase the efficiency of the process while balancing the need to ensure that certified IDR entities are free of conflict.

After the certified IDR entity is preliminarily selected pursuant to 26 CFR 54.9816-8(c)(1)(iii), 29 CFR 2590.716-8(c)(1)(iii), and 45 CFR 149.510(c)(1)(iii), the Departments propose that the preliminarily selected certified IDR entity would review the selection and attest to the Departments whether it meets the conflict-of-interest requirements as outlined in proposed

26 CFR 54.9816-8(c)(1)(iv)(A)(*1*) through (*3*), 29 CFR 2590.716-8(c)(1)(iv)(A)(*1*) through (*3*), and 45 CFR 149.510(c)(1)(iv)(A)(*1*) through (*3*). The Departments are not proposing new conflict-of-interest requirements, however, the Departments are proposing to make non-substantive amendments to improve clarity and align with the structure of the reorganized provisions as follows: (1) the certified IDR entity does not have a conflict of interest as defined in paragraphs 26 CFR 54.9816-8(a)(2)(iv), 29 CFR 2590.716-8(a)(2)(iv), and 45 CFR 149.510(a)(2)(iv); (2) the certified IDR entity will only assign personnel to a dispute and make decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute in a manner that is not based upon the likelihood that the assigned personnel will support a particular party to the dispute; and (3) the certified IDR entity will not assign any personnel to a dispute who would have any conflicts of interest, as defined in paragraphs 26 CFR 54.9816-8(a)(2)(iv), 29 CFR 2590.716-8(a)(2)(iv), and 45 CFR 149.510(a)(2)(iv), regarding any party to the dispute or whose relationship with a party within the 1 year immediately preceding the assignment to the dispute would violate the restrictions on aiding or advising a former employer or principal in a manner similar to the restrictions set forth in 18 U.S.C. 207(b).

Under 26 CFR 54.9816-8(c)(1)(iv)(B), 29 CFR 2590.716-8(c)(1)(iv)(B), and 45 CFR 149.510(c)(1)(iv)(B), the Departments also propose that if the certified IDR entity notifies the Departments within 3 business days of the date of preliminary selection of the certified IDR entity that it does not meet the conflict-of-interest requirements or does not respond within 3 business days after the date of preliminary selection of the certified IDR entity, the Departments would randomly select another certified IDR entity. The Departments would notify the parties of the new randomly preliminarily selected certified IDR entity no later than 1 business day after the previously selected certified IDR entity notifies the Departments that it has a conflict of interest, or if the previously selected certified IDR entity fails to respond within 3 business days

after the date of preliminary selection of the certified IDR entity, no later than 1 business day after the end of the 3-business-day period.

These proposed rules would streamline the process for certified IDR entity selection when the preliminarily selected certified IDR entity fails to timely respond or notifies the Departments that it cannot meet the conflict-of-interest requirements in proposed 26 CFR 54.9816-8(c)(1)(iv)(A), 29 CFR 2590.716-8(c)(1)(iv)(A), and 45 CFR 149.510(c)(1)(iv)(A). Under the October 2021 interim final rules, when a selected certified IDR entity is unable to attest that it has no conflict of interest within 3 business days of certified IDR entity selection, the parties to the dispute are given another opportunity to jointly agree on a certified IDR entity, and the end of the 3-business-day period is treated as the date of initiation of the Federal IDR process. Under these proposed rules, when a preliminarily selected certified IDR entity provides notice of a conflict of interest, the Departments would select another certified IDR entity through random selection, as opposed to allowing the parties additional opportunities to jointly select a different certified IDR entity, in order to create operational efficiencies and minimize delays in processing disputes. Additionally, if the certified IDR entity does not respond to the conflict-of-interest review by the end of the 3-business-day period after preliminary selection of the certified IDR entity, the Departments would randomly select another certified IDR entity. If a certified IDR entity cannot review and provide a response related to a conflict of interest within a 3-business-day period, the dispute would move to a different certified IDR entity that may have the capacity to review the dispute in a timelier manner, which would improve the overall timeliness of dispute processing.

Under 26 CFR 54.9816-8(c)(1)(iv)(C), 29 CFR 2590.716-8(c)(1)(iv)(C), and 45 CFR 149.510(c)(1)(iv)(C) of these proposed rules, if the certified IDR entity that has been preliminarily selected attests within 3 business days that it meets the conflict-of-interest requirements, the Departments would notify the parties of the final selection of that certified IDR entity no later than 1 business day after the certified IDR entity attests that it meets the conflict-

of-interest requirements The date of final selection of the certified IDR entity is the date that the Departments provide this notice to the parties.

Lastly, the Departments also propose to remove 26 CFR 54.9816-8T(c)(1)(v), 29 CFR 2590.716-8(c)(1)(v), and 45 CFR 149.510(c)(1)(v), as these requirements regarding certified IDR entity conflict of interest and Federal IDR process eligibility review would be required under the paragraphs at 26 CFR 9816-8(c)(1)(iv)(A), 29 CFR 2590.716-8(c)(1)(iv)(A), and 45 CFR 149.510(c)(1)(iv)(A) and 26 CFR 9816-8(c)(2), 29 CFR 2590.716-8(c)(2), and 45 CFR 149.510(c)(2), respectively.

The Departments seek comment on these proposals.

b. Federal IDR Process Eligibility Review

i. Federal IDR Process Eligibility Determination by Certified IDR Entity

The No Surprises Act does not specify a timeframe or process for which the Departments or certified IDR entities must assess a dispute's eligibility for the Federal IDR process. Under the October 2021 interim final rules, certified IDR entities are required to review the information in the notice of IDR initiation and notice of certified IDR entity selection to determine whether the Federal IDR process applies and if not, to notify the Departments within 3 business days of making that determination.[150] The Departments further clarified in the *Federal IDR Process Guidance for Certified IDR Entities*[151] that certified IDR entities must make this eligibility determination within 3 business days after they are selected, which is before the parties must submit an offer of an out-of-network rate (not later than 10 business days after the date of selection of the certified IDR entity) and before the certified IDR entity must make a payment determination (30 business days after the date of selection of the certified IDR entity).

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[150] 26 CFR 54.9816-8T(c)(1)(v), 29 CFR 2590.716-8(c)(1)(v), and 45 CFR 149.510(c)(1)(v).

[151] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. (Oct. 2022). *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities*. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Federal-Independent-Dispute-Resolution-Process-Guidance-for-Certified-IDR-Entities.pdf*.

To provide certified IDR entities additional time to conduct eligibility reviews before the parties must submit their offers, the Departments propose to remove 26 CFR 54.9816-8T(c)(1)(v), 29 CFR 2590.716-8(c)(1)(v), and 45 CFR 149.510(c)(1)(v), and add proposed 26 CFR 54.9816-8(c)(2)(i), 29 CFR 2590.716-8(c)(2)(i), and 45 CFR 149.510(c)(2)(i), which would allow certified IDR entities 5 business days after the date of final selection of the certified IDR entity to make an eligibility determination. Under these proposed rules, unless the departmental eligibility review described in section II.E.1.b.ii. of this preamble applies, the selected certified IDR entity would be required to review the information in the notice of IDR initiation, the notice of IDR initiation response, and any additional information as discussed in proposed 26 CFR 54.9816-8(c)(2)(iii), 29 CFR 2590.716-8(c)(2)(iii), and 45 CFR 149.510(c)(2)(iii), and make a final determination as to whether the item or service is a qualified IDR item or service that is eligible for the Federal IDR process. The certified IDR entity would be required to make this eligibility determination and notify the Departments and both parties no later than 5 business days after the date of final selection of the certified IDR entity. If the certified IDR entity determines that the item or service is not a qualified IDR item or service, the dispute would be closed, and the selected certified IDR entity would not take any action with regard to the dispute.

The Departments propose to provide 2 additional business days for certified IDR entities to review the notices and make an eligibility determination. This proposal would provide additional time while meeting the statutory requirement that the submission of offers be submitted no later than 10 days after the date of certified IDR entity selection.[152] More specifically, under these proposed rules, the certified IDR entity would be required to determine whether a dispute was eligible for the Federal IDR process not later than 5 business days after the date of final selection of the certified IDR entity and if eligible, the parties to the dispute would be required to submit their offers not later than 10 business days after the final selection of

[152] Section 9816(c)(5)(B) of the Code, section 716(c)(4)(B) of ERISA, and section 2799A-1(c)(4)(B) of the PHS Act.

the certified IDR entity (which would be at least 5 business days after the eligibility determination). Although currently eligibility reviews are generally taking certified IDR entities longer than 5 business days, these proposed rules are intended to facilitate more efficient processing of eligibility reviews, and the Departments therefore expect that 5 business days would be sufficient for this purpose if these proposed rules are finalized. Further, these proposed rules intend to balance the time certified IDR entities have to conduct eligibility reviews with the time parties are given to submit their final offers. Because the No Surprises Act provides only 10 days from the date of certified IDR entity selection for the parties to submit their offers, these proposed rules would provide equal time for eligibility review and for the parties to submit their offers after the eligibility review.

A non-initiating party's attestation that a dispute is ineligible for the Federal IDR process, alone, would be insufficient to substantiate a determination of ineligibility. The certified IDR entity (or the Departments, if conducting eligibility reviews as described in section II.E.1.b.ii. of this preamble) would review disputes for eligibility in all instances.

The Departments seek comment on these proposals, including the appropriate amount of time certified IDR entities should be provided to conduct eligibility reviews.

ii. Departmental Eligibility Review for Federal IDR Process Eligibility Determinations

Even if the proposals in these proposed rules are finalized and the intended results of a more efficient eligibility review process and fewer ineligible initiated disputes are realized, circumstances may still arise where the Departments would need to take actions to facilitate more timely dispute processing, such as when the volume of disputes outpaces the capacity of certified IDR entities to timely process eligibility determinations. To address such circumstances, and provide for such flexibility, the Departments propose adding 26 CFR 54.9816-8(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii), which would establish an eligibility review process whereby, when the conditions set forth in 26 CFR 54.9816-8(c)(2)(ii)(A), 29 CFR 2590.716-8(c)(2)(ii)(A), and 45 CFR 149.510(c)(2)(ii)(A) are met, as described in section

II.E.1.b.ii. of this preamble, the Departments would conduct the eligibility review and make the eligibility determination on behalf of the certified IDR entity (departmental eligibility review).

Under these proposed rules, if the Departments determine that an item or service is not a qualified IDR item or service, the dispute would be closed, and the preliminarily selected certified IDR entity would not take any action regarding the dispute. If the dispute were found to be eligible, the Departments would inform the preliminarily selected certified IDR entity of eligibility so that it may conduct its conflict-of-interest assessment, and the dispute would otherwise continue through the Federal IDR process, including notification of the eligibility determination to the disputing parties by the preliminarily selected certified IDR entity.

From the disputing parties' perspectives, Federal IDR process operations during departmental eligibility reviews would largely be unchanged. Timeframes and processes to initiate the Federal IDR process, conduct certified IDR entity selection, and submit offers would be the same. The noticeable differences for disputing parties would be that correspondence related to a dispute's eligibility, including any related information requests, would come from the Departments, rather than one of the certified IDR entities, and the potential impact departmental eligibility reviews may have on the administrative fee as outlined in section II.E.3.a. of this preamble. Additionally, depending on dispute volume and other factors impacting the Departments' decision to conduct eligibility reviews, the Departments may choose to exercise their authority to extend time periods for extenuating circumstances as discussed in section II.E.5. of this preamble to allow more time for the Departments to conduct eligibility reviews. This proposed approach is similar to what is currently occurring under the technical assistance provided to certified IDR entities that was announced in November 2022.[153] The principal difference is that under these proposed rules, when departmental eligibility review is in effect, the Departments would be able to close a case after determining it is ineligible, rather than

[153] *See https://www.cms.gov/files/document/idre-eligibility-support-guidance-11212022-final-updated.pdf.*

forwarding the Departments' eligibility recommendation to the certified IDR entity to make the final eligibility determination.

For certified IDR entities, the Federal IDR process operations under the proposed departmental eligibility reviews would also function similarly to current operations except that, to prevent certified IDR entities from conducting duplicative eligibility screenings, a certified IDR entity would not be notified of their selection for the purposes of their conflict-of-interest review until after eligibility has been determined by the Departments. The Departments are proposing the departmental eligibility review under certain circumstances to relieve the burden on certified IDR entities and to ensure that they can focus their time and resources on payment determinations in accordance with statutory timeframes. For the reasons discussed in section I.H. of this preamble, eligibility determinations have proven to be complex and time-consuming for certified IDR entities, and certified IDR entities are not compensated for the time and effort expended in assessing dispute eligibility when a dispute is determined ineligible for the Federal IDR process. This is because the statute provides that certified IDR entities may only retain their fees from the non-prevailing party to a dispute (unless the dispute is withdrawn or settled as discussed in section II.E.1.d. of this preamble). Moreover, some certified IDR entities have been unable to accept new disputes because they are overburdened with making eligibility determinations. Certified IDR entities have informally reported to the Departments during regular communications that they spend 50-80 percent of their time on making eligibility determinations and a few certified IDR entities have had to temporarily suspend accepting new disputes to manage their backlogs. When they are focused on eligibility challenges, certified IDR entities have less time and fewer resources to devote to making timely payment determinations.

Ultimately, the certified IDR entities' participation in the Federal IDR process is voluntary and must be financially sustainable. Furthermore, the No Surprises Act directs the Departments to administer the Federal IDR process in a manner that ensures participation by a

sufficient number of certified IDR entities.[154] If certified IDR entities decline to participate because it is not economically viable to do so, the directive of the statute is defeated. Thus, the ability for certified IDR entities to obtain fair compensation for the work conducted is critical to the success of the Federal IDR process, and the Departments are therefore of the view that it is in the best interests of all parties to reduce the burden of eligibility determinations when feasible.

The Departments intend for their role in conducting eligibility determinations to be temporary. The Departments are of the view that when eligibility determinations are less burdensome and the volume of disputes is manageable, certified IDR entities are better equipped to conduct eligibility determinations. Further, the Departments do not possess the staff or resources to carry out the eligibility determinations in the long term and must retain contract support to carry out the eligibility determinations in the short term. The Departments acknowledge that any increased expenditures related to conducting final eligibility determinations would be reflected in the non-refundable Federal IDR administrative fees because these fees must reflect the amount of expenditures estimated to be made by the Departments for the year in carrying out the Federal IDR process.[155] Therefore, the Departments would not intend to continue this role if the other proposed policies in these rules, along with ongoing Federal IDR portal improvements, are successful in improving dispute processing and reducing the volume of ineligible disputes.

iii. Application of the Departmental Eligibility Review

The departmental eligibility review would apply when the Departments determine that extenuating circumstances under proposed 26 CFR 54.9816-8(g)(1), 29 CFR 2590.716-8(g)(1), and 45 CFR 149.510(g)(1) require application of the departmental eligibility review to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process.

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[154] Section 9816(c)(4)(E) of the Code, section 716(c)(4)(E) of ERISA, and section 2799A-1(c)(4)(E) of the PHS Act.
[155] Section 9816(c)(8) of the Code, section 716(c)(8) of ERISA, and section 2799A-1(c)(8) of the PHS Act. *Also see* IDR Process Fees proposed rules at 88 FR 65893 (Sept. 26, 2023).

iv. Notification Regarding Applicability of the Departmental Eligibility Review

Before invoking the application of the departmental eligibility review, the Departments propose to post advance public notification of the date on which the departmental eligibility review would take effect, and the reasons for invoking the application of the departmental eligibility review. Before ending the application of the departmental eligibility review, the Secretary will post advance public notification of the date on which the departmental eligibility review would no longer be in effect and the reasons for ending the application of the departmental eligibility review, as applicable.

The Departments seek comment on these proposals, including whether the departmental eligibility reviews, when they are applicable, should be applied to all certified IDR entities or if the Departments should apply these proposed rules to only the certified IDR entities with significant dispute backlogs.

c. Request for Additional Information

Based on the Departments' experience operating the Federal IDR process, disputing parties have not consistently submitted all information necessary for a certified IDR entity to make an eligibility determination, a conflict-of-interest assessment, or a payment determination. Certified IDR entities frequently must reach out to the disputing parties, sometimes multiple times, to obtain the required information. Such outreach is time intensive, inefficient, and costly. Even as the Departments propose other methods to promote information submission by disputing parties throughout the Federal IDR process (as described throughout this preamble), certified IDR entities and the Departments likely will still need to collect additional information to make accurate determinations in a timely fashion. Thus, using the general rulemaking authority granted to the Departments to establish the Federal IDR process under section 9816(c)(2)(A) of the Code, section 716(c)(2)(A) of ERISA, and section 2799A–1(c)(2)(A) of the PHS Act, the Departments are proposing in new 26 CFR 54.9816-8(c)(2)(iii), 29 CFR 2590.716-8(c)(2)(iii), and 45 CFR 149.510 (c)(2)(iii) to establish that the Departments and the certified IDR entity may

request additional information from either party to a dispute at any time, including for the purpose of assessing whether a conflict of interest exists, conducting an eligibility determination, or making a payment determination. Under this proposal, a party must submit the requested additional information within 5 business days to the Departments or the selected certified IDR entity, as applicable, through the Federal IDR portal. Following a request for additional information, under these proposed rules, the time period for the applicable stage of the Federal IDR process would be tolled until the earlier of the date either all of the requested information is provided or the 5-business-day period expires, and each subsequent timeframe in the Federal IDR process would be determined based on the date of completion of the stage of the Federal IDR process that was tolled for provision of the requested information.

However, under the statute, the timeframe for parties making payment after the payment determination cannot be extended. Therefore, payments required as a result of a payment determination must be provided within 30 calendar days of that payment determination. If a party fails to submit the additional information as required, the related determination, including the eligibility determination, conflict-of-interest review, or payment determination will be made without the requested information unless a good-cause extension of the 5-business-day period, as specified in 26 CFR 54.9816-8(g)(1)(i), 29 CFR 2590.716-8(g)(1)(i), and 45 CFR 149.510(g)(1)(i) has been provided, and the party subsequently submits the additional information requested within the extended period.

The Departments are of the view that a 5-business-day period is sufficient for a response without unduly delaying the Federal IDR process. This 5-business-day period is consistent with the 5-business-day outreach period set forth in the *August 2022 Technical Assistance for Certified IDR Entities*.[156] The Departments anticipate that this deadline would incentivize parties

[156] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. (Oct. 2022) (Federal Independent Dispute Resolution (IDR) Process Technical Assistance for Certified IDR Entities. August 2022, available at: *https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf.*

to submit information promptly, and that tolling any applicable time periods would give the Departments and certified IDR entities sufficient time to make such additional information requests without encroaching on other timeframes.

The Departments seek comment on these proposals, including whether certified IDR entities should still be required to make a payment determination and provide notification of the payment determination to the parties not later than 30 business days after the date of final selection of the certified IDR entity, after a preceding timeframe in the process has been tolled, such as for an eligibility determination.

d. Authority to Continue Negotiations or Withdraw

i. Authority to Continue to Negotiate

To correct an omission, HHS is proposing a non-substantive change to 45 CFR 149.510(c)(3)(i) to add the term "enrollee" to references to participants and beneficiaries. HHS is proposing to add the term "enrollee" to account for individuals who are enrolled in the individual health insurance market when referencing whose cost sharing must be considered as part of the total out-of-network rate agreed upon by both parties and to clarify who may not be billed for additional payments if the agreed upon out-of-network rate exceeds the QPA.

ii. Withdrawals

The Departments propose to add 26 CFR 54.9816–8(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii) to establish a process for disputes to be withdrawn from the Federal IDR process. Under these proposed rules, a dispute may be withdrawn from the Federal IDR process by the initiating party, the Departments, or the certified IDR entity before a payment determination is made if any one of the following four conditions is met. Under the proposed new 26 CFR 54.9816–8(c)(3)(ii)(A), 29 CFR 2590.716–8(c)(3)(ii)(A), and 45 CFR 149.510(c)(3)(ii)(A), the first condition would allow for withdrawal when the initiating party provides notification through the Federal IDR portal to the Departments and the certified IDR entity (if selected) that both parties to the dispute agree to withdraw the dispute from the Federal

IDR process without agreement on an out-of-network rate. An initiating party generally should not be able to unilaterally withdraw a dispute once it is initiated because the non-initiating party may not wish to withdraw the dispute. Therefore, under these proposed rules, the notification must include the dispute number, a statement about both parties' agreement to withdraw and authorized signatures from both parties. A withdrawal that is agreed to by both parties would remove disputes from the system in the most efficient manner without the need for additional outreach.

The Departments also propose to add 26 CFR 54.9816–8(c)(3)(ii)(B), 29 CFR 2590.716–8(c)(3)(ii)(B), and 45 CFR149.510(c)(3)(ii)(B), to allow for withdrawal when the initiating party provides a standard withdrawal request notice through the Federal IDR portal to the Departments, the certified IDR entity (if selected), and the non-initiating party of its request to withdraw the dispute from the Federal IDR process, and the non-initiating party notifies the Departments, certified IDR entity (if selected), and the initiating party through the Federal IDR portal of its agreement to withdraw from the Federal IDR process within 5 business days of the initiating party's request. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party would be considered to have agreed to the withdrawal, and the dispute would be withdrawn. The Departments propose adding withdrawal of a dispute in this situation to address circumstances in which the non-initiating party fails to respond because they are not engaging in the process. Permitting withdrawal of a dispute in such cases would decrease the number of payment determinations the certified IDR entity is required to adjudicate. These proposals strike a balance between fairness to the disputing parties and efficiency of the Federal IDR process by generally requiring mutual agreement by the disputing parties to withdraw the dispute but providing that the dispute would be withdrawn in the event the non-initiating party is nonresponsive within the specified timeframe.

Under proposed new 26 CFR 54.9816–8(c)(3)(ii)(C), 29 CFR 2590.716–8(c)(3)(ii)(C), and 45 CFR 149.510(c)(3)(ii)(C), the third condition under which a dispute may be withdrawn is

when a certified IDR entity or the Departments cannot determine eligibility because both parties are unresponsive to a request for additional information as described in proposed 26 CFR 54.9816–8(c)(2)(iii), 29 CFR 2590.716–8(c)(2)(iii) and 45 CFR 149.510(c)(2)(iii). In situations where neither party responds to the requested information, the Departments believe it appropriate for the dispute to be withdrawn because the certified IDR entity lacks the appropriate information to make the required eligibility determination properly and the parties are failing to engage in the process.

Under proposed new 26 CFR 54.9816–8(c)(3)(ii)(D), 29 CFR 2590.716–8(c)(3)(ii)(D), and 45 CFR 149.510(c)(3)(ii)(D), the fourth condition under which a dispute may be withdrawn is when the certified IDR entity cannot make a payment determination because both parties have failed to submit an offer as described in proposed 26 CFR 54.9816–8(c)(5)(i), 29 CFR 2590.716– 8 (c)(5)(i) and 45 CFR 149.510(c)(5)(i). The Departments are of the view that such disputes should be withdrawn from the Federal IDR process because under the statute, parties have ceased to participate in the Federal IDR process and failed to submit an offer that the certified IDR entity must select as the out-of-network payment amount. In addition, if neither party has submitted an offer, there is nothing from which the certified IDR entity may select.[157]

In addition to the proposals described in this section of the preamble, the Departments also propose technical revisions to the existing requirements for the authority to continue negotiations, which are currently set forth at 26 CFR 54.9816–8T(c)(2), 29 CFR 2590.716–8(c)(2), and 45 CFR 149.510(c)(2). These proposed rules would redesignate paragraph (c)(2) as (c)(3) and amend the title at current paragraph (c)(2) by adding to the end of it "or withdraw".

The Departments seek comment on these proposals, including if there are other circumstances for which the Departments should consider a dispute withdrawn.

2. Treatment of Batched Items and Services and Bundled Payment Arrangements

[157] Section 9816(c)(5)(A)(i) of the Code, section 716(c)(5)(A)(i) of ERISA, and section 2799A–1(c)(5)(A)(i) of the PHS Act.

The Departments propose revisions to the requirements for the treatment of batched items and services which are currently set forth at 26 CFR 54.9816–8T(c)(3)(i), 29 CFR 2590.716–8(c)(3)(i), and 45 CFR 149.510(c)(3)(i). However, as discussed in section I.D. of this preamble, the requirements at 26 CFR 54.9816–8T(c)(3)(i)(C), 29 CFR 2590.716–8(c)(3)(i)(C), and 45 CFR 149.510(c)(3)(i)(C) have been vacated by the District Court in *TMA IV* order. The Departments also propose technical changes to the treatment of bundled payment arrangements, currently set forth at 26 CFR 54.9816–8T(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii). The batching and bundling payment proposals are informed by the Departments' experience implementing the regulatory requirements on the batching of items and services related to the treatment of a similar condition and relevant feedback from interested parties, including comments submitted in response to the October 2021 interim final rules.

a. Treatment of Batched Items and Services and Bundled Payment Arrangements Under Current and Vacated Rules

Under the October 2021 interim final rules, multiple qualified IDR items and services were required to meet four conditions to be batched and considered as part of a single payment determination. First, the qualified IDR items and services must be billed by the same provider or group of providers, the same facility, or same provider of air ambulance services, which means the items and services must be billed under the same NPI or TIN.

Second, the initial payment (or notice of denial of payment) for the items and services must be made by the same group health plan or health insurance issuer. The Departments clarified in *August 2022 Technical Assistance for Certified IDR Entities* that qualified IDR items or services can be batched if payment is made by the same issuer even if the qualified IDR items and services relate to claims from different fully-insured group or individual health plan coverage offered by the issuer; and that for self-insured group health plans, qualified IDR items or services can be batched only if payment is made by the same plan, even if the same TPA administers multiple self-insured plans.

Third, the October 2021 interim final rules established that qualified IDR items and services were related to the treatment of a similar condition if the qualified IDR items and services were the same or similar items or services, meaning that those items and services are billed under the same service code with modifiers (if applicable), or billed under a comparable service code with modifiers (if applicable) under a different procedural code system.[158] However, as discussed in section I.D. of this preamble, on August 3, 2023, the District Court vacated this provision on the grounds that it violated the notice-and-comment requirement of the Administrative Procedure Act. The *TMA IV* order vacated the parts of the *August 2022 Technical Assistance for Certified IDR Entities* that stated that multiple qualified IDR items or services may be batched in a single dispute if the qualified IDR items or services were billed under the same service code with modifiers, or billed under comparable codes with modifiers under different procedural code systems. Further, as discussed in section I.D. of this preamble, on August 24, 2023, the District Court vacated that portion of the *August 2022 Technical Assistance for Certified IDR Entities* on the basis that the guidance prohibits a single air ambulance transport, which is billed under two service codes (one for the base rate and one for the mileage rate), to be submitted as a single dispute, and instead required two separate disputes to be submitted. The District Court vacated this provision as a violation of the statute which defines each air ambulance transport as a single service.[159]

Fourth, all the qualified IDR items and services must have been furnished within the same 30-business-day period or the 90-calendar-day suspension period (also referred to as the "cooling-off period") under 26 CFR 54.9816-8T(c)(5)(vii)(B), 29 CFR 2590.716-8(c)(5)(vii)(B), and 45 CFR 149.510(c)(5)(vii)(B).[160] As stated in the preamble to the October 2021 interim final

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[158] In the July 2021 interim final rule (86 FR 36890), the Departments defined the service code as the code that describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and the Diagnosis-Related Group (DRG) codes. *See also* 26 CFR 54.9816–6T(a)(14), 29 CFR 2590.716–6(a)(14), and 45 CFR 149.140(a)(14).

[159] 42 U.S.C. 300gg-112(b)(1)(B), (c)(1).

[160] The Departments propose a non-substantive amendment to 26 CFR 54.9816–8(c)(4)(i)(D), 29 CFR 2590.716–8(c)(4)(i)(D), and 45 CFR 149.510(c)(4)(i)(D) to correct the cross-reference to the cooling-off period from 26 CFR

rules, for claims for an item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process for any item or service affected by the suspension. For these items or services, the initiating party must submit the notice of IDR initiation within 30 business days following the end of the 90-calendar-day suspension 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 90-calendar-day suspension period.

Section 9816(c)(3)(B) of the Code, section 716(c)(3)(B) of ERISA, and section 2799A–1(c)(3)(B) of the PHS Act direct the Departments, as part of specifying criteria for batched disputes, to provide that qualified IDR items and services included by a provider or facility as part of a bundled payment may be part of a single determination. The October 2021 interim final rules specify that items and services may be submitted as a bundled payment arrangement when qualified IDR items and services are billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment. The *August 2022 Technical Assistance for Certified IDR Entities* clarified that for the purposes of the Federal IDR process, a bundled arrangement is an arrangement under which: (1) a provider, facility, or provider of air ambulance services bills for multiple items or services under a single service code; or (2) a plan or issuer makes an initial payment or notice of denial of payment to a provider, facility, or provider of air ambulance services under a single service code that represents multiple items or services (for example, a DRG).[161] The Departments also specified that bundled payment arrangements submitted under 26 CFR 54.9816–8T(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii) are

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54.9816–8T(c)(4)(vi)(B), 29 CFR 2590.716–8(c)(4)(vi)(B), and 45 CFR 149.510(c)(4)(vi)(B) to 26 CFR 54.9816–8T(c)(5)(vii)(B), 29 CFR 2590.716–8(c)(5)(vii)(B), and 45 CFR 149.510(c)(5)(vii)(B).

[161] U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. (August 2022). *Technical Assistance for Certified IDR Entities. https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf.*

subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

b. Feedback from Interested Parties on Current Batching Rules

Since the publication of the October 2021 interim final rules, the Departments have reviewed comments in response to the rules and continue to engage interested parties to identify opportunities for improvements in the Federal IDR process. In particular, the Departments have received substantial feedback from interested parties on the batching criteria that specifies how multiple qualified IDR items or services that relate to the treatment of a similar condition may be batched. Specifically, some providers of air ambulance services have expressed that the now-vacated batching rule finalized in the October 2021 interim final rules was burdensome because it prohibited a single air ambulance transport service from being the subject of a single dispute (for example, charges for fuel and mileage are two separate codes and could not be batched under the vacated batching rule). They highlighted that this essentially doubled their costs to dispute an out-of-network payment through the Federal IDR process. Some radiologists asserted that the vacated batching rule prohibited them from batching radiology items and services for multiple body parts for a single patient (for example, lumbar and thoracic spine) because these items and services are billed under different service codes, even though they may relate to a similar condition. They further asserted that, absent the ability to batch, radiologists are effectively denied access to the Federal IDR process because the reimbursements for most individual radiology codes are low-dollar and therefore are not cost-effective to dispute individually. The Departments received similar feedback from other specialty providers, including laboratory and pathology physicians. Emergency physicians have stated that the nature of emergency care makes it difficult for them to batch claims under the vacated batching rule. For example, emergency physicians note that emergency care is characterized by a range of severity that patients present with, and a corresponding range of diagnostic, therapeutic, and decision-making intensity, which is different from scheduled surgery or office visits where the

patient's diagnosis or condition is most often explicitly known. For this reason, emergency physicians recommend that for the purpose of emergency physicians, the "condition" should be defined as "emergency medical care" or "EMTALA-related care"[162] and that limiting batching to individual "conditions" would result in a high number of disputes in the Federal IDR process, expense, and administrative burden.

Anesthesiologists have recommended two different mechanisms by which claims for services should be able to be batched. First, anesthesiologists have stated that anesthesia services should be batched based on anesthesia code families. Anesthesia services are classified in a distinct code set in which CPT codes are grouped according to body parts (for example, head, neck, thorax, etc.). Anesthesiologists have highlighted that if they are not permitted to batch claims for services within a related body-part code group, they will be confronted with unique and significant administrative burdens in the Federal IDR process. Second, anesthesiologists have raised that they should be able to batch all claims with the same anesthesia conversion factor because this reflects industry practice. The conversion factor is the basis for their negotiations with payers for in-network services; a payer generally contracts with an anesthesiologist or their group for payment for the full range of anesthesia services based upon a single, common anesthesia conversion factor (expressed in dollars per unit). Whether the anesthesia service is for a surgical procedure on the head, shoulder, arm, or leg, the anesthesia conversion factor for each service is the same[163] and the assigned base units vary based on the procedure and the time units vary as determined by actual time.

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[162] An emergency medical condition is defined in the Emergency Medical Treatment and Active Labor Act (EMTALA) in part as: "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health [or the health of an unborn child] in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of bodily organs." 42 U.S.C. 1395dd(e)(1).

[163] In the *August 2022 Technical Assistance for Certified IDR Entities*, the Departments noted that plans and issuers generally calculate payment amounts for anesthesia services by multiplying the rate for the anesthesia conversion factor by (1) the base unit for the anesthesia service code, (2) the time unit, and (3) the physical status modifier unit. The base unit, time unit, and physical status modifier unit are specific to the individual receiving the anesthesia services. These base units are assigned to the services codes for anesthesia services, specifically CPT codes 00100 to 01999.

The Departments also have received feedback from certified IDR entities regarding the batching rules and potential impacts of expanding batching. Certified IDR entities have indicated that disputes involving batched items and services under the current and now-vacated rules are more administratively burdensome than non-batched disputes, often due to the extra time and resources they must expend in verifying that the items and services are properly batched and eligible for the Federal IDR process. Further, certified IDR entities have stated that a substantial portion of the time and expense related to resolving disputes is spent on these administrative and eligibility-related tasks; and once the dispute reaches the certified IDR entities, they are able to make the substantive payment determinations relatively efficiently. However, in providing feedback to the Departments on ways to improve batching in the Federal IDR process, certified IDR entities signaled that processing batched disputes would become substantially more difficult if broad categories of items and services could be submitted to the Federal IDR process in a single batched dispute. This is because, in addition to adding further complexity to the eligibility review process, certified IDR entities would also need to closely review the potentially unique factual circumstances of each item and service contained within the batch in making the payment determination. This could include differing evidence of the additional circumstances described in section 9816(c)(5)(C) of the Code, section 716(c)(5)(C) of ERISA, and section 2799A-1(c)(5)(C) of the PHS Act for each batched item and service.

Certified IDR entities recommended implementing a cap on the number of qualified IDR items and services (or "line items") included in batched disputes in order to ensure that they can resolve payment determinations within the 30-business-day requirement. Specifically, many certified IDR entities suggested imposing a 25-line-item cap on the number of items and services that could be submitted in a batched dispute, to the extent factual circumstances among them differed. Some certified IDR entities mentioned that the necessary line-item cap would depend on how the parties would be permitted to batch items and services; however, certified IDR entities generally indicated that in any circumstance, it would not be feasible to resolve disputes

in excess of 100 items and services within the 30-business-day period for making payment determinations. Certified IDR entities indicated they could manage batched claims containing a larger number of items and services (for example, 25 to 50) to the extent they involved the same type of claim and when the relevant facts are identical across the items or services in the batch. For example, some certified IDR entities stated that batching items and services from a single patient encounter and claim would be manageable and create efficiencies. However, certified IDR entities maintained that once the line items included in a batch reach a certain number, efficiencies are lost, and the batched dispute becomes unmanageable.

Plans and issuers have also indicated that the relatively frequent submission of incorrectly batched items and services as a single dispute by providers and facilities poses a substantial administrative burden for them. This is because the initiating party may need to resubmit the dispute, which, under the current rules, could also result in the non-initiating party paying the applicable administrative fee, potentially multiple times. Such interested parties urged the Departments to avoid adding further complexity or ambiguity with respect to the ability to batch items and services.

c. Proposals to Improve Batching in the Federal IDR Process

After considering comments and feedback from interested parties (including certified IDR entities, plans and issuers, providers, facilities, and providers of air ambulance services), and the Departments' general experience with operationalizing the Federal IDR process to date, the Departments are of the view that, under some circumstances, allowing multiple qualified IDR items and services that treat a similar condition to be batched together in a single payment determination proceeding, in accordance with the requirements of 26 CFR 54.9816–8T(c)(3)(i), 29 CFR 2590.716–8(c)(3)(i), and 45 CFR 149.510(c)(3)(i), encourages efficiency and can result in cost savings for disputing parties.[164]

[164] Section 9816(c)(3)(A)(iv) of the Code, section 716(c)(3)(A)(iv) of ERISA, and section 2799A–1(c)(3)(A)(iv) of the PHS Act.

In these proposed rules, the Departments are proposing new batching provisions that are intended to achieve a balance among several important objectives, including ensuring the batching rules do not unreasonably impede parties' access to the Federal IDR process considering relative costs and administrative burden, and simplifying Federal IDR process operations while avoiding new operational complexities that could create or exacerbate dispute backlogs. The Departments are of the view that the proposed provisions would help ensure that qualified IDR items and services included in batched determinations have clear definitional principles that would yield logical payment determinations across certified IDR entities, including determinations of whether items or services are properly submitted as batched determinations. The Departments are also of the view that these proposals would reduce potential risk that large and complicated batches would extend the time needed for certified IDR entities to make eligibility and payment determinations.[165] In addition to these proposals, the Departments are considering altering current guidance on the resubmission of incorrectly batched disputes. In the *August 2022 Technical Assistance for Certified IDR Entities,* the Departments stated that inappropriately batched or bundled disputes may be re-submitted as properly batched or single disputes if the qualified IDR items and services that are subject to the disputes meet all other applicable requirements, including requirements for timely initiation of the Federal IDR process. The Departments are considering removing this flexibility 90 business days after the proposed batching provisions, as finalized, would become applicable. This would allow parties time to adjust to the new proposed batching rules, if finalized.

i. Treatment of Batched Items and Services

The Departments first propose to redesignate paragraph (c)(3) as paragraph (c)(4) under 26 CFR 54.9816–8, 29 CFR 2590.716–8, and 45 CFR 149.510. Newly redesignated paragraph

[165] Under this notice of proposed rulemaking, the Departments propose new requirements related to the treatment of batched items and services and bundled payment arrangements. While the Departments consider and discuss feedback from interested parties in the context of these new proposals, they do not specifically address all public comments on batching and bundling received in response to the October 2021 interim final rule.

(c)(4)(i) of these sections would provide that up to 25 qualified IDR items and services may be batched and considered jointly as part of one payment determination only if all requirements under paragraphs (c)(4)(i)(A) through (D) are met.

A. Line-Item Limit for Batched Items and Services

The Departments propose to limit batched determinations to 25 line items in a single dispute. Without such a limit, the additional batching provisions in these proposed rules could increase the time and level of effort certified IDR entities spend on resolving payment determinations, which, in turn, would hinder their ability to make timely payment determinations. The Departments must ensure that the Federal IDR process operates efficiently, as section 9816(c)(3)(A) of the Code, section 716(c)(3)(A) of ERISA, and section 2799A–1(c)(3)(A) of the PHS Act direct the Departments to "specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of encouraging the efficiency (including minimizing costs) of the IDR process." The Departments, therefore, and in line with the feedback from certified IDR entities discussed in section II.E.2.b of the preamble, propose a 25-line-item limit as a reasonable cap to ensure that large and complicated batches do not extend the timeframe needed for certified IDR entities to make eligibility and payment determinations. Further, a 25-line-item limit is intended to help ensure that certified IDR entities are able to reasonably forecast and cover their costs through the fees they set for batched disputes and to process batched disputes in a more timely manner.

The Departments seek comment on the proposed limit on the number of qualified IDR items and services in a batched determination and whether an alternative line-item limit that is higher or lower than 25 line items would be more appropriate to promote efficiencies and cost savings in the Federal IDR process. The Departments are considering whether a 50-line-item limit is a more reasonable cap to encourage efficiencies for disputing parties, while still allowing certified IDR entities sufficient time to review the eligibility of batched disputes and make

payment determinations within the 30-business-day requirement. The Departments also solicit comment on whether the line-item limit should vary depending on the type of batched dispute. For example, there could be a 25-line-item limit for items and services furnished to a single patient on the same or consecutive dates of service and billed on the same claim, and a 50-line-item limit for items and services furnished to one or more patients under the same service code.

The Departments also seek comment on whether a line-item limit should be imposed and whether and how such a provision could increase efficiency and process disputes in a more timely manner. The Departments also solicit comment on whether the certified IDR entity fee structure for batched determinations should be adjusted given the proposed changes to the batching rules.

B. Batched Items and Services Must be Billed by the Same Provider, Facility, or Provider of Air Ambulance Services

The Departments propose to redesignate 26 CFR 54.9816–8(c)(3)(i)(A), 29 CFR 2590.716–8(c)(3)(i)(A), and 45 CFR 149.510(c)(3)(i)(A) as 26 CFR 54.9816–8(c)(4)(i)(A), 29 CFR 2590.716–8(c)(4)(i)(A), and 45 CFR 149.510(c)(4)(i)(A), respectively. The Departments propose no substantive changes to this provision, which provides that qualified IDR items and services may be considered as part of a single batched determination only where they were billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. The provision also provides that qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same NPI or TIN. This provision reflects the first of four statutory requirements that must be satisfied for a qualified IDR item or service to be considered as part of a batched determination.[166]

C. Batched Items and Services Must be Paid by the Same Plan or Issuer

[166] Section 9816(c)(3)(A) of the Code, section 716(c)(3)(A) of ERISA, and section 2799A–1(c)(3)(A) of the PHS Act.

Under proposed 26 CFR 54.9816–8(c)(4)(i)(B), 29 CFR 2590.716–8(c)(4)(i)(B), and 45 CFR 149.510(c)(4)(i)(B), the Departments propose that qualified IDR items and services may be batched and considered jointly as part of one payment determination if payment for the qualified IDR items and services is made by the same group health plan or health insurance issuer. Because the Departments have received questions about how to batch for claims involving group health plans that are fully-insured versus self-insured, the proposed rules specify that this requirement would be satisfied if the same issuer is required to make payment for the qualified IDR items and services, even if the qualified IDR items and services relate to claims from different group health plans or individual market policies. For self-insured group health plans, this requirement would be satisfied if the same self-insured group health plan is required to make payment for the qualified IDR items and services, including when the plan makes payments through a TPA: the requirement would not be satisfied if multiple self-insured group health plans are required to make payments for the qualified IDR items and services, even if those group health plans make payments through the same third party administrator. While a given TPA may administer multiple self-insured plans, the self-insured group health plan generally is the responsible party for payment or reimbursement of the qualified IDR items and services.

D. Batched Items and Services Must Be Related to the Treatment of a Similar Condition

The Departments propose to add 26 CFR 54.9816–8(c)(4)(i)(C), 29 CFR 2590.716–8(c)(4)(i)(C), and 45 CFR 149.510(c)(4)(i)(C) to permit initiating parties to batch qualified IDR items and services in specific circumstances, so long as the items and services relate to the treatment of a similar condition and the batching of the items and services would encourage efficiency (including minimizing costs) in the Federal IDR process. As the Departments explained earlier in section II.E.2. of this preamble, the Departments are proposing new batching criteria for multiple qualified IDR items and services that relate to the treatment of a similar condition in an effort to ensure the Federal IDR process is efficient and economically feasible for providers, facilities, providers of air ambulance services, plans, and issuers. The Departments

must also ensure that the Federal IDR process operates efficiently, as section 9816(c)(3)(A) of the Code, section 716(c)(3)(A) of ERISA, and section 2799A–1(c)(3)(A) of the PHS Act directs the Departments to "specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of encouraging the efficiency (including minimizing costs) of the IDR process." However, there is a threshold number of items and services in a single batch at which that batch becomes so large that no efficiencies are gained, and an additional burden is imposed on the certified IDR entity, as discussed in section II.E.2.i.A. of this preamble (regarding line-item limits). Therefore, the Departments do not intend for the additional flexibility proposed under these rules to be unlimited or available in circumstances that would not promote efficiency in the Federal IDR process. The Departments propose four circumstances under which qualified IDR items and services would be considered to relate to the treatment of a similar condition such that a certified IDR entity's consideration of the items and services in a single payment determination would promote efficiency in the Federal IDR process.

Under new 26 CFR 54.9816–8(c)(4)(i)(C)(1), 29 CFR 2590.716– 8(c)(4)(i)(C)(1), and 45 CFR 149.510(c)(4)(i)(C)(1), the Departments propose that qualified IDR items and services would be considered to relate to the treatment of a similar condition and encourage efficiency in the Federal IDR process when they were furnished to a single patient during the same patient encounter. For purposes of these proposed regulations, the Departments propose to define a single patient encounter as a patient encounter on one or more consecutive days during which the qualified IDR items or services were furnished to the same patient and billed on the same claim form.

The Departments understand from engagement with providers, medical coding professionals, and certified IDR entities that while there may be some instances where a patient is treated for two or more unrelated or dissimilar conditions during a single patient encounter, in general, items and services furnished during a patient encounter and billed by the same provider,

facility, or provider of air ambulance services on one claim form tend to relate to the treatment of the same or similar condition. The Departments are of the view that the proposed definition of a single patient encounter would promote efficiency by avoiding the requirement that an initiating party file separate disputes to obtain payment determinations for each of the items and services that were part of a single claim and patient encounter.

Allowing qualified IDR items or services to be included in a batched determination when they were furnished to the same patient on one or more consecutive days and billed on the same claim form would simplify and encourage efficiency of the Federal IDR process. For example, evidence of the additional circumstances described in section 9816(c)(5)(C) of the Code, section 716(c)(5)(C) of ERISA, and section 2799A-1(c)(5)(C) of the PHS Act would generally be identical for each qualified IDR item and service furnished during a single patient encounter. This would limit the burden on certified IDR entities considering such additional circumstances and making a payment determination for the batch. In addition, permitting batching of items and services furnished to a single patient during the same patient encounter would help the non-initiating party more readily identify the claims involved since the dispute submitted by the initiating party to the Federal IDR process would relate to a single claim form in the non-initiating party's records, as opposed to having to locate and review multiple claim forms.

The Departments note that the proposed requirement to permit batching by patient encounter would increase procedural efficiency compared to the vacated batching provision for providers of air ambulance services by allowing them to submit a single dispute for a patient's air ambulance transport (provided the other batching requirements are met). This approach is consistent with the *TMA III* order and opinion, which vacated provisions of the *August 2022 Technical Assistance for Certified IDR Entities* that in effect required each air ambulance service code to be submitted as a single dispute, requiring two separate IDR disputes for a single air ambulance transport. Under these proposed rules, mileage and base rates, as well as any other item or service furnished during a single air transport and billed for on the same claim form,

could be batched in a single payment determination. The Departments request comment on this proposal, including any data or other information that supports or contradicts the Departments' understanding underlying this proposal.

At new 26 CFR 54.9816–8(c)(4)(i)(C)(*2*), 29 CFR 2590.716–8(c)(4)(i)(C)(*2*), and 45 CFR 149.510(c)(4)(i)(C)(*2*), the Departments would reestablish the provision that qualified IDR items and services also would be considered to relate to the treatment of a similar condition and encourage efficiency when they were furnished to one or more patients during different patient encounters and were billed under the same service code or a comparable code under a different procedural code system, such as CPT codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or DRG codes with modifiers, if applicable. As discussed in section I.D. of this preamble, in *TMA IV*, the District Court's decision vacated this previously established provision only on the grounds that it violated the notice-and-comment requirement under the Administrative Procedure Act and did not address whether this criterion is a reasonable interpretation of the No Surprises Act.

Qualified IDR items or services billed under the same code or under comparable codes of different coding systems would be considered to generally relate to treatment of a similar condition because they essentially would be the same item or service. For example, CPT code 93000 and HCPCS code G0403 both correspond to a routine electrocardiogram (with 12 leads). The proposal would simplify and encourage the efficiency of the Federal IDR process by retaining a clearly defined methodology for disputing parties and certified IDR entities to determine whether qualified IDR items and services are appropriately batched, which would contribute to the efficiency and consistency of such determinations across certified IDR entities. However, the Departments request comment on whether there are circumstances in which a single provider, facility, or provider of air ambulance services—as a practical matter—would bill for the same qualified IDR item or service using different code sets or whether the proposed flexibility could potentially incentivize billing practices specifically intended to circumvent these

batching rules or other requirements of the Federal IDR process. The Departments request comment on this proposal, including any data or other information that supports or contradicts the Departments' understanding underlying this proposal.

Some interested parties have suggested that the Departments should deem all qualified IDR items and services within the same major CPT Category I codes or "family" to relate to the treatment of similar conditions. These sub-categories include Evaluation and Management, Anesthesia, Surgery, Radiology/Diagnostic Radiology/Diagnostic Ultrasound, Pathology and Laboratory/Proprietary Laboratory Analysis, and Medicine. The Departments seek to balance the breadth of the interpretation of the statutory requirement that batched items and services relate to the treatment of a "similar condition" with the goal of efficiency. The Departments have heard from certified IDR entities that significant variability among items or services in a batched claim often leads to payment determinations that are significantly more time-intensive and burdensome to review than claims for items and services that are significantly similar. Efficiency in making eligibility and payment determinations is affected by several factors including the payer, the provider, the circumstances of each patient's treatment, and the QPA for the items and services under dispute. Grouping larger numbers of items and services together into a single batch can lower costs to the extent that it minimizes effort on the part of the certified IDR entity in evaluating factors related to the dispute or disputing parties, such as eligibility for the Federal IDR process. However, larger batches of services with greater variability can also increase review time and costs of certified IDR entities, because larger batches that include disparate services and patient circumstances associated with different supporting information submitted by disputing parties, require certified IDR entities to analyze more information, often taking longer to review. For example, if the Departments permitted batching across the entirety of the Category I CPT code subcategory for radiology, an individual dispute could contain an X-ray of the eye for detection of a foreign body (CPT code 70030), a bilateral screening mammography (CPT code 77067), and simple intensity modulated radiation treatment (IMRT) delivery (CPT code

77385). These services would have different circumstances for the treatment of the patient and would result in the certified IDR entity evaluating a unique set of factors and supporting documentation for each of these services, thus reducing the ability of the certified IDR entity to make timely payment determinations for such disputes.

The Departments are of the view that the variability of the conditions represented within the CPT Category I sub-categories would reduce, rather than promote greater efficiency of the Federal IDR process and would be less likely to relate to the treatment of a similar condition. Thus, the Departments propose to specify in guidance ranges of CPT codes within sub-categories of CPT Category I codes that may be batched, in order to promote efficiency in the Federal IDR process. Specifically, the Departments propose at 26 CFR 54.9816–8(c)(4)(i)(C)(*3*), 29 CFR 2590.716–8(c)(4)(i)(C)(*3*), and 45 CFR 149.510(c)(4)(i)(C)(*3*) that for anesthesiology, radiology, pathology, and laboratory qualified IDR items and services, items and services would be considered to relate to the treatment of similar conditions when they are furnished to one or more patients and were billed under service codes belonging to the same Category I CPT code ranges, which would be specified in guidance published by the Departments.

The Departments propose to divide Category I CPT codes into ranges based on the Departments' characterization of those codes as being related to the treatment of a similar condition. In Tables 2 through 4, the Departments detail proposed ranges of Category I CPT sub-categories for anesthesiology, radiology, pathology, and laboratory items or services that an initiating party may batch together within a single dispute (provided the other batching requirements are met). Under this proposal, the Departments would permit batching only of codes within these ranges for anesthesiology, radiology, pathology, and laboratory qualified IDR items and services. By allowing for the more narrowly defined Category I CPT code spans for batched determinations indicated in Tables 2 through 4, the Departments could increase the probability that the items or services in a dispute both relate to the treatment of a similar condition and increase the efficiency of the Federal IDR process, since the associated items or

services would share the clinical commonality of pertaining to patients who require diagnostic imaging, radiation oncology, similar laboratory tests, etc.

If these proposed rules are finalized, the Departments would establish descriptions of each sub-category of CPT codes, and update periodically as necessary the allowable ranges of service codes belonging to the same CPT sub-category for purposes of batching under proposed 26 CFR 54.9816–8(c)(4)(i)(C)(*3*), 29 CFR 2590.716–8(c)(4)(i)(C)(*3*), and 45 CFR 149.510(c)(4)(i)(C)(*3*) in guidance. CPT codes are defined in the American Medical Association's (AMA's) "CPT Manual," which is updated and published annually. The AMA releases the CPT manual in the fall of each year to precede their January 1st effective date. The Departments would review the modifications made to the CPT manual once available and determine if the modifications necessitate updates to the Category I CPT code spans for batched determinations based on the Departments' interpretation of the pre-existing descriptive categories with which a new Category I CPT code most closely aligns. For example, if a new CPT manual established a new Category I CPT code for diagnostic radiology (imaging) that would fall outside of CPT code spans 70010 – 71555, the Departments would need to release updated guidance for batched determinations to advise parties of which pre-existing descriptive categories of CPT code spans most closely align with the new code, and, thus, with which it can be batched. In such circumstances, the Category I CPT code spans for batched determinations most recently established by the Departments would stand until the publication of further guidance.

TABLE 2: Proposed Radiology CPT Code Spans for Permissible Batched Determinations-Level I HCPCS Codes (CPT)

Code Span		Description
Level I HCPCS Codes (CPT)		
Diagnostic Radiology (Imaging)		
Diagnostic Radiology (Imaging)	70010 – 71555	Head and Neck, Chest
	72020 – 72295	Spine and Pelvis
	73000 – 73725	Upper Extremities, Lower Extremities

Code Span		Description
	74018 – 74363	Abdomen, Gastrointestinal Tract
	74400 – 74775	Urinary Tract, Gynecological and Obstetrical
	75557 – 75989	Heart, Vascular
	76000 – 76499	Other Procedures
	R0070 – R0076	Transportation, Portable Radiology Equipment
Diagnostic Ultrasound		
Diagnostic Ultrasound	–76506 - 76642	Head and Neck, Chest
	76700 – 76776	Abdomen and Retroperitoneum
	–76800 - 76873	Spinal Canal, Pelvis, Genitalia
	76881 – 76886	Extremities
	76392 – 76965	Ultrasonic Guidance Procedures
	76975 – 76999	Other Procedures
Radiologic Guidance		
Radiologic Guidance	77001 – 77003	Fluoroscopic Guidance
	77011 – 77014	CT Guidance
	77021 – 77022	MRI Guidance
Breast Mammography		
Breast Mammography	77076 – 77067	Mammography
Bone/Joint Studies		
Bone/Joint Studies	–77071 - 77092	Bone/Joint Studies
Radiation Oncology		
Radiation Oncology	77261 – 77370	Clinical Treatment Planning, Medical Radiation Physics
	77371 – 77425	Stereotactic Radiation Treatment Delivery, Other, Radiation Treatment Delivery, Neutron Beam Radiation Delivery
	–77427 - 77499	Radiation Treatment Management
	77520 – 77525	Proton Beam Treatment Delivery
	–77600 - 77620	Hyperthermia, Clinical Intracavitary Hyperthermia
	–77750 - 77799	Clinical Brachytherapy
Nuclear Medicine		
Nuclear Medicine	78012 – 78999	Diagnostic Nuclear Medicine
	79005 – 79999	Therapeutic Nuclear Medicine

TABLE 3: Proposed Pathology and Laboratory CPT Code Spans for Permissible Batched Determinations

Code Span		Description
Level I HCPCS Codes (CPT)		
Pathology and Laboratory Diagnostic Radiology (Imaging)		
	80047 – 80081	Organ or Disease Oriented Panels[a]
	80305 – 80377, 83992, 80143 – 80299	Drug Assay, Therapeutic Drug Assay
	80400 – 80439	Evocative Suppression Testing
	80503 – 80506	Pathology Clinical Consultations, Molecular Pathology
	81105 – 81383	Molecular Pathology Tier I
	81400 – 81408, 81479	Molecular Pathology Tier II
	81410 – 81471, 81490 – 81599	Genomic Sequencing and Other Molecular Multianalyte Assays, Multianalyte Assays with Algorithmic Analysis
	81000 – 81099	Urinalysis[b]
	82009 – 84999	Chemistry[c]
	85002 – 85999	Hematology and Coagulation
	86015 – 86849, –86850 - 86999	Immunology, Transfusion Medicine
	87003 – 87999	Microbiology
	88104 – 88199, –88230 - 88299	Cytopathology and cytogenetic studies
	88000 – 88099	Anatomic Pathology
	88300 – 88399	Surgical Pathology
	88720 – 88749, –89049 - 89240	In Vivo, Other Procedures
	89250 – 89398	Reproductive Medicine Procedures
	0001U – 0284U	Proprietary Laboratory Analysis
	P2028 – P2038, P3000 – P3001, P7001, P9603 – P9604, P9612 – P9615	Laboratory Tests of Blood and Hair, Pap Smears, Urine Bacterial Culture and Sensitivity Studies, Specimen Collection Travel Allowance, Specimen Collection, Catheterization
	P9010 – P9100	Blood and Blood Products

[a]/ The Departments note that organ or disease-oriented panels, urinalysis, and chemistry CPT codes could also be combined. The Departments understand that these are frequently-billed codes, and that such high volume would be a reason to not combine these three code-span ranges together.
[b]/ Id.
[c]/ Id.

TABLE 4: Proposed Anesthesiology CPT Code Spans for Permissible Batched Determinations

Code Span		Description
Level I HCPCS Codes (CPT)		
Anesthesiology		
	00100 – 01999	Anesthesia
	00100 – 00222	Head
	00300 – 00352	Neck
	00400 – 00474	Thorax (Chest Wall and Shoulder Girdle)
	00500 – 00580	Intrathoracic
	00600 – 00670	Spine and Spinal Cord
	00700 – 00797	Upper Abdomen
	00800 – 00882	Lower Abdomen
	00902 – 00952	Perineum
	01112 – 01173	Pelvis (Except Hip)
	01200 – 01274	Upper Leg (Except Knee)
	01320 – 01444	Knee and Popliteal Area
	01462 – 01522	Lower Leg (Below knee, Includes Ankle and Foot)
	01610 – 01680	Shoulder and Axilla
	01710 – 01782	Upper Arm and Elbow
	01810 – 01860	Forearm, Wrist and Hand
	01916 – 01942	Radiological Procedures
	01951 – 01953	Burn Excisions or Debridement
	01958 – 01969	Obstetric
	01990 – 01999	Other Procedures

Another goal of this proposal is to ensure that the batching rules facilitate access to the Federal IDR process considering the relative costs and administrative burden associated with participating. Consistent with feedback from interested parties, this proposal would also allow providers of lower-dollar qualified IDR items and services, such as providers of radiology, pathology, and laboratory items or services, to batch more services than was permitted under the October 2021 interim final rules, because such qualified IDR items and services may not be cost-effective to dispute individually.

As discussed earlier in section II.E.2.c of this preamble, the Departments are proposing new batching provisions to ensure the batching rules do not unreasonably impede the parties' access to the Federal IDR process considering relative costs and administrative burden. The Departments intend these provisions to improve the efficiency of the Federal IDR process while avoiding new operational complexities that could create or exacerbate dispute backlogs. The

proposed rule would provide new flexibility in two ways: first, it would allow initiating parties to batch all items and services related to a single patient encounter; second, it would allow batching of certain items and services within the same Category I CPT code sub-sections. For the purposes of this proposal, the Departments are primarily focusing on provider specialties that have been involved in a majority of disputes under the Federal IDR process, with one exception (emergency medicine, discussed in further detail below). The Departments solicit comment on whether there are other Category I CPT code subsections (for example, Medicine and Surgery) that would satisfy the statutory requirements that batched items and services relate to the treatment of a similar condition and encourage efficiency of the Federal IDR process. Although batching of items and services within the same Category I CPT code subsection is not available for all medical specialties, the Departments are of the view that the proposed batching provisions that would allow batching for a single patient encounter would improve efficiency of the Federal IDR process for medical, surgical, and emergency providers.

As discussed in section II.E.2.b. of this preamble, emergency providers have recommended that the Departments permit batching of the most common evaluation and management CPT codes (99281-99285) for items and services furnished in emergency departments. After considering this feedback, the Departments are concerned that the variability of the conditions that are represented across the emergency medicine evaluation and management CPT codes would increase the likelihood for dissimilar conditions and patient acuities to be batched, which would be inefficient and highly burdensome for certified IDR entities. For instance, if these five different emergency medicine evaluation and management codes could be batched together, the conditions represented in one batched dispute could include such diverse situations as a patient evaluated for an insect bite and one patient treated for a heart attack. The Departments seek comment on whether there are ways to provide additional batching flexibility for emergency department services in a way that mitigates the Departments' concerns that such flexibility would increase the likelihood that claims for treatment of dissimilar

conditions would be batched and promotes the efficiency of the IDR process, for example, data or estimates related to a potential decrease in the number of disputes involving emergency department services that would be realized if emergency department providers were permitted to batch items and services across the five evaluation and management Level I CPT codes, without a commensurate increase in the diversity of documentation that certified IDR entities would need to review to evaluate disputes related to different, but similar conditions.

The Departments seek comment on the proposal to permit anesthesiology, radiology, pathology, and laboratory qualified IDR items and services that were furnished under service codes belonging to the same Category I CPT code section, as specified in guidance published by the Departments, including the proposed Category I CPT code spans for batched determinations, and whether there are any items and services similar to pathology, radiology, and laboratory qualified IDR items and services to which this policy should apply. For example, the Departments seek comment on whether additional batching flexibility, consistent with the statutory requirements, is necessary or appropriate for providers of lower-dollar items or services other than laboratory, pathology, or radiology services, to remove impediments and promote reasonable access to the Federal IDR process. The Departments also request comment on the proposed pathology and laboratory Category I CPT code spans for batched determinations. Specifically, the Departments solicit comment on whether Organ or Disease Oriented Panels, Urinalysis, and Chemistry Category I CPT codes should be combined for batched determinations. The Departments understand that these are frequently billed codes, and that such high volume would be a reason to not combine these three code-span ranges together. The Departments seek comment on this assumption, including any data or other information that supports or contradicts the Departments' understanding, such as if the volume of these codes for out-of-network services would be substantially less.

Further, consistent with feedback from anesthesiologists, this proposal would allow anesthesiologists to batch items and services within a related body-part code group, which would

align with the established framework in the field. Anesthesiologists have expressed to the Departments that while an anesthesia service for one spinal procedure may be related to multiple different medical conditions, the anesthesia administration itself is substantially similar. For example, for spinal procedures, the anesthesia service may be related to different spinal conditions such as stenosis or discectomy. Since the anesthesia administration itself is substantially similar for these different conditions, the Departments are of the view that these conditions could be considered similar and that the payment considerations a certified IDR entity would evaluate are similar.

As discussed in section II.E.2.b. of this preamble, anesthesiologists have requested that claims be batched by the same conversion factor, since contracting practices for anesthesiology items and service focus on conversion factor rates, and not traditional codes like CPT codes. The Departments have not identified a basis upon which such conversion factor rates would satisfy the statutory requirement that batched items and services relate to a similar condition at section 9816(c)(3)(A)(iii) of the Code, section 716(c)(3)(A)(iii) of ERISA, and section 2799A–1(c)(3)(A)(iii) or how conversion factors are a meaningful method of encouraging efficiency. It is the Departments' understanding that because conversion factors would be identical for every out-of-network service furnished by an anesthesiologist provider or provider group, use of the "same conversion factor" for batching would result in the provider or provider group being able to batch every out-of-network service it furnishes that otherwise satisfies the remaining batching factors. Instead, the Departments are of the view that batching based on CPT code categories would lead to greater efficiency, would more closely align with the statutory requirement that batched items and services relate to the treatment of a similar condition, and would lead to less variability among the items and services and factual circumstances that certified IDR entities must consider.

The Departments request comment on the proposal that would govern whether anesthesiology qualified IDR items and services are considered to relate to the treatment of

similar conditions. Specifically, the Departments solicit comment on whether and how items and services that share the same anesthesia conversion factor could be considered to relate to the treatment of similar conditions and could meaningfully encourage efficiency in the Federal IDR process. The Departments request comment on these proposals, including any data or other information that supports or contradicts the Departments' understanding underlying this proposal.

E. Batched Items and Services Must Have Been Furnished Within the Same Time Period

Finally, the Departments propose at 26 CFR 54.9816–8(c)(4)(i)(D), 29 CFR 2590.716–8(c)(4)(i)(D), and 45 CFR 149.510(c)(4)(i)(D) that batched qualified IDR items and services must have been furnished within the same 30-business-day period following the date on which the first item or service included in the batched determination was furnished and have been the subjects of a 30-business-day open negotiation period that ended within 4 business days of IDR initiation, except as provided in proposed 26 CFR 54.9816–8(c)(5)(vii)(B), 29 CFR 2590.716–8(c)(5)(vii)(B), and 45 CFR 149.510(c)(5)(vii)(B), which refer to the 90-calendar-day "cooling off" period. This is consistent with section 9816(c)(3)(B) of the Code, section 716(c)(3)(B) of ERISA, and section 2799A–1(c)(3)(B) of the PHS Act and is in effect the same as the current regulations at 26 CFR 54.9816-8T(c)(3)(i)(D), 29 CFR 2590.716-8(c)(3)(i)(D), and 45 CFR 149.510(c)(3)(i)(D). The Departments are also proposing a non-substantive amendment at 26 CFR 54.9816–8(c)(4)(i)(D), 29 CFR 2590.716–8(c)(4)(i)(D), and 45 CFR 149.510(c)(4)(i)(D) to both remove the redundant language on the 90-calendar-day "cooling off" period and correct the cross-reference to paragraph 26 CFR 54.9816-8T(c)(5)(vii)(B), 29 CFR 2590.716-8(c)(5)(vii)(B), and 45 CFR 149.510(c)(5)(vii)(B). The Departments do not propose any alternative time periods for batched determinations, as the Departments are of the view that the batching rules proposed in these rules are sufficient to encourage procedural efficiency and minimize administrative costs for the disputing parties.

The Departments solicit comment on the application of the cooling off period after a determination on a dispute consisting of multiple items and services batched by patient encounter or CPT code ranges. For example, if provider X submitted a notice of IDR initiation that included as part of a batched determination a single view x-ray of the abdomen (CPT code 74018) to payer Y and the certified IDR entity made a determination on the dispute, should provider X be allowed to submit another dispute, such as a batched patient encounter dispute, within the 90-day period following such determination that involves a single view x-ray of the abdomen (CPT code 74018) to payer Y? It is the Departments' understanding that under these proposed batching rules, the 90-calendar-day cooling off period could result in operational challenges and barriers both to disputing parties submitting subsequent IDR disputes and certified IDR entities' review. In the example of provider X that submitted a batched dispute with an x-ray of the abdomen (CPT code 74018) to payer Y, and for which a certified IDR entity had made a determination, provider X under the proposed rules would have to ensure to not include an x-ray of the abdomen (CPT code 74018) in any subsequent notices of IDR initiation to payer Y within the 90-calendar-day period following such determination. Where subsequent disputes involve larger numbers of items or services, such as batched disputes based on patient encounters or CPT code ranges, this could result in additional time a party must spend excluding the specific item or service subject to the cooling off period from the batch and could also present additional burdens on certified IDR entities in assessing whether the cooling off period applies to one item or service within a batch and therefore whether the batched dispute is eligible for initiation of the Federal IDR process. In addition, the Departments have heard from some providers that since cooling off periods are allowed to overlap, and with each new written determination issued the current cooling off period is extended before it has ended**,** there are certain high-volume payers with which providers may be required to wait multiple years before the Federal IDR process could be initiated again. Batches for single patient encounters may exacerbate this situation.

Under section 9816(c)(9) of the Code, section 716(c)(9) of ERISA, and section 2799A-1(c)(9) of the PHS Act, the time periods required under the No Surprises Act and 26 CFR 54.9816-8T, 26 CFR 54.9816-8, 29 CFR 2590.716-8, and 45 CFR 149.510 (other than the timing of the payments to prevailing parties) may be modified at the Departments' discretion to ensure that all claims that occur during a 90-day period following a payment determination for which a notification is not permitted to be submitted during such period by reason of the cooling-off-period requirements are eligible for the IDR process. If the proposed batching provisions are finalized, the Departments are considering using this statutory waiver authority under section 9816(c)(9) of the Code, section 716(c)(9) of ERISA, and section 2799A-1(c)(9) of the PHS Act, to shorten the 90-day cooling off time period with respect to qualified IDR items and services for which a certified IDR entity makes a payment determination as part of a batched dispute. This would increase the efficiency of processing subsequently submitted batched disputes and ensure that claims that occur during the cooling off period are eligible for the Federal IDR process. The Departments seek comment on this exception and alternative time periods the Departments should consider for the cooling off period in this circumstance. The Departments are considering shortening the cooling off period for batched disputes to between 1 to 30 business days, if the batching proposals are finalized. As discussed in this section of the preamble, the Departments are of the view that the interaction of the 90-day cooling off period with the proposed batching provisions would reduce inefficiencies for the disputing parties, certified IDR entities, and the Federal IDR process. Further, as discussed in section II.E.2.c. of this preamble, section 9816(c)(3)(A) of the Code, section 716(c)(3)(A) of ERISA, and section 2799A–1(c)(3)(A) of the PHS Act directs the Departments to ensure that the Federal IDR process operates efficiently. Thus, the Departments are of the view that to encourage the efficiency of the Federal IDR process (including minimizing costs), the Departments should exercise their waiver authority to reduce the length of the cooling off period to be as short as 1 business day. Under these proposed rules, disputing parties would not be able to realize the efficiencies of batching by patient

encounter if both parties may have to wait 90 business days before submitting a subsequent dispute. For example, it is the Departments understanding that it is highly likely that provider X could have multiple patient encounter batched disputes that involve payer Y where at least one common item or service would overlap in each of those disputes. The Departments are also aware of concerns that due to throughput issues, when payment determinations are made, and the inability to submit disputes either because they could not be submitted as batched disputes under the vacated batching rules or because the cooling off period applied, the Federal IDR process has not been economically feasible for all providers. The Departments are of the view that markedly reducing the cooling off period, in combination with the other proposed provisions in these rules, would help make the Federal IDR process both more economically feasible and efficient for disputing parties. The Departments have also heard from some payers that they are inundated with multiple open negotiation notices and disputes from certain providers making it difficult to meet the deadlines for each dispute. For this reason, the Departments are considering as much as 30 business days for the duration of the cooling off period for batched disputes as it may help ensure parties are not inundated with disputes and provide parties sufficient time to meet the different time-period requirements of the Federal IDR process. The Departments solicit comment on this proposal, including specific alternative time periods the Departments should consider for the cooling off period. The Departments request any data or other information that supports or contradicts the Departments' understanding.

The Departments request comment on these proposals, including whether there are different or additional ways to encourage procedural efficiency and minimize administrative costs through the batching rules.

ii. Treatment of Bundled Payment Arrangements

The Departments propose at 26 CFR 54.9816–8(c)(4)(ii), 29 CFR 2590.716–8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii) that qualified IDR items and services that meet the definition of a bundled payment arrangement at proposed 26 CFR 54.9816-3, 29 CFR 2590.716-3, and 45 CFR

149.30 may be submitted and considered as a single payment determination for which the certified IDR entity must make one payment determination for the multiple items and services included in the bundled payment arrangement. The Departments further propose that bundled payment arrangements submitted under paragraph (c)(4)(ii) would continue to be subject to the certified IDR entity fee for single determinations as described at 26 CFR 54.9816-8T(e)(2)(vii), 29 CFR 2590.716-8(e)(2)(vii), and 45 CFR 149.510(e)(2)(vii). These proposed technical amendments to 26 CFR 54.9816-8(c)(4)(ii), 29 CFR 2590.716-8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii) would include a reference to the definition of "bundled payment arrangement,"[167] a correction that the certified IDR entity must make one payment determination for the multiple qualified IDR items and services included in the bundled payment arrangement, removal of the language that bundled payment arrangements are subject to the rules for batched determinations, and an updated cross reference to paragraph (c)(4)(ii).

3. Administrative and Certified IDR Entity Fee Collection

The Departments propose to amend the administrative and certified IDR entity fee provisions of 26 CFR 54.9816-8(d), 29 CFR 2590.716-8(d), and 45 CFR 149.510(d) to adjust the timing of collection of the administrative fee and make changes to the administrative fee structure to ensure that the financial costs to the Departments to administer the Federal IDR process align with the assessed administrative fees, to encourage disputing parties to engage in meaningful open negotiations, to accelerate dispute processing, and to reduce the burden on certified IDR entities.

a. Establishment of the Administrative Fee Amount

Under section 9816(c)(8)(A) of the Code, section 716(c)(8)(A) of ERISA, section 2799A-1(c)(8)(A) of the PHS Act, and the October 2021 interim final rules,[168] each party to a determination must pay an administrative fee for participating in the Federal IDR process. Under

[167] As discussed in section II.A. of the preamble, the Departments propose to amend 26 CFR 54.9816–3, 29 CFR 2590.716–3, and 45 CFR 149.30 to define the term "bundled payment arrangement."
[168] 26 CFR 54.9816-8T(d)(2)(i), 29 CFR 2590.716-8(d)(2)(i), and 45 CFR 149.510(d)(2)(i).

section 9816(c)(8)(B) of the Code, section 716(c)(8)(B) of ERISA, section 2799A-1(c)(8)(B) of the PHS Act, and the October 2021 interim final rules,[169] the administrative fee is established annually in a manner so that the total administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Departments to carry out the Federal IDR process for that year.

On September 26, 2023, the Departments issued the IDR Process Fees proposed rules,[170] proposing to amend the language at 26 CFR 54.9816-8(d)(2)(ii), 29 CFR 2590.716-8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii) to establish the Federal IDR process administrative fee amount through notice and comment rulemaking, rather than in guidance.[171] In the IDR Process Fees proposed rules, the Departments proposed the methodology to calculate the administrative fee amount for disputes initiated on or after the later of the effective date of the IDR Process Fees proposed rules or on January 1, 2024, by projecting the amount of expenditures to be made by the Departments in carrying out the Federal IDR process and dividing this by the projected number of administrative fees to be paid by the parties. Using this methodology, the Departments proposed an administrative fee of $150 per party per dispute. Additionally, the Departments proposed that the administrative fee amount specified in rulemaking would remain in effect until a new administrative fee amount is specified in subsequent rulemaking. Furthermore, in the IDR Process Fees proposed rules, the Departments proposed to remove the requirement to set the administrative fee amount annually, allowing the Departments the flexibility to update the administrative fee amount more or less frequently than annually to increase the Departments' ability to respond to changes in expenditures or collections that would require a new

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[169] 26 CFR 54.9816-8T(d)(2)(ii), 29 CFR 2590.716-8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii).
[170] 88 FR 65888 (September 26, 2023).
[171] In *TMA IV*, the District Court issued an opinion and order holding that the process by which the Departments amended the December 2022 fee guidance to increase the administrative fee for the Federal IDR process from $50 to $350 per party for disputes initiated during the calendar year beginning January 1, 2023, was a violation of the Departments' obligation under the Administrative Procedure Act to give affected parties notice of and an opportunity to comment on the administrative fee. In light of the District Court's opinion and order, as well as the Departments' reassessment regarding the practicability of establishing the administrative fee through notice and comment rulemaking, the Departments proposed in the IDR Process Fees proposed rules to establish the amount of the administrative fee through notice and comment rulemaking.

administrative fee amount. The comment deadline on the IDR Process Fees proposed rules is October 26, 2023. The Departments will review all public comments received on the IDR Process Fees proposed rules.

The Departments note that a number of the proposed provisions in these proposed rules would impact the collection of administrative fees, including the time of collection of the administrative fee discussed in section II.E.3.b. of this preamble, the proposed reduced administrative fee for both parties in low-dollar disputes discussed in section II.E.3.e. of this preamble, and the proposed reduced administrative fee for non-initiating parties in ineligible disputes discussed in section II.E.3.f. of this preamble and would therefore impact the methodology that the Departments use to determine the administrative fee. Accordingly, in these proposed rules, the Departments propose to adjust the methodology for calculating the administrative fee amount that was proposed in the IDR Process Fees proposed rules. As discussed in greater detail below, while in the IDR Process Fees proposed rules the Departments proposed to calculate the projected number of administrative fees to be paid using the total volume of disputes to be closed, in these proposed rules, the Departments propose to instead use the total volume of disputes to be initiated, due to the proposal to collect the administrative fee earlier in the Federal IDR process, as discussed further in section II.E.3.b. of this preamble.

In addition, the Departments are proposing other policies in these proposed rules that, if finalized, would impact the Departments' expenditures in carrying out the Federal IDR process, including the proposed departmental eligibility review discussed in section II.E.1.b.ii. of this preamble, the direct collection of the administrative fee by the Departments discussed in section II.E.3.c. of this preamble, and the proposed Federal IDR process registry discussed in section II.F. of this preamble, which would impact the inputs under the methodology used to calculate the administrative fee amount.

The Departments note that, using the base methodology as proposed in the IDR Process Fees proposed rules, and taking into account the additional proposed policies in these rules and

their impact on the inputs under the administrative fee methodology proposed in the IDR Process Fees proposed rules, the administrative fee amount would continue to be $150 per party per dispute.

In light of the proposals in these rules, the Departments project the annual expenditures to carry out the Federal IDR process, if the proposals in these rules are finalized, to be approximately $100.2 million. The proposed expenditures upon which the administrative fee amount in these rules is based include contract costs and Federal resources associated with:

- Maintaining the Federal IDR portal, including the proposed Federal IDR process registry discussed in section II.F. of this preamble, which is intended to make the parties' and certified IDR entities' experiences using the portal more efficient, clear, and streamlined;
- Certifying IDR entities and collecting data from them, which is intended to increase the number of certified IDR entities, improve the speed of eligibility and payment determinations, and assist the Departments in understanding where efficiencies may still be gained in the process;
- Conducting program integrity activities, such as QPA audits and IDR decision audits, which are intended to ensure the program integrity by reducing and preventing errors in the Federal IDR process;
- Investigating relevant complaints, which is intended to ensure compliance with the Federal IDR process requirements;
- Providing outreach to parties and technical assistance to certified IDR entities, which is intended to streamline the experience and further improve the speed and integrity of eligibility and payment determinations;
- Collecting administrative fees directly from disputing parties, which is intended to reduce burden on certified IDR entities, increasing capacity of certified IDR entities to perform other required functions;

- Conducting eligibility determinations when any of the extenuating circumstances described in proposed 26 CFR 54.9816-8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g) require application of the departmental eligibility review to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process; and
- Retaining and making available Federal personnel dedicated to carrying out Federal IDR process activities.

Further, as described above, estimates for these expenditures assume that the Departments would determine that extenuating circumstances exist to invoke the departmental eligibility review, as discussed in sections II.E.1.b.ii. through iv. of this preamble and as proposed in 26 CFR 54.9816-8(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii). The Departments began conducting pre-eligibility reviews in 2023 to allow the certified IDR entities to complete their eligibility determinations more efficiently. As discussed in section II.E.1.b.ii. of this preamble, the departmental eligibility review proposed in these proposed rules contemplates a similar process except that the Departments would make eligibility determinations, rather than eligibility recommendations, to certified IDR entities.

With respect to the Departments' projected number of administrative fees to be paid, in the IDR Process Fees proposed rules, the Departments proposed to base this number on the total volume of disputes that were projected to be *closed*. However, in these proposed rules, the Departments propose to project the number of administrative fees to be paid based on the total volume of disputes projected to be initiated. In the IDR Process Fee proposed rules, the Departments proposed to use the total volume of disputes projected to be closed, rather than the total volume of disputes projected to be initiated, because the total volume of closed disputes would be more indicative of the total volume of disputes for which fees are paid under the Departments' current collections process.[172] In these proposed rules, the Departments propose to instead use the total volume of disputes projected to be initiated because the proposed

[172] 88 FR 65888, 65893.

operational changes in these proposed rules, if finalized, would result in the Departments' collection of administrative fees closer to a dispute's date of initiation, and therefore, the total volume of initiated disputes would be indicative of the total volume of disputes for which fees would be paid.

Additionally, in projecting the administrative fees to be paid, the Departments consider that, if the proposed policies described in sections II.E.3.e. and II.E.3.f. of this preamble are finalized, the initiating and non-initiating parties in ineligible and low-dollar disputes may pay a reduced administrative fee, which would be percentages of the full administrative fee amount. To arrive at the proposed reduced administrative fee percentages, the Departments analyzed historical trends of low-dollar and ineligible disputes and include further discussion of the calculation of these percentages in sections II.E.3.e. and II.E.3.f. of this preamble. As with the full administrative fee amount, the Departments propose at 26 CFR 54.9816-8(d)(2)(iii), 29 CFR 2590.716-8(d)(2)(iii), and 45 CFR 149.510(d)(2)(iii) that the reduced administrative fee amounts would remain in effect until changed by subsequent rulemaking. Accordingly, the total amount of projected administrative fees paid is calculated to reflect that the Departments would not collect a full administrative fee from both parties on a portion of disputes.

To determine the administrative fees to be paid, the Departments project approximately 420,000 disputes will be initiated annually. This projection is based on the most recent 6-month period of continuous Federal IDR process data before Federal IDR process operations were temporarily paused on August 3, 2023.[173] Using this projected volume of disputes, the Departments assume a prospective reduction of approximately 25 percent in the volume of initiated disputes because of the anticipated impact of the proposed batching policies in these proposed rules, if finalized. As previously explained, to calculate the number of administrative fees to be paid from the projected volume of disputes initiated, the Departments consider that

173 The Departments applied the approximate 25 percent reduction described in these rules to the average monthly volume and multiplied this number by 12 to project the annual volume of initiated disputes.

non-initiating and initiating parties may pay a reduced administrative fee in low-dollar and ineligible disputes if the proposed policies described in sections II.E.3.e. and II.E.3.f. of this preamble are finalized. Additionally, the Departments consider the proposals in these rules pertaining to open negotiation, initiation, batching, registration, and the other administrative fee policies, if finalized, in calculating the number of disputes initiated and this administrative fee amount.

Therefore, the Departments estimate that 420,000 initiated disputes, which include low-dollar and ineligible disputes with reduced administrative fees, would translate to an amount approximately equal to 691,000 full administrative fees paid. This estimate reflects that both parties to a dispute pay an administrative fee. Further, based on Federal IDR process data, the Departments estimate that 20 percent of initiated disputes would qualify as low-dollar disputes and 22 percent of initiated disputes would be ineligible. As described in Table 5, the Departments estimate that low-dollar and ineligible disputes will overlap such that some low-dollar disputes are determined to be ineligible. As explained further in sections II.E.3.e and II.E.3.f. of this preamble, non-initiating parties would pay 20 percent of the full administrative fee in ineligible disputes and both initiating and non-initiating parties would pay 50 percent of the full administrative fee in low-dollar disputes.

Using the proposed methodology and inputs discussed above, the administrative fee for disputes initiated on or after January 1, 2025, and continuing until changed by subsequent rulemaking, would be calculated by dividing the projected annual expenditures of approximately $100.2 million to be made by the Departments in carrying out the Federal IDR process by the projected annual number of administrative fees to be paid by the disputing parties of 691,000. This results in a full administrative fee amount of $150 per party per dispute, which is the same amount as the Departments proposed in the IDR Process Fees proposed rules. However, as described in this preamble section, the methodology and inputs for calculating the administrative fee in these proposed rules differ from those in the IDR Process Fees proposed rules. In the IDR

Process Fees proposed rules, the Departments calculated the proposed administrative fee by dividing projected annual expenditures of $70 million by approximately 450,000 full administrative fees paid on 225,000 closed disputes.

As discussed further in sections II.E.3.e. and II.E.3.f. of these rules, the reduced administrative fee for both parties in low-dollar disputes would be 50 percent of the full administrative fee (or $75) per party per dispute, and the reduced administrative fee for non-initiating parties in ineligible disputes would be 20 percent of the full administrative fee (or $30) per party per dispute. These fee estimates, as set forth in Table 5, are based on the best available data, the Departments' projected expenditures as of the publication of these proposed rules, and the assumptions that the administrative fee of $150 per party per dispute in the IDR Process Fees proposed rules is finalized and applicable starting January 1, 2024. These projections may change between the publication of the proposed and final rules based on more recent data available at that time; thus, the Departments propose to finalize an administrative fee amount that follows the methodology proposed here, as finalized, using the updated data, if applicable. In the event one or more of the policies proposed in these rules are not finalized or the departmental eligibility review is not anticipated to be invoked, the Departments would recalculate the proposed administrative fee amount to reflect relevant changes to the proposed policies when finalizing the administrative fee amount.

TABLE 5: Proposed Administrative Fee Amounts for Disputes Initiated On or

After January 1, 2025

Type of Dispute	Proposed Fee Charged per Party per Dispute	
Standard Dispute, Eligible for Federal IDR Process *Initiating party does not attest that the highest offer (or aggregate offers for the dispute, whether the dispute is for one item or service, a bundled arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation for such dispute by either party was less than the amount of the standard administrative fee and the dispute is determined eligible for the Federal IDR process*	Initiating Party	100 percent of the administrative fee; anticipated to be $150
	Non-initiating Party	100 percent of the administrative fee; anticipated to be $150
Standard Dispute, Ineligible for Federal IDR Process *Initiating party does not attest that the highest offer (or aggregate offers for the dispute, whether the dispute is for one item or service, a bundled arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation for such dispute by either party was less than the amount of the standard administrative fee and the dispute is determined ineligible for the Federal IDR process*	Initiating Party	100 percent of the administrative fee; anticipated to be $150
	Non-initiating Party	20 percent of the administrative fee; anticipated to be $30
Low-Dollar Dispute, Eligible for Federal IDR Process *Initiating party attests that the highest offer (or aggregate offers for the dispute, whether the dispute is for one item or service, a bundled arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation for such dispute by either party was less than the amount of the standard administrative fee and the dispute is determined eligible for the Federal IDR process*	Initiating Party	50 percent of the administrative fee; anticipated to be $75
	Non-initiating Party	50 percent of the administrative fee; anticipated to be $75
Low-Dollar Dispute, Ineligible for Federal IDR Process *Initiating party attests that the highest offer (or aggregate offers for the dispute, whether the dispute is for one item or service, a bundled arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation for such dispute by either party was less than the amount of the standard administrative fee and the dispute is determined ineligible for the Federal IDR process*	Initiating Party	50 percent of the administrative fee; anticipated to be $75
	Non-initiating Party	20 percent of the administrative fee; anticipated to be $30

The Departments solicit comments on the methodology for calculating the administrative fee, additional inputs used to calculate the administrative fee and proposed administrative fee

amounts, including the reduced administrative fee amounts, as well as the proposed implementation date of the proposed administrative fee.

b. Time of Collection of Certified IDR Entity Fee and Administrative Fee

i. Time of Collection of Certified IDR Entity Fee

The Departments propose to amend 26 CFR 54.9816-8(d)(1)(i), 29 CFR 2590.716-8(d)(1)(i), and 45 CFR 149.510(d)(1)(i) to reflect that each party to a dispute that either the certified IDR entity or the Departments determine is eligible for the Federal IDR process must pay to the certified IDR entity the predetermined certified IDR entity fee no later than the time the parties submit their offers, as described in proposed 26 CFR 54.9816-8(c)(5)(i), 29 CFR 2590.716-8(c)(5)(i), and 45 CFR 149.510(c)(5)(i).

The Departments also propose to codify in 26 CFR 54.9816-8(d)(1)(iii), 29 CFR 2590.716-8(d)(1)(iii), and 45 CFR 149.510(d)(1)(iii) the current practice established in section 10.2 of the Federal IDR Process Guidance for Certified IDR Entities[174] that the certified IDR entity must retain the certified IDR entity fee described in 26 CFR 54.9816-8(d)(1)(i), 29 CFR 2590.716-8(d)(1)(i), and 45 CFR 149.510(d)(1)(i) paid by the party whose offer was not selected (the non-prevailing party, as defined in proposed 26 CFR 54.9816-8(c)(5)(ii)(A)(2), 29 CFR 2590.716-8(c)(5)(ii)(A)(2), and 45 CFR 149.510(c)(5)(ii)(A)(2)), consistent with the No Surprises Act.[175] The Departments further propose to move the existing requirement in current paragraph 26 CFR 54.9816-8T(d)(1)(ii), 29 CFR 2590.716-8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii), which requires the certified IDR entity to return the fee paid by the prevailing party within 30 business days following the date of the certified IDR entity's payment determination, to 26 CFR 54.9816-8(d)(1)(iii), 29 CFR 2590.716-8(d)(1)(iii), and 45 CFR 149.510(d)(1)(iii). Further, the Departments propose that in the event of a batched dispute in

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[174] Centers for Medicare & Medicaid Services (Mar. 2023). *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities*. *https://www.cms.gov/files/document/federal-idr-guidance-idr-entities-march-2023.pdf*.

[175] Section 9816(c)(5)(F)(i) of the Code, section 716(c)(5)(F)(i) of ERISA, and section 2799A-1(c)(5)(F)(i) of the PHS Act.

which each party prevails in an equal number of determinations, the certified IDR entity fee would be split evenly between the parties. In that case, the certified IDR entity would be required to return half of the fee paid by each party within 30 business days following the date of the certified IDR entity's payment determination.

Additionally, the Departments propose to add 26 CFR 54.9816-8(d)(1)(iv), 29 CFR 2590.716-8(d)(1)(iv), and 45 CFR 149.510(d)(1)(iv) to provide that when the parties reach an agreement on an out-of-network rate for qualified IDR items or services, as described in proposed 26 CFR 54.9816-8(c)(3)(i), 29 CFR 2590.716-8(c)(3)(i), and 45 CFR 149.510(c)(3)(i), or agree to withdraw a dispute under the circumstances set forth at proposed 26 CFR 54.9816-8(c)(3)(ii), 29 CFR 2590.716-8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii), for a dispute that has already been assigned to a certified IDR entity and determined eligible for the Federal IDR process but for which the certified IDR entity has not made a payment determination, the certified IDR entity must return half of each party's certified IDR entity fee within 30 business days of the agreement or withdrawal, unless directed otherwise by both parties. This proposed new paragraph would relocate the similar requirement when parties reach an agreement, currently captured in 26 CFR 54.9816-8T(c)(2)(ii) and (e)(2)(viii), 29 CFR 2590.716-8(c)(2)(ii) and (e)(2)(viii), and 45 CFR 149.510(c)(2)(ii) and (e)(2)(viii), which require the certified IDR entity to return half of each party's certified IDR entity fee within 30 business days of an agreement, and codifies the Departments' interpretation that a withdrawal of a dispute should be treated similarly to a settlement. Similar to when parties settle prior to an eligibility determination and therefore do not need to pay the certified IDR entity fee because the certified IDR entity did not make an eligibility and/or payment determination, when a dispute is withdrawn prior to an eligibility determination, the Departments are of the view that the parties similarly should not be required to pay the fee because the certified IDR entity again did not make an eligibility and/or payment determination. Accordingly, because the certified IDR entity fee is only assessed for disputes that are determined eligible for the Federal IDR process, the

Departments clarify that the certified IDR entity fee would not be assessed for a dispute that is withdrawn or settled before the Departments or the certified IDR entity, as applicable, make a determination on the eligibility of the dispute for the Federal IDR process. However, because the obligation to pay the certified IDR entity fee applies to all eligible disputes, both parties would still be required to pay the certified IDR entity fee if the dispute is withdrawn or settled after the dispute is determined eligible but before the certified IDR entity makes a payment determination.

Finally, the Departments propose to add 26 CFR 54.9816-8(d)(1)(v), 29 CFR 2590.716-8(d)(1)(v), and 45 CFR 149.510(d)(1)(v) to provide that when the parties reach an agreement on an out-of-network rate or agree to withdraw the dispute for which there is a final selection of the certified IDR entity but that has not yet had a final eligibility determination, unless directed otherwise by both parties, the certified IDR entity would be required to return each party's full certified IDR entity fee within 30 business days of the date both parties notify the certified IDR entity that they have agreed on an out-of-network rate or agreed to withdraw the dispute. The purpose of this proposal is to codify the responsibilities of the parties and certified IDR entities when the parties agree to settle or withdraw the dispute, but the dispute has not yet been determined eligible for the Federal IDR process. Similar to the proposal regarding settlements and withdrawals for eligible disputes, because the certified IDR entity fee is only assessed for disputes that are determined eligible for the Federal IDR process, the certified IDR entity fee would not be assessed for a dispute that is withdrawn or settled before the Departments or the certified IDR entity, as applicable, determine the eligibility of the dispute for the Federal IDR process.

The Departments seek comment on these proposals including the treatment of a withdrawal of a dispute similar to a settlement.

ii. Time of Collection of Administrative Fee

The Departments are also proposing multiple changes to the timing of the collection of the administrative fee in proposed 26 CFR 54.9816-8(d)(2)(i)(A), 29 CFR 2590.716-

8(d)(2)(i)(A), and 45 CFR 149.510(d)(2)(i)(A). The Departments propose to require the initiating party to pay the administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity pursuant to proposed 26 CFR 54.9816-8(c)(1)(iii), 29 CFR 2590.716-8(c)(1)(iii), and 45 CFR 149.510(c)(1)(iii). The Departments further propose that the non-initiating party must pay the administrative fee within 2 business days of the date of notice that an eligibility determination for the Federal IDR process has been reached by either the certified IDR entity or the Departments, if the departmental eligibility review applies as proposed in 26 CFR 54.9816-8(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii).

As discussed in section II.E.3.f. of this preamble, the Departments propose that the non-initiating party would pay a reduced administrative fee for disputes that are determined ineligible for the Federal IDR process; therefore, eligibility would need to be determined before the non-initiating party is charged the administrative fee. The Departments are of the view that 2 business days to pay the administrative fee would be an appropriate amount of time from the date of preliminary selection of the certified IDR entity (for initiating parties) and from the date of notice of an eligibility determination (for non-initiating parties), because it balances the need for the parties to have adequate notice of the fee being due and adequate time to pay the fee with the need to continue to move the Federal IDR process forward and provide parties with timelier payment determinations.

Although the Departments considered requiring both parties to pay the administrative fee within the same 2-business-day period, failure of the initiating party to pay the administrative fee would result in dispute dismissal as discussed in section II.E.3.d. of this preamble, and neither party would owe the administrative fee for such a dispute. Additionally, the Departments are of the view that it is appropriate to align the non-initiating party's deadline to pay the administrative fee with the date of the eligibility determination because, as proposed in these rules and described in section II.E.3.f. of this preamble, the non-initiating party's administrative fee amount would be determined based on the eligibility of the dispute.

The Departments are of the view that this timing would better ensure that the financial costs to the Departments to administer the Federal IDR process align with the assessed administrative fees. Specifically, as explained in section II.E.3.f. of this preamble, the Departments are of the view that requiring non-initiating parties to pay a reduced administrative fee if the dispute is ineligible would be appropriate because it would take into account the benefits that non-initiating parties receive from having access to the Federal IDR process. Currently, for administrative efficiency, the Departments' guidance allows certified IDR entities the discretion to delay collection of the administrative fee until a party submits its offer,[176] which is the same time that each party is required to pay the certified IDR entity fee described in 26 CFR 54.9816-8T(d)(1), 29 CFR 2590.716-8(d)(1), and 45 CFR 149.510(d)(1). Amending the timing for administrative fee collection would accelerate dispute processing and ensure that the costs of using the Federal IDR process are being allocated to all parties accessing the process, regardless of whether their disputes are eligible or ineligible.

Furthermore, the Departments propose at 26 CFR 54.9816-8(d)(2)(i)(B), 29 CFR 2590.716-8(d)(2)(i)(B), and 45 CFR 149.510(d)(2)(i)(B) that when the parties reach an agreement on an out-of-network rate for qualified IDR items or services or agree to withdraw the dispute after the dispute is initiated, the administrative fee would not be returned to the parties if preliminary selection of the certified IDR entity has occurred, as described in 26 CFR 54.9816-8(c)(1)(i), 29 CFR 2590.716-8(c)(1)(i), and 45 CFR 149.510(c)(1)(i). This new paragraph would relocate the similar requirement when parties reach an agreement, currently captured in 26 CFR 54.9816-8T(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii), which provides that the administrative fee will not be returned to the parties in the event of an agreement, and extends those requirements in the event of a dispute withdrawal. The Departments are of the view that these proposed policies would help ensure that disputing parties

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[176] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. (Oct. 2022). *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities*. *https://www.cms.gov/files/document/federal-independent-dispute-resolution-guidance-disputing-parties.pdf.*

are appropriately incentivized to settle disputes through open negotiation before initiating the Federal IDR process. The Departments expect that submission of ineligible disputes would decrease because of this financial incentive combined with the proposed changes to open negotiation, discussed in section II.D. of this preamble, requiring the initiating party to attest that the item or service under dispute is a qualified IDR item or service and to identify the basis for the attestation, which would necessitate the initiating party actively evaluating eligibility before initiating the Federal IDR process.

The Departments also propose in this paragraph that the administrative fee would still be required to be paid if the parties have not yet paid it at the time of settlement or withdrawal, unless the dispute is closed for nonpayment of the administrative fee by the initiating party 2 business days after preliminary selection of the certified IDR entity. This proposal aligns with the current regulation at 26 CFR 54.9816-8T(d)(2)(i), 29 CFR 2590.716-8(d)(2)(i), and 45 CFR 149.510(d)(2)(i) providing that the administrative fee is non-refundable, as discussed in the October 2021 interim final rules.[177] As stated in the October 2021 interim final rules, the Departments will have incurred expenditures to administer the Federal IDR process even in instances in which the parties reach an agreement before the certified IDR entity makes a payment determination. Thus, the Departments are proposing to codify the requirement that parties must pay the administrative fee for these disputes.

Requiring the initiating party to pay the administrative fee within 2 business days of the date the certified IDR entity is preliminarily selected, which would occur before a dispute's eligibility determination is made, would provide an incentive to initiating parties to reduce the number of ineligible disputes submitted and ensure that the financial burden for administering the Federal IDR process is shared across the parties accessing the process. Consequently, the Departments anticipate that fewer ineligible disputes would be submitted, and all disputes in which a certified IDR entity is preliminarily selected would contribute to the funds available to

[177] 86 FR 56001.

administer the Federal IDR process, regardless of eligibility. The Departments are of the view that this would improve overall efficiency in the Federal IDR process and potentially enable the Departments to lower the administrative fee at a future date in notice and comment rulemaking, as the costs of carrying out the Federal IDR process would be more equally allocated across a larger proportion of submitted disputes.

The Departments seek comment on these proposals.

c. Manner of Administrative Fee Collection

The Departments propose to amend 26 CFR 54.9816-8(d)(2)(i), 29 CFR 2590.716-8(d)(2)(i), and 45 CFR 149.510(d)(2)(i) to require each party participating in the Federal IDR process to pay the administrative fee directly to the Departments, instead of to the certified IDR entity for remittance to the Departments, as is currently required. The purpose of this proposal would be to improve dispute processing times and reduce certified IDR entities' administrative burden. To support the transition to this proposed approach of directly collecting the administrative fee and to improve the operation of current processes, the Departments also propose to make conforming amendments to 26 CFR 54.9816-8(e)(2)(vi) and (ix), 29 CFR 2590.716-8(e)(2)(vi) and (ix), and 45 CFR 149.510(e)(2)(vi) and (ix) to reflect that certified IDR entities must maintain appropriate safeguards, controls, and procedures for any administrative fees they may be in possession of before the effective date of the proposed change to the manner of administrative fee collection, if finalized.

The October 2021 interim final rules established that each disputing party's administrative fee was due upon selection of the certified IDR entity and payable to the certified IDR entity.[178] The Departments explained that allowing the certified IDR entity to collect the administrative fee on behalf of the Departments could increase efficiency, streamline the Federal IDR process, and allow for more convenient payment for the disputing parties and the

[178] 86 FR 56001.

Departments.[179] However, there are many disputes in the Federal IDR process for which no fee has been collected for the work associated with processing the dispute, and the Departments are now of the view that collection of the administrative fee by the Departments directly rather than the certified IDR entities would be more efficient. The Departments are also of the view that, in light of the proposal to collect the administrative fee earlier in the process as proposed in these rules, collection of the administrative fee by the Departments would significantly reduce the burden on certified IDR entities because they would not have to collect fees at two different points in time, track collection of both fees, and then remit payment of the administrative fee to the Departments, as would be required if the proposal to change the administrative fee timing was finalized but the manner of collection was unchanged. Additionally, enabling the Departments to directly collect the administrative fee from the disputing parties may improve collection of the fee, in part through Federal debt collection mechanisms as outlined in section II.E.3.d. of this preamble. Finally, since these proposed rules would require parties to submit open negotiation notices, open negotiation notice responses, notices of initiation, and notice of initiation responses through the Federal IDR portal, as discussed in section II.D. of this preamble, the Departments would be in the best position to determine the appropriate time to bill and collect the administrative fee from the parties given the Departments' access to this information.

The Departments seek comment on this proposal. Additionally, the Departments seek comment on restricting the manner of payment of administrative and certified IDR entity fees to only electronic payments, including electronic funds transferred from a bank account, rather than allowing payment by check.

d. Application of Federal IDR Process Requirements in Circumstances Involving a Failure to Pay Certified IDR Entity Fees or Administrative Fees

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[179] *Id*.

To further streamline dispute processing, these proposed rules outline certain consequences that would apply for failure to timely pay the certified IDR entity fee, the administrative fee, or both fees. Specifically, the Departments propose in paragraph 26 CFR 54.9816-8(d)(1)(ii), 29 CFR 2590.716-8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii) that if either party fails to pay the certified IDR entity fee by the time the offer is due, that party's offer would not be considered received. The Departments also propose that if a party fails to submit an offer or a party's offer is not considered received due to nonpayment of the certified IDR entity fee, the non-prevailing party would continue to be responsible for payment of the certified IDR entity fee. This means that a certified IDR entity would be able to take all steps consistent with applicable law to collect any certified IDR entity fee owed to it.

The Departments do not propose to change the requirement that each party to a dispute for which a certified IDR entity is selected must pay a non-refundable administrative fee to participate in the Federal IDR process.[180] Further, the Departments do not propose to change the requirement that the party whose offer is not selected by the certified IDR entity is ultimately responsible for payment of the certified IDR entity fee.[181]

Additionally, the Departments propose to add new proposed paragraph 26 CFR 54.9816-8(d)(2)(i)(C), 29 CFR 2590.716-8(d)(2)(i)(C), and 45 CFR 149.510(d)(2)(i)(C) setting forth that if the initiating party fails to pay the administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity under paragraph (c)(1)(iii), the dispute would be closed due to nonpayment and neither party would be responsible for the administrative fee. If a dispute is closed for nonpayment of the administrative fee by the initiating party, the Departments would not impose an obligation to pay the administrative fee on either party, since the dispute was terminated before substantial work was undertaken to process it. The Departments also propose in new paragraph (d)(2)(i)(C) that if the non-initiating party fails to

[180] *See* 26 CFR 54.9816-8T(d)(2)(i), 29 CFR 2590.716-8(d)(2)(i), and 45 CFR 149.510(d)(2)(i).
[181] *See id*.

pay the administrative fee within 2 business days of an eligibility determination, that party's offer would not be considered received. Even if the non-initiating party fails to submit an offer or the non-initiating party's offer is not considered received due to nonpayment of the administrative fee in accordance with paragraph (d)(2)(i)(A), the non-initiating party would continue to be responsible for payment of the administrative fee. In addition, if the dispute is determined to be ineligible for the Federal IDR process, the non-initiating party would continue to be responsible for payment of the reduced administrative fees discussed in section II.E.3. of this preamble.

Further, the Departments propose to provide in 26 CFR 54.9816-8(d)(2)(i)(D), 29 CFR 2590.716-8(d)(2)(i)(D), and 45 CFR 149.510(d)(2)(i)(D) that any party that fails to timely pay the administrative fee owed in accordance with paragraph (d)(2)(i)(A) of this section is still obligated to pay the administrative fee otherwise due and owing, and that failure to pay the administrative fee would result in a debt owed to the Federal Government, after netting any amounts owed by the Federal Government in accordance with 45 CFR 156.1215, as applicable.[182] The debt would then be collected pursuant to applicable debt collection authorities, including those that prescribe government-wide standards for administrative collection, compromise, disclosure of debt information to credit reporting agencies, referral of claims to private collection contractors for resolution, and referral to the Department of Justice for litigation.

Additionally, the Departments propose that the party to the dispute that incurs the debt would be determined by the TIN or NPI associated with the plan, issuer, provider, facility, or provider of air ambulance services that is a party to the dispute, which may not be the entity that filed the dispute. This means that when a plan that is a party to a dispute utilizes a TPA or other

[182] HHS intends to propose in notice and comment rulemaking in the near future to amend 45 CFR 156.1215 to provide that administrative fees for utilizing the No Surprises Act Federal IDR process for health insurance issuers that participate in financial programs under the ACA would be subject to netting as part of HHS' integrated monthly payment and collections cycle. The netting proposals at 45 CFR 156.1215 would only apply to those issuers and their affiliates operating under the same TIN that participate in the financial programs under the ACA.

representative, it is the plan that would incur the administrative fee debt, not the TPA or representative. Similarly, if a provider or facility engages a revenue cycle management company or other representative, the provider or facility would be responsible for the administrative fee debt, not the revenue cycle management company or other representative. A TPA, revenue cycle management company, or other representative would still be allowed to manage or initiate the Federal IDR process on behalf of a disputing party, including remitting the administrative fee amount on behalf of the party to the dispute.

The Departments are of the view that codifying the consequences of failure to pay the certified IDR entity fees and administrative fees would increase transparency and reduce the incidence of nonpayment. The Departments seek comment on these proposals.

e. Administrative Fee Structure for Disputing Parties in Low-Dollar Disputes

The Departments are proposing a framework to reduce the administrative fee for parties in low-dollar disputes to promote equitable access across the spectrum of parties seeking to initiate the Federal IDR process, such as providers in rural communities, small practices, specialties that regularly bill for services that have low-dollar costs, and issuers with a smaller pool of claims to absorb the impact of a standard administrative fee assessed for low-dollar disputes.

The Departments propose to add 26 CFR 54.9816-8(d)(2)(iii)(A) through (C), 29 CFR 2590.716-8(d)(2)(iii)(A) through (C), and 45 CFR 149.510(d)(2)(iii)(A) through (C) to establish a framework for reducing the administrative fee in certain situations. The Departments propose in 26 CFR 54.9816-8(d)(2)(iii)(A), 29 CFR 2590.716-8(d)(2)(iii)(A), and 45 CFR 149.510(d)(2)(iii)(A) to charge both parties a reduced administrative fee when the initiating party attests that the highest offer made during open negotiation by either party was less than the predetermined threshold proposed in these rules. The Departments propose that in order for both parties to be charged a reduced administrative fee for a dispute, the highest offer (or aggregate offers for a dispute, whether the dispute is for one item or service, a bundled payment

arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation for such dispute by either party must be less than the amount of the full administrative fee. As such, the Departments propose that the threshold that would apply for disputes initiated on or after January 1, 2025 would equal the amount of the standard administrative fee as proposed in section II.E.3.a. of this preamble, which is proposed to be $150 for disputes initiated on or after January 1, 2025.

Further, the Departments propose in 26 CFR 54.9816-8(d)(2)(iii)(A), 29 CFR 2590.716-8(d)(2)(iii)(A), and 45 CFR 149.510(d)(2)(iii)(A) that the reduced administrative fee amount for these low-dollar disputes would be 50 percent of the administrative fee amount, equating to $75 per party per dispute for disputes initiated on or after January 1, 2025, if the proposed administrative fee amount of $150 per party per dispute is finalized. To determine the amount of the reduced administrative fee, the Departments evaluated various factors pertaining to low-dollar disputes. This discussion appears in section II.E.3.f. of this preamble.

As discussed in section II.E.2. of this preamble, interested parties have expressed concerns that disputes over relatively low-dollar claims, such as radiology claims, are being priced out of the Federal IDR process due to difficulties with batching items and services of sufficient value to make the Federal IDR process feasible. While the Departments anticipate that the new batching provisions proposed in these rules and discussed in section II.E.2. of this preamble would make the Federal IDR process more accessible to many parties, the Departments also want to consider other mechanisms to ensure that the Federal IDR process is financially accessible to a greater number of parties, including parties from rural communities, smaller organizations, and parties disputing services related to specialties that bill for low-dollar services. These parties may have more claims for low-dollar services than other types of parties due to the nature of their practice, which may result in fewer disputes that meet the batching requirements, making batching claims impractical for such parties. Even though the Departments recognize that disputes vary in complexity, resolving a dispute generally costs the Departments the same

amount regardless of whether the dispute involves low-dollar or high-dollar items or services. Accordingly, the Departments are proposing this administrative fee structure to further the goal of financial accessibility while ensuring that the Departments can collect sufficient funds to cover the costs of carrying out the Federal IDR process. If either or both parties to the dispute attest to satisfying the requirements for a reduced administrative fee but the Departments determine that either or both parties did not act in good faith in their submissions or responses, the Departments may decline to charge a reduced administrative fee. The Departments solicit comments on situations in which it would be appropriate for the Departments to decline to charge a party the reduced administrative fee, such as if the initiating party incorrectly attests that no offer submitted during open negotiation exceeded the threshold, and the Departments also solicit comments on additional approaches the Departments should consider to mitigate potential abuse of the proposed reduced administrative fee structure.

Under these proposed rules, a party initiating a dispute in the Federal IDR portal using the notice of IDR initiation form discussed in section II.D.2.a. of this preamble would be required to attest in the Federal IDR portal that the highest offer (including the cumulative total of all line items for batched disputes) made during open negotiation by either party was less than the predetermined threshold, which the Departments propose would equal the amount of the full administrative fee ($150 per party for disputes initiated on or after January 1, 2025, as discussed in section II.E.3.a. of this preamble). If the initiating party attests that the highest offer made during open negotiation by either party was less than the threshold, the administrative fee amount charged to both parties may be the reduced administrative fee for low-dollar disputes of 50 percent of the administrative fee. If the initiating party does not attest that the highest offer (or aggregate offers for a dispute, whether the dispute is for one item or service, a bundled payment arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation by either party was less than the threshold, both parties may be charged the full amount of the proposed administrative fee.

The Departments seek comment on the proposed administrative fee structure for low-dollar disputes, including any guardrails that may be necessary to prevent potential abuse. Specifically, the Departments seek comment on capping the offers of parties to a low-dollar dispute when the reduced administrative fee for low-dollar disputes applies, such that these parties would be prevented from submitting an offer above the low-dollar dispute threshold amount to ensure that parties requesting to pay the reduced administrative fee actually have disputes that are considered to be low-dollar. The Departments also seek comment on whether the offer cap should be set at the same value as the threshold, or whether the offer cap should be higher than the threshold to allow for some increase between offers made during open negotiation and offers made during the Federal IDR process.

f. Administrative Fee Structure for Non-Initiating Parties in Ineligible Disputes

The Departments are proposing a framework to more equitably allocate costs between disputing parties while also incentivizing non-initiating parties to be responsive throughout the Federal IDR process, especially with respect to challenging the eligibility of a dispute. The Departments propose in 26 CFR 54.9816-8(d)(2)(iii)(B), 29 CFR 2590.716-8(d)(2)(iii)(B), and 45 CFR 149.510(d)(2)(iii)(B) to charge a non-initiating party a reduced administrative fee when either the certified IDR entity or the Departments determine the entire dispute is ineligible for the Federal IDR process. The Departments also propose in 26 CFR 54.9816-8(d)(2)(iii)(B), 29 CFR 2590.716-8(d)(2)(iii)(B), and 45 CFR 149.510(d)(2)(iii)(B) that the reduced administrative fee amount for non-initiating parties in ineligible disputes would be 20 percent of the full administrative fee amount (proposed in section II.E.3.a. of this preamble), equating to $30 per non-initiating party per dispute if the administrative fee is finalized as proposed.

For the reasons discussed in section II.D.1. of this preamble, implementing an efficient Federal IDR process requires both parties to be active participants in the process. As described in the "Contested Dispute Eligibility" section of the *Initial Report on the Federal Independent*

Dispute Resolution (IDR) Process, April 15 – September 30, 2022,[183] submission of ineligible and incomplete disputes delays processing of disputes. The Departments are of the view that charging a reduced administrative fee to the non-initiating party for an ineligible dispute would more fairly allocate the costs to the Departments associated with ineligible disputes by assigning the majority of those costs to the party best suited to prevent submission of such disputes—the initiating party. If the Departments determine either or both parties have not acted in good faith in their submissions or responses, the Departments may decline to charge a reduced administrative fee. The Departments solicit comments on situations in which the Departments should decline to charge the non-initiating party a reduced administrative fee for an ineligible dispute, such as if the Departments obtain evidence that the non-initiating party withheld key information during open negotiation or initiation that the dispute was ineligible, and the Departments also solicit comments on additional approaches the Departments should consider to mitigate potential abuse of the proposed reduced administrative fee structure.

Additionally, the No Surprises Act requires the administrative fee to be assessed to each party, but does not require the fee amount assessed to each party to be equal.[184] While the non-initiating party did not actively choose to bring the dispute to the Federal IDR process, it would nonetheless utilize the features of the Federal IDR process proposed in these proposed rules, such as open negotiation and the Federal IDR Registry. However, the Departments are of the view that payment of a reduced administrative fee amount for non-initiating parties is appropriate when disputes are not eligible for the Federal IDR process.

The Departments propose that this reduction would only be applied when the entire dispute is determined ineligible for the Federal IDR process. For example, if a batched dispute were determined to be partially ineligible (that is, some line items were eligible and some were

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[183] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury, *Initial Report on the Federal Independent Dispute Resolution (IDR) Process, April 15 – September 30, 2022*. *https://www.cms.gov/files/document/initial-report-idr-april-15-september-30-2022.pdf.*

[184] *See* section 9816(c)(8)(A) of the Code, section 716(c)(8)(A) of ERISA, and section 2799A-1(c)(8)(A) of the PHS Act.

ineligible), the non-initiating party may still be required to pay the full administrative fee amount, because the eligible line item(s) of the dispute would continue to move through the Federal IDR process.

To develop the proposed administrative fee amounts for low-dollar disputes and ineligible disputes, the Departments considered several factors. Specifically, compared to ineligible disputes, the Departments are of the view that charging a higher reduced administrative fee amount for both parties in low-dollar disputes would be appropriate because low-dollar disputes generally proceed further in the Federal IDR process and result in either a payment determination or a negotiated settlement, and the additional Federal IDR process steps utilized by the parties incur additional expenses. However, non-initiating parties in ineligible disputes utilize fewer Federal IDR process steps because the dispute is closed before reaching a payment determination. In the event a low-dollar dispute is ineligible, the non-initiating party may be assessed the lower of the reduced administrative fee amounts, which would be the ineligible dispute reduced administrative fee amount. The Departments are of the view that this would be an equitable structure for both initiating and non-initiating parties and would help the Departments ensure that the total amount of administrative fees for each year is estimated to be equal to the amount of expenditures estimated to be made by the Departments to carry out the Federal IDR process, in compliance with the requirements of the No Surprises Act.

To determine the projected amounts of the reduced administrative fees, the Departments evaluated various factors based on the data available to the Departments on both ineligible and low-dollar disputes, including:

- Reduction of follow-up required for ineligible disputes;
- Lower utilization of the Federal IDR portal for disputes that are closed as ineligible before a payment determination; and
- The proportion of total disputes that are ineligible or low-dollar.

After evaluating these factors, the Departments balanced the need to collect an administrative fee from all parties to disputes that utilize the Federal IDR portal with the need to equitably allocate burden across the parties, as well as the need to enable greater access to the Federal IDR process, and determined that assessing a reduced administrative fee amount of 50 percent of the full administrative fee for both parties in a low-dollar dispute and 20 percent of the full administrative fee for the non-initiating party in an ineligible dispute would be appropriate.

The Departments seek comment on this proposal, including whether the amount of the reduced administrative fee for non-initiating parties in ineligible disputes should be the same as the amount of the reduced administrative fee for both parties in low-dollar disputes discussed in section II.E.3.e. of this preamble.

4. Payment Determination

a. Submission of Offers Deadline

Sections 9816(c)(5)(B) and 9817(b)(5)(B) of the Code, sections 716(c)(5)(B) and 717(b)(5)(B) of ERISA, and sections 2799A-1(c)(5)(B) and 2799A-2(b)(5)(B) of the PHS Act set forth that not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the plan or issuer and the provider, facility, or provider of air ambulance services must each submit to the certified IDR entity an offer for a payment amount for such qualified IDR item or service. Under the October 2021 interim final rules, the Departments established that the offer must be submitted not later than 10 business days after the selection of the certified IDR entity. The Departments specified that parties to the Federal IDR process must also submit information requested by the certified IDR entity relating to the offer.

To establish that the submission of offer is due from the provider, facility, or provider of air ambulance services and plan or issuer not later than 10 business days after the date of final selection of the certified IDR entity, as discussed in section II.E.1.a.ii. of this preamble, the Departments propose to redesignate 26 CFR 54.9816-8(c)(4), 29 CFR 2590.716-8(c)(4), and 45

CFR 149.510(c)(4) as 26 CFR 54.9816-8(c)(5), 29 CFR 2590.716-8(c)(5), and 45 CFR 149.510(c)(5) and amend redesignated 26 CFR 54.9816-8(c)(5)(i), 29 CFR 2590.716-8(c)(5)(i), and 45 CFR 149.510(c)(5)(i). This proposed amendment would establish that the time period for submission of offers would commence when the Departments notify the parties that the certified IDR entity has attested it has no conflicts of interest, or if the Departments have granted an extension to the eligibility determination timeframe described at proposed 26 CFR 54.9816-8(g)(1)(ii)(A), 29 CFR 2590.716-8(g)(1)(ii)(A), and 45 CFR 149.510(g)(1)(ii)(A) due to extenuating circumstances, when an eligibility determination has been made.

b. Payment Determination and Notification Deadline

Sections 9816(c)(5)(A) and 9817(b)(5)(A) of the Code, sections 716(c)(5)(A) and 717(b)(5)(A) of ERISA, and sections 2799A-1(c)(5)(A) and 2799A-2(b)(5)(B) of the PHS Act set forth that not later than 30 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the certified IDR entity will select one of the submitted offers to be the amount of payment for such item or service and will notify the provider or facility and the plan or issuer of the offer selected. Under the October 2021 interim final rules, the Departments established that the certified IDR entity must select an offer no later than 30 business days after the selection of the certified IDR entity and set forth other requirements for certified IDR entities when rendering payment determinations.

These rules propose to redesignate 26 CFR 54.9816-8(c)(4), 29 CFR 2590.716-8(c)(4), and 45 CFR 149.510(c)(4) as 26 CFR 54.9816-8(c)(5), 29 CFR 2590.716-8(c)(5), and 45 CFR 149.510(c)(5), respectively, and the proposal described in this section reflects that redesignation. With regard to the requirements for payment determination and notification, at redesignated 26 CFR 54.9816-8(c)(5)(ii), 29 CFR 2590.716-8(c)(5)(ii), and 45 CFR 149.510(c)(5)(ii), the Departments propose several amendments to align with other proposed updates to regulatory text, to make technical amendments, and to codify existing subregulatory guidance. The Departments propose to amend the regulatory text at 26 CFR 54.9816-8(c)(5)(ii), 29 CFR

2590.716-8(c)(5)(ii), and 45 CFR 149.510(c)(5)(ii) to reflect that the payment determination and notification deadline would be based on the date of final selection of the certified IDR entity, under proposed paragraph 26 CFR 54.9816-8(c)(1)(iv)(C), 29 CFR 2590.716-8(c)(1)(iv)(C), and 5 CFR 149.510(c)(1)(iv)(C), which is described further in section II.E.1.a.ii. of this preamble. Similar to the proposed amendment to the submission of offers deadline, this proposed amendment would align the sections of regulatory text and specify that these time periods would not commence at the date of preliminary selection of the certified IDR entity (before the certified IDR entity attests it has no conflicts of interest), but rather would be based on the date of final selection of the certified IDR entity. Additionally, if the Departments grant an extension to the eligibility determination timeframe described at proposed 26 CFR 54.9816–8(g)(1)(ii)(A), 29 CFR 2590.716–8(g)(1)(ii)(A), and 45 CFR 149.510(g)(1)(ii)(A) for extenuating circumstances, the submission of offers deadline would be based on the date of eligibility determination. This would create consistency across the timeframes for the Federal IDR process described in these rules and improve implementation of the Federal IDR process.

Further, the Departments propose technical amendments to update the cross references in paragraphs 26 CFR 54.9816-8(c)(5)(ii)(A) and (B), 29 CFR 2590.716-8(c)(5)(ii)(A) and (B), and 45 CFR 149.510(c)(5)(ii)(A) and (B) to reflect the proposed redesignation of paragraph 26 CFR 54.9816-8(c)(5), 29 CFR 2590.716-8(c)(5), and 45 CFR 149.510(c)(5). Within these paragraphs, reference to paragraphs (c)(4)(i) and (c)(4)(iii) would be updated to paragraphs (c)(5)(i) and (c)(5)(iii), respectively, and reference to paragraphs (c)(4)(ii)(A) and (c)(4)(vi) would be updated to paragraphs (c)(5)(ii)(A) and (c)(5)(vi), respectively.

Finally, the Departments propose to codify definitions for the prevailing and non-prevailing parties, which were described in the Calendar Year 2022 Fee Guidance for the Independent Dispute Resolution Process and in the October 2021 interim final rules. The Departments propose to add paragraphs 26 CFR 54.9816–8(c)(5)(ii)(A)(*1*) and (*2*), 29 CFR 2590.716–8(c)(5)(ii)(A)(*1*) and (*2*), and 45 CFR 149.510(c)(5)(ii)(A)(*1*) and (*2*), which would

establish the definitions of prevailing and non-prevailing party in the case of single determinations or batched determinations. The Departments propose that a prevailing party, in the case of single determinations, would be the party whose offer is selected by the certified IDR entity. In the case of batched determinations, the prevailing party would be the party with the most determinations in its favor. The Departments propose that the non-prevailing party, in the case of single determinations, would be the party whose offer is not selected by the certified IDR entity and would be responsible for paying the certified IDR entity fee. In the case of batched determinations, the party with the fewest determinations in its favor is considered the non-prevailing party and would be responsible for paying the certified IDR entity fee. Codifying these definitions, already used by the certified IDR entities, would increase the clarity and consistency of regulatory requirements related to payment determinations and improve the parties' understanding of certified IDR entity determinations.

The Departments solicit comment on the proposals related to payment determination and notification.

5. Extension of Time Periods for Extenuating Circumstances

Under section 9816(c)(9) of the Code, section 716(c)(9) of ERISA, and section 2799A-1(c)(9) of the PHS Act, and as explained in the October 2021 interim final rules and subregulatory guidance issued by the Departments, the time periods required under the No Surprises Act and 26 CFR 54.9816-8T, 29 CFR 2590.716-8, and 45 CFR 149.510 (other than the timing of the payments to prevailing parties) may be modified in the case of extenuating circumstances at the Departments' discretion.

Under current regulations,[185] 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 as due to a natural disaster that prevents certified IDR entities, providers, facilities, providers of air ambulance services, plans, or issuers from complying with

[185] 26 CFR 54.9816-8T(g)(1), 29 CFR 2590.716-8(g)(1), and 45 CFR 149.510(g)(1).

an applicable time period. In addition, the parties must attest that prompt action will be taken to ensure that a payment determination is made as soon as administratively practicable under the circumstances. As the October 2021 interim final rules explain, parties may request an extension by submitting a Request for Extension due to Extenuating Circumstances through the Federal IDR portal, including an explanation about the extenuating circumstances and why the extension is needed.[186] However, requesting an extension does not toll any of the Federal IDR process timeframes unless and until an extension is granted.

Therefore, under this authority, the Departments propose, in accordance with sections 9816(c)(9) of the Code, section 716(c)(9) of ERISA, and section 2799A-1(c)(9) of the PHS Act, to amend and add new provisions to 26 CFR 54.9816-8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g). The Departments are proposing to amend 26 CFR 54.9816–8T(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g) to combine the information in existing paragraphs (g)(1)(i) and (g)(1)(ii) into paragraph (g)(1)(i) and to establish at paragraph (g)(1)(i) that the Departments, or at the request of a certified IDR entity or a party, would determine whether an extension is necessary because the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of the certified IDR entity or one or both parties, or for other good cause. Under these proposed rules, the Departments would provide an extension of the time periods if they identify unforeseen or good cause delays on a case-by-case basis, as opposed to solely relying on one of the parties to submit an extension request. The Departments may detect these issues before either party would and could immediately grant the necessary extension without having to wait for the submission of a formal request. Further, these proposed changes would create greater flexibility for certified IDR entities. For example, a certified IDR entity may receive a high volume of disputes that could lead to the certified IDR entity being unable to resolve payment determinations within the 30-business-day period. With the proposed changes to 26 CFR 54.9816–8(g)(1)(i), 29 CFR 2590.716-8(g)(1)(i), and 45 CFR

[186] 86 FR 56009 through 56010.

149.510(g)(1)(i), the certified IDR entity could submit an extension request for the Departments' consideration. Often, the certified IDR entity may be best positioned to identify issues that warrant such an extension on a case-by-case basis.

The Departments also propose to establish at 26 CFR 54.9816–8(g)(1)(ii), 29 CFR 2590.716-8(g)(1)(ii), and 45 CFR 149.510(g)(1)(ii) a generally applicable extension of time periods when the Departments determine that such extension is necessary due to extenuating circumstances that contribute to systematic delays in processing disputes under the Federal IDR process, such as a high volume of disputes or Federal IDR portal system failures. The Departments would post a public notice about any generally applicable extensions of time periods. For example, this proposed flexibility would be used, in addition to the generally applicable permission to toll timeframes during pending requests for additional information, to provide extensions when the volume of disputes initiated exceeds the certified IDR entities' capacity to complete eligibility determinations within the 5-business-day timeframe proposed in these rules, and to provide extensions when systematic failures within the Federal IDR portal impact the parties' and or certified IDR entities' ability to comply with any of the required timeframes in the Federal IDR process.

Under extenuating circumstances caused by an unforeseen high volume of disputes, the Departments would grant certified IDR entities an extension of the eligibility determination timeframe. The amount of time provided in such an extension would be determined by the Departments based on the volume of disputes and the number of active certified IDR entities at the time the extension is granted. An extension of the eligibility determination deadline, if granted by the Departments, would not alter the length of the subsequent timeframes in the Federal IDR process. Rather, the extended eligibility deadline would be a starting point for the other established IDR deadlines. Accordingly, the submission of an offer would be due 10 business days after the extended eligibility determination timeframe and the payment

determination would be due 30 business days after the extended eligibility determination timeframe, in accordance with the requirements established in statute and regulation.

For example, if while monitoring IDR initiation data, the Departments detect a high volume of disputes initiated during the month of June and anticipate that the volume increase would prevent the certified IDR entities from reaching a payment determination within 30 business days of final selection of the certified IDR entity, as required by regulation, the Departments would post a public notice indicating a 30-business-day extension of the eligibility timeframe for all disputes in which the certified IDR entity was selected on June 1 through July 1. Rather than the 5-business-day eligibility determination deadline, certified IDR entities would have 30 business days to review eligibility on disputes initiated within this time period. In this example, a certified IDR entity was selected for a dispute on June 5 and attested to having no conflict of interest with respect to the dispute on June 6. The Departments would provide notice to the disputing parties that the certified IDR entity was selected on June 7, which would be the date of final selection of the certified IDR entity. The certified IDR entity would timely communicate the eligibility determination for the dispute by June 20, under the extension granted by the Departments. The date of eligibility determination (June 20) would become day 0 for calculating the remaining deadlines in the timeframe for the IDR process. As such, the submission of offer would be due from the disputing parties 10 business days (July 5) after the eligibility determination, and the payment determination would be due from the certified IDR entity 30 business days (August 2) after the eligibility determination.

Under a second scenario, when a systematic failure of the Federal IDR portal impacts parties' or certified IDR entities' ability to comply with one or more of the required Federal IDR process timeframes, the Departments would grant the parties and /or the certified IDR entities an extension to the timeframe(s) which the Departments determine relevant. An extension under these circumstances would not alter the duration of the subsequent timeframes within the Federal IDR process, but, similar to the extension of eligibility determinations, would update the start

dates of the subsequent timeframes. For example, if a systems failure crashed the Federal IDR portal on June 1 and 2, the Departments could grant a general extension across all the Federal IDR process timeframes and apply an additional 2 business days to each relevant deadline on active disputes in the portal. In this example, if a non-initiating party's deadline to submit the notice of IDR initiation response occurred during the portal outage, they would receive a 2-business-day extension beginning the day that the systems failure is rectified. The party's new deadline for submitting the notice of IDR initiation response would be June 6.

Under these proposed changes the Departments would extend the time periods under the Federal IDR process without requiring a case-by-case analysis of individual extension requests. The Departments are of the view that granting certain extensions in this manner would provide protection for parties engaged in the Federal IDR process from the impact of systematic processing delays and ensure that unforeseen circumstances do not unfairly disadvantage a party or hinder its ability to comply with the Federal IDR process timeframes. This would also provide more transparency into the timing it would take for a dispute to be processed.

The Departments seek comment on these proposals.

F. Federal IDR Process Registration of Group Health Plans, Health Insurance Issuers, and Federal Employees Health Benefits Carriers

The proposed addition of 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 would require that plans and issuers subject to the Federal IDR process submit certain information to the Departments through a registry. As explained later in section IV., OPM's regulations at 5 CFR 890.114 would require Federal Employees Health Benefits (FEHB) Program carriers to submit certain information through this registry. Upon submission of this information, each plan, issuer, or FEHB carrier would receive an IDR registration number ("registration number"). This registration number would make it easier for parties initiating disputes to acquire the information needed to ensure those disputes are eligible for the Federal IDR process. The registration number would help parties distinguish between different types of

coverage (such as distinguishing between insurance coverage offered by an issuer, a self-insured group health plan for which an issuer serves as a TPA, or coverage offered by a FEHB carrier). The registry would be searchable, and parties would have access to the relevant registration number through the disclosure described in proposed 26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d), the notice described in proposed 26 CFR 54.9816-8(b)(1)(ii), 29 CFR 2590.716-8(b)(1)(ii), and 45 CFR 149.510(b)(1)(ii), and the response notice in proposed 26 CFR 54.9816-8(b)(1)(iii), 29 CFR 2590.716-8(b)(1)(iii), and 45 CFR 149.510(b)(1)(iii). Specifically, plans, issuers, and FEHB carriers would be required to provide the following information upon registration: (1) the legal business name (if any) of the group health plan, issuer, or FEHB carrier and, if applicable, the legal business name of the group health plan sponsor; (2) whether the plan or coverage is a self- or fully-insured group health plan subject to ERISA, individual health insurance coverage, a plan offered by a FEHB carrier, a self- or fully-insured non-Federal governmental plan, or a self- or fully-insured church plan; (3) the State(s) in which the plan or coverage is subject to a specified State law for any items or services to which the protections against balance billing apply; (4) the State(s) in which the plan or coverage is subject to an All Payer Model Agreement under section 1115A of the Social Security Act for any items or services to which the protections against balance billing apply; (5) for self-insured group health plans not otherwise subject to State law, any State(s) in which the group health plan has properly effectuated an election to opt in to a specified State law, if that State allows a plan not otherwise subject to the State law to opt in; and, for FEHB plans that adopt a specified State law pursuant to their FEHB carrier's contract terms, any State(s) in which they have made such an adoption; (6) contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service; (7) the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier has not been assigned, the 5-digit HIOS identifier, or if no HIOS identifier is available, the plan's or the plan sponsor's

Employer Identification Number (EIN) and the plan's plan number (PN), if a PN is available; or for FEHB carriers, the applicable contract number(s) and plan code(s); (8) any additional information needed to identify the plan or issuer and the applicable Federal and State requirements for determining appropriate out-of-network payment rates for items or services to which the protections against balance billing apply, as specified by the Departments in guidance, or such additional information needed with respect to FEHB carriers as specified by OPM in guidance; and (9) any additional information needed for purposes of administrative fee collection, as specified by the Departments in guidance, or such additional information needed with respect to FEHB carriers as specified by OPM in guidance.

The Departments would gather the registration information in a centralized IDR registry, which the Departments would make available through the Federal IDR portal to parties seeking to initiate an open negotiation or a dispute. The Departments solicit comment on whether to also make the registry available to the public.

Plans and issuers with coverage subject to the Federal IDR process on the effective date of the final rules would be required to register within 30 business days after the effective date of the final rules, if finalized, while plans and issuers that begin offering coverage subject to the Federal IDR process after the effective date of the final rules, if finalized, would be required to complete their initial registration on the date that they begin offering such coverage. In the event that the registry becomes available after the effective date of the final rule, plans and issuers would be required to register 30 business days after the registry becomes available. Registered plans and issuers would be required to update the information associated with their Federal IDR registration number through the Federal IDR portal within 30 business days of any change to the information reported in the registry and to confirm accuracy annually during the fourth quarter of each calendar year. A group health plan's or health insurance issuer's initial registration and subsequent updates to its registration information could be completed and submitted by a third party with authority to act on behalf of the group health plan or health insurance issuer.

However, if a group health plan or health insurance issuer chooses to enter into such an agreement with a third party, the plan or issuer would retain responsibility for compliance with the proposed registration requirements.

The Departments solicit comment on whether plans and issuers with coverage subject to the Federal IDR process on the effective date of the final rules would be able to register by 30 business days after the effective date of the final rules or would need additional time to register. The Departments also solicit comment on the potential impact on providers, facilities, and providers of air ambulance services if plans and issuers are permitted additional time to register.

In addition, the Departments are aware that plans and issuers often engage TPAs or other service providers to manage payment disputes subject to the Federal IDR process on their behalf. Accordingly, to reflect this existing industry practice, the Departments propose that the aforementioned requirements with respect to the registry under proposed 26 CFR 54.9816-9(b)(1)-(3), 29 CFR 2590.716-9(b)(1)-(3), and 45 CFR 149.530(b)(1)-(3) may be performed by a TPA or service provider with authority to act on behalf of the group health plan or health insurance issuer offering group or individual health insurance coverage subject to the Federal IDR process. The Departments propose that if the registration requirements are performed by such TPA or service provider, the group health plan or health insurance issuer offering group or individual health insurance coverage must require that such TPA or service provider clearly delineate each group health plan or health insurance issuer offering group or individual health insurance coverage for which the TPA or service provider has authority to act. Even where a third party performs the registration requirements, these proposed rules would still require that each group health plan or health insurance issuer offering group or individual health insurance coverage subject to the Federal IDR process be assigned a unique registration number. The Departments also propose to make clear that if such third party fails to provide the information in compliance with proposed 26 CFR 54.9816-9(b)(1)-(3), 29 CFR 2590.716-9(b)(1)-(3), and 45 CFR 149.530(b)(1)-(3), the plan or issuer would be in violation of the requirements of this

section. The Departments solicit comments on this approach and whether there are any additional clarifications or flexibilities needed to ensure that the registry includes all relevant information for all parties that engage in the Federal IDR process.

Proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 are intended to address concerns that providers, facilities, and providers of air ambulance services shared with the Departments about initiating both open negotiation and the Federal IDR process. Initiating parties, particularly those that are providers, facilities, and providers of air ambulance services, report that they are often missing or cannot locate key information needed for open negotiation and the Federal IDR process despite the disclosure requirements established in sections 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1). First, the parties report difficulty finding the appropriate contact information to initiate open negotiation and the Federal IDR process. Second, they report difficulty determining whether the out-of-network rate for applicable items or services is governed by State or Federal law, including whether a self-insured plan has opted into a specified State law in States that allow these opt-ins. Third, they assert that it can be difficult to differentiate between multiple group health plans offered by the same plan sponsor, as well as between a fully-insured plan offered by an issuer versus a self-insured group health plan administered by that issuer in its capacity as a TPA. Likewise, issuers and group health plan sponsors expressed concerns to the Departments that providers, facilities, and providers of air ambulance services sometimes initiate open negotiations or the Federal IDR process using incorrect contact information, or even initiate negotiations against the wrong plan or issuer. These communication difficulties present problems related to: (1) initiating open negotiation and the Federal IDR process with the correct party; (2) determining whether the items or services are eligible for the Federal IDR process; and (3) initiating correctly batched and bundled disputes that group together only items and services paid by the same plan or issuer.

Given these concerns, the Departments are proposing to create a single registry of plans and issuers subject to the Federal IDR process to foster better communication between disputing

parties. These changes would benefit all parties by reducing the need for time-consuming and expensive follow-up by disputing parties, certified IDR entities, and the Departments to obtain necessary information.

The Departments recognize that plans and issuers have expressed concern about the burden of additional required disclosures. However, while plans and issuers would incur some additional administrative burden from providing plan and contact information through mandatory registration, the Departments are of the view that this approach also mitigates some administrative burden if the registry reduces the number of incorrectly submitted or incorrectly batched disputes.

The Departments seek to minimize burden and ease compliance for plans and issuers by avoiding the issuance of duplicate registration numbers for the same plan or a single registration number for multiple plans. OPM similarly seeks to resolve concerns as discussed above, minimize burden and ease compliance for FEHB carriers. To that end, the Departments seek comment on the best way to separately identify multiple group health plans offered by the same plan sponsor, or multiple FEHB plans offered by the same FEHB carrier, and whether plans, issuers, or FEHB carriers would need to register multiple points of contact in their submissions to the IDR registry.

To further minimize the reporting burden on plans, issuers, and FEHB carriers, the Departments are considering and solicit comment on whether to require plans, issuers, and FEHB carriers to register only after submitting or receiving their first open negotiation notice or only after receiving a certain number of disputes in a calendar year (for example, five disputes). Many group health plans are party to few, or no surprise billing disputes annually; excepting such parties from the registration requirement may minimize the regulatory burden on group health plans that receive few or no surprise billing disputes in a given year and could keep the registry size manageable. However, if registration is not universal, providers, facilities, and providers of air ambulance services may still experience difficulty accessing all information

needed to initiate open negotiation and engage in the Federal IDR process with the subset of plans and issuers that would not be required to register.

The Departments expect that providers, facilities, and providers of air ambulance services would make decisions about how and whether to initiate batched disputes based on the information submitted to the registry. The Departments, therefore, are considering and solicit comment on appropriate measures to address circumstances in which a provider or facility initiates a batched dispute in good faith based on information submitted by a plan or issuer as part of its registration and this dispute is later determined to be incorrectly batched.

Finally, the Departments seek comment on this registration policy and what approaches should be adopted to ensure its accuracy, as well as whether submission of the offer as described in newly redesignated 26 CFR 54.9816-8(c)(5)(i), 29 CFR 2590.716-8(c)(5)(i), and 45 CFR 149.510(c)(5)(i) should be restricted until completion of the proposed registration.

G. Transparency Regarding In-Network and Out-of-Network Deductibles and Out-of-Pocket Limitation

In addition to the challenges discussed previously, some interested parties have stated that it is difficult to know at the point of care whether a patient's plan or coverage is subject to Federal or State surprise billing protections. In general, section 9816(e) of the Code, section 716(e) of ERISA, and section 2799A-1(e) of the PHS Act, as added by section 107 of division BB of the CAA, require a group health plan or a health insurance issuer offering group or individual health insurance coverage and providing or covering any benefit with respect to items or services to include, in clear writing, on any physical or electronic plan or insurance ID card issued to participants, beneficiaries, or enrollees, any applicable deductibles, any applicable out-of-pocket maximum limitations, and a telephone number and website address for individuals to seek consumer assistance information, such as information related to in-network hospitals and urgent care facilities. The Departments are considering, under the general rulemaking authority granted to the Departments to establish the Federal IDR process under section 9816(c)(2)(A) of

the Code, section 716(c)(2)(A) of ERISA, and section 2799A–1(c)(2)(A) of the PHS Act, whether requiring that each plan or insurance card include information about whether the individual's plan or coverage is subject to Federal or State surprise billing protections would facilitate information sharing with respect to the Federal IDR process. The Departments acknowledge that the ID cards may not be able to clarify the applicability of the Federal IDR process in all contexts, because in some States the Federal protections will apply for some items, services, and providers, while the State protections will apply for others. The Departments seek comment on this potential approach, including whether ID cards should display the plan or coverage type (such as, self-insured or fully-insured ERISA plan, non-Federal governmental plan, church plan, FEHB plan, or individual health insurance coverage), as well as whether a symbol or code could be included on cards that would indicate the applicable regulatory authority of the plan or coverage (that is, State or Federal entity, or both).

H. Applicability

1. Applicability Dates

These proposed rules would modify and add to certain provisions of the July 2021 and October 2021 interim final rules. Those interim final rules generally became applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

The provision proposed in 26 CFR 54.9816-3, 29 CFR 2590.716-3, and 45 CFR 149.30 to add the definition of bundled payment arrangement would apply beginning on the effective date of the final rules. These proposed rules would codify the existing definition set forth in guidance and would not require providers, facilities, providers of air ambulance services, plans, issuers, or certified IDR entities to modify existing processes or their own portals or systems to align with the proposed definition. Therefore, it would be appropriate for this definition to become applicable immediately upon the effective date of the final rules, if finalized.

The provision in proposed new 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100 that plans and issuers communicate information using CARCs and RARCs, as specified

in guidance, would apply beginning on the effective date of the final rules, if finalized. The Departments would issue future guidance on the use of CARCs and RARCs in both electronic transactions and formats outside the purview of the HIPAA transaction standards, including paper remittance advice, to implement this proposed regulatory requirement. Should this proposal be finalized, the Departments recognize that plans and issuers would need time to make systems changes and other modifications to operationalize the use of CARCs and RARCs and are considering an approach under which the final rules would establish the implementation timeframe for the use of CARCs and RARCs following the issuance of guidance. For example, the final rules could specify that the requirement to use a specified CARC or RARC applies beginning on the date that is a certain timeframe, such as 6 months or 1 year, after the issuance of guidance. Alternatively, the final rules could provide that guidance issued by the Departments would establish an interval of not less than, for example, 6 months between when guidance is issued and when plans and issuers must begin using a specified CARC or RARC. This would balance plans' and issuers' interest in certainty in a minimum implementation timeframe while allowing for flexibility where the Departments determine necessary. The Departments seek comments on these potential approaches, including what timeframe would provide plans and issuers sufficient time to comply.

The proposed modifications to the regulations at 26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) addressing information to be shared about the QPA would apply to disclosures required to be provided on or after the effective date of the final rules, if finalized. The Departments note that many of these proposed changes are simply corrections or clarifications that would not substantially affect current plan or issuer operations. While these disclosures would be required to include some new content – namely a statement that a provider, facility, or provider of air ambulance services must notify the Departments when initiating open negotiation, the legal business name of the plan and plan sponsor (if applicable) and issuer, and the registration number assigned under these proposed rules – the Departments do not anticipate

significant operational burden for plans and issuers to modify existing processes to include this information. The proposed regulatory text makes clear that plans and issuers would not be required to include a statement about notifying the Departments to initiate open negotiation until the open negotiation notice can be submitted through the Federal IDR portal. Further, plans and issuers would not be required to include their assigned registration number until the Federal IDR registry becomes available and the plan or issuer is registered.

The proposed modifications to the Federal IDR process that would apply to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the final rules, if finalized, include:

- The requirements for batched qualified IDR items and services in 26 CFR 54.9816-8(a)(2)(i), 29 CFR 2590.716-8(a)(2)(i) and 45 CFR 149.510(a)(2)(i);
- The provisions regarding the open negotiation notice, open negotiation response notice, notice of IDR initiation, and notice of IDR initiation response in 26 CFR 54.9816-8(b), 29 CFR 2590.716-8(b) and 45 CFR 149.510(b);
- The proposed rules governing the selection of a certified IDR entity, the Federal IDR process eligibility review, the authority to continue negotiations or withdraw, and the treatment of batched and bundled qualified IDR items and services in 26 CFR 54.9816-8(b) and (c)(1) through (c)(4), 29 CFR 2590.716-8(b) and (c)(1) through (c)(4), and 45 CFR 149.510(b) and (c)(1) through (c)(4); and
- Modifications made to the deadline for the submission of offers and payment determination and notification in 26 CFR 54.9816-8(c)(5)(i) and (ii), 29 CFR 2590.716-8(c)(5)(i) and (ii), and 45 CFR 149.510(c)(5)(i) and (ii); and
- Modifications made to the suspension of certain subsequent IDR requests and subsequent submission of requests submitted in 26 CFR 54.9816-8(c)(5)(vii)(B) and (C), 29 CFR 2590.716-8(c)(5)(vii)(B) and (C), and 45 CFR 149.510(c)(5)(vii)(B) and (C).

The Departments recognize that each of these proposed changes would require providers, facilities, providers of air ambulance services, plans, issuers, and certified IDR entities to modify existing processes and their own portals or systems to align with the proposed requirements. For example, some certified IDR entities may need to update their own proprietary portals used to facilitate their eligibility and payment determinations to align with the new batching requirements. Further, the Departments would need to design and implement system changes to the Federal IDR portal, such as allowing the disputing parties to submit new and updated notices through the Federal IDR portal and updating the system's collection of newly permissible batched disputes. This proposed applicability date is intended to ensure the Departments, disputing parties, and certified IDR entities have sufficient time to understand the proposed changes to the Federal IDR process and modify current operations.

The proposed modifications to the regulations at 26 CFR 54.9816-8(d), 29 CFR 2590.716-8(d), and 45 CFR 149.510(d) addressing the time and manner of payment and collection of the administrative and certified IDR entity fees, the procedures in the event that either party fails to timely pay the administrative or certified IDR entity fee, and the framework for establishing the administrative and certified IDR entity fee structures would apply to disputes initiated on or after January 1, 2025. Similar to the proposed open negotiation, IDR initiation, and batched determination requirements, the Departments would need sufficient time to modify current operations so that the Departments could charge and collect the administrative fees directly from the parties, which are currently collected by the certified IDR entities and subsequently remitted to the Departments. The Departments would also need to update their payment systems and the Federal IDR portal to implement the proposed consequences when either party fails to pay the certified IDR entity fee or the administrative fee, such as the proposals to close a dispute when the initiating party fails to pay the administrative fee on time and to prohibit the non-initiating party from submitting an offer when the non-initiating party

fails to pay the administrative fee or certified IDR entity fee in accordance with the proposed timeframes.

The proposed changes at 26 CFR 54.9816-8(e)(2)(vi), (viii), and (ix), 29 CFR 2590.716-8(e)(2)(vi), (viii), and (ix), and 45 CFR 149.510(e)(2)(vi), (viii), and (ix) regarding the certified IDR entity's controls to prevent and detect improper financial activities, and procedures to retain the certified IDR entity fee and administrative fee are minor in nature, and therefore these proposed rules would be applicable upon the effective date of the final rules, if finalized.

The proposed changes at 26 CFR 54.9816-8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g) regarding the extension of time periods for extenuating circumstances would be applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the final rules, if finalized.

Until the relevant applicability date for the requirements of 26 CFR 54.9816-8, 29 CFR 2590.716-8, and 45 CFR 149.510, plans, issuers, providers, facilities, providers of air ambulance services, and certified IDR entities are required to continue to comply with the corresponding section of 26 CFR 54.9816-8, 29 CFR 2590.716-8, and 45 CFR 149.510, contained in the CFR as of October 25, 2022. In order to ensure compliance with these proposed requirements, the Departments would generally use existing processes for enforcing the relevant provisions of the Code, ERISA, and PHS Act that apply to group health plans and health insurance issuers, including the provisions added by the No Surprises Act.[187] The Departments intend to monitor for non-compliance with these proposed requirements when applicable, if finalized.

Finally, provisions that would establish the Federal IDR registry, and the associated requirements at proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 145.530 would

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[187] *See* Section 504 of ERISA (providing DOL with authority to determine whether any person has violated or is about to violate any provision of ERISA or any regulation or order thereunder, including with regard to group health plans); section 2723 of the PHS Act and 45 CFR 150.101 *et seq.* (setting forth HHS's enforcement procedures related to the provisions of title XXVII of the PHS Act, including bases for initiating investigations and performing market conduct examinations). For an overview of applicable enforcement mechanisms, *see also* Staman, Jennifer (2020). "Federal Private Health Insurance Market Reforms: Legal Framework and Enforcement," Congressional Research Service, available at *https://crsreports.congress.gov/product/pdf/R/R46637.*

become applicable on the effective date of the final rules, if finalized. Pursuant to the establishment of the registry, the requirements in proposed new 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 145.530 would require that each plan or issuer subject to the Federal IDR process complete its initial registration in the newly established Federal IDR registry by the later of the date that is 30 business days after the registry becomes available or the date the group health plan or health insurance issuer begins offering group or individual health insurance coverage.

The Departments seek comment on whether disputing parties and certified IDR entities would need additional time to implement the proposed modifications after the final rules are published, if finalized.

2. Applicability of Surprise Billing Protections to Ground Ambulance Services

The Departments have received questions about how the surprise billing protections under the No Surprises Act apply to ground ambulance services. In particular, the Departments understand that some plans and issuers have construed a statement in the preamble to the July 2021 interim final rules addressing when a participant, beneficiary, or enrollee is in a condition to receive notice and provide consent to waive surprise billing protections for post-stabilization services[188] to mean that the No Surprises Act surprise billing protections apply to post-stabilization inter-facility ground ambulance transports. The Departments do not interpret the No Surprises Act's surprise billing provisions to apply to emergency or non-emergency ground ambulance services.[189] This includes transport by ground ambulance after a participant, beneficiary, or enrollee has been stabilized and needs to be transferred to another facility for

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[188] The preamble to the July 2021 interim final rules states, "In contrast to situations where a participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation following stabilization, in the event that the individual requires medical transportation to travel, including transportation by either ground or air ambulance vehicle, the individual is not in a condition to receive notice or provide consent. Therefore, the surprise billing protections continue to apply to post-stabilization services provided in connection with the visit for which the individual received emergency services." 86 FR 36872, 36881 (July 13, 2021).

[189] Beginning in 2025, the President's Fiscal Year 2024 budget proposal extends surprise billing protections to ground ambulance services across the commercial market. *See* U.S. Department of Health and Human Services. Fiscal Year 2024 Budget in Brief, (2023), p.99, available at *https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf*.

continued observation or treatment.[190] Instead, Congress enacted section 117 of the No Surprises Act, which requires the Departments to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing. The advisory committee must submit a report that includes recommendations for the disclosure of charges and fees for ground ambulance services and insurance coverage, consumer protections and enforcement authorities of the Departments and States, and the prevention of balance billing to consumers.[191]

III. Severability

It is the Departments' intent that if any provision of these proposed rules, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, these rules shall be construed so as to continue to give maximum effect to these rules as permitted by law, unless the holding shall be one of utter invalidity or unenforceability. In the event a provision is found to be utterly invalid or unenforceable, the provision shall be severable from these proposed rules as finalized, as well as the interim final rules and final rules they amend and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

According to the statute,[192] the Departments must establish a Federal IDR process that plans and issuers and nonparticipating providers and facilities may utilize to resolve certain disputes regarding out-of-network rates under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act, including the time, manner, and amount each party to a

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[190] In contrast, if a plan or issuer provides or covers benefits for air ambulance services (such as inter-facility air ambulance transports), those services are subject the No Surprises Act surprise billing protections. *See* FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55, Q7 (Aug. 19, 2022), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-55.pdf* and *https://www.cms.gov/files/document/faqs-part-55.pdf.*

[191] For more information about the Advisory Committee on Ground Ambulance and Patient Billing, *see https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb*.

[192] Sections 9816(c)(2)(A) and 9817(b)(2)(A) of the Code, sections 716(c)(2)(A) and 717(b)(2)(A) of ERISA, and sections 2799A-1(c)(2)(A) and 2799A-2(b)(2)(A) of the PHS Act.

determination must pay to participate in the Federal IDR process. Further, under section 9816(a)(2)(B)(ii) of the Code, section 716(a)(2)(B)(ii) of ERISA, and section 2799A-1(a)(2)(B)(ii) of the PHS Act, the Departments have authority to establish through rulemaking the information that a plan or issuer must share with a provider or facility when determining the QPA, including the form and manner of such disclosures. Under section 9816(c)(9) of the Code, section 716(c)(9) of ERISA, and section 2799A-1(c)(9) of the PHS Act, the Departments also may, at their discretion, modify any deadline or other timing requirement of the Federal IDR process (except for the timing of payment following a payment determination) in cases of extenuating circumstances, as specified by the Departments, or to ensure that all claims that are subject to the 90-calendar-day cooling-off period submitted to the Federal IDR process are in fact eligible for the Federal IDR process.

For the reasons described in section II. of this preamble, the Departments are of the view that their authority to implement each of these aspects in the proposed regulation is well-supported in law and practice and should be upheld in any legal challenge. The Departments are also of the view that the exercise of their authority reflects sound policy. However, if any portion of these proposed rules is declared invalid, the Departments intend that the various aspects related to the Federal IDR process be severable. For example, if a court were to find unlawful (1) the requirement to use CARC and RARCs, (2) the standards for the open negotiation period, (3) the provision for the treatment of batched determinations, (4) the provision for departmental eligibility review, (5) the administrative fee requirements, or (6) the provision of extensions of timeframes under extenuating circumstances, or some combination thereof, the Departments still would intend the remaining features of the policy to stand. Further, the Departments also intend for parts of certain provisions in these rules to be severable. For example, if a court were to find unlawful (1) the policy of batching qualified IDR items and services furnished to a single patient on the same or consecutive dates of service and billed on the same claim form (single patient encounter), (2) the policy of batching qualified IDR items and services billed under the same

service code or a comparable code under a different procedural coding system, or (3) the policy of batching anesthesiology, radiology, pathology, and laboratory qualified IDR items and services under service codes belonging to the same Category I CPT code section, or some combination thereof, the Departments still would intend the remaining features of the policy to stand.

While the proposed policies in combination in these proposed rules would ameliorate different difficulties in the Federal IDR process and result in a more efficient and transparent process for the disputing parties and certified IDR entities, the Departments intend for each of the proposed policies to function independently and be severable from another. The Departments have added severability clauses to these proposed rules to emphasize the Departments' intent that, to the extent a reviewing court holds that any provision of the final rules is unlawful, the remaining rules should take effect and be given the maximum effect permitted by law. The Departments have also added severability clauses to these proposed rules to emphasize the Departments' intent that the provisions in 26 CFR 54.9816-6A, 54.9816-6, 54.9816-8, and 54.9816-9; 29 CFR 2590.716-6A, 2590.716-6, 2590.716-8, and 2590.716-9; and 45 CFR 149.100, 149.140, 149.510 and 149.530 are intended to be severable from one another.

The proposed severability provisions in these rules, if finalized, would not conflict with the proposed severability provisions in the IDR Process Fees proposed rules, if those provisions are finalized. In the IDR Process Fees proposed rules the Departments proposed severability provisions in new proposed paragraphs 26 CFR 54.9816-8(d)(3)(i) and (ii), 29 CFR 2590.716-8(d)(3)(i) and (ii), and 45 CFR 149.510(d)(3)(i) and (ii). Those proposed paragraphs state that if any of the administrative fee or certified IDR entity fee proposals in the IDR Process Fees proposed rules, as finalized, are held to be unlawful by a court, the remaining rules should take effect and be given the maximum effect permitted by law.

If the severability provisions proposed in the IDR Process Fees proposed rules are finalized and subsequently, the severability provisions proposed in these rules in new proposed

paragraphs 26 CFR 54.9816-8(i)(1) and (2), 29 CFR 2590.716-8(i)(1) and (2), and 45 CFR 149.510(i)(1) and (2) are also finalized, the Departments would remove the severability provisions proposed in the IDR Process Fees proposed rules at 26 CFR 54.9816-8(d)(3)(i) and (ii), 29 CFR 2590.716-8(d)(3)(i) and (ii), and 45 CFR 149.510(d)(3)(i) and (ii).The purpose for this proposed approach would be to simplify the Federal IDR process regulations and have one regulation section for the severability provisions applicable to the entire Federal IDR process, as proposed 26 CFR 54.9816-8(i)(1) and (2), 29 CFR 2590.716-8(i)(1) and (2), and 45 CFR 149.510(i)(1) and (2).

IV. Overview of the Proposed Rules – Office of Personnel Management

OPM proposes to amend existing 5 CFR 890.114(a) to include references to the Departments' regulations.[193] OPM has the responsibility of administering the Federal Employees Health Benefits (FEHB) Program. This responsibility includes maintaining oversight and enforcement authority for FEHB plans, which are Federal governmental plans. In the July and October 2021 interim final rules, OPM adopted the Departments' regulations that implement the sections of the Code, ERISA, and the PHS Act that are referenced in 5 U.S.C. 8902(p). Generally, under 5 U.S.C. 8902(p), each FEHB contract must require a carrier to comply with requirements described in the Code, ERISA, and PHS Act in the same manner as they apply to a group health plan or health insurance issuer.

Subject to OPM regulations and contract provisions, FEHB carriers must comply with the specified provisions of the Departments' regulations. The proposed amendments to 5 CFR 890.114 would allow for continued conformity, oversight, and enforcement. Specifically, through 5 CFR 890.114 and its proposed amendments, FEHB carriers and their plans would be required to comply with all provisions of these proposed rules. Among other things, FEHB

[193] OPM also proposes a technical correction in 5 CFR 890.114 that would add a cross-reference to 26 CFR 54.9817-2, which concerns the independent dispute resolution process for air ambulance services. The addition of this cross-reference is necessary because 5 CFR 890.114 also cites to parallel provisions at 29 CFR 2590.717-2 and 45 CFR 149.520.

carriers would be required to:

- Comply with the proposed rules' new requirements relating to the disclosure of information that FEHB carriers must include along with the initial payment or notice of denial of payment for certain items and services subject to the surprise billing protections in the No Surprises Act;
- Communicate information by using CARCs and RARCs when providing any paper or electronic remittance advice to an entity that does not have a contractual relationship with the FEHB carrier;
- Comply with amended requirements related to the open negotiation period preceding the Federal IDR process, the initiation of the Federal IDR process, the Federal IDR dispute eligibility review, and the payment and collection of administrative fees;
- Comply with amended requirements related to the extension of timeframes due to extenuating circumstances, batched items and services, and bundled payment arrangements; and
- Register in the Federal IDR portal established by the Departments and provide the required data elements as applicable to FEHB carriers.

V. Economic Impact and Paperwork Burden

A. Summary – Departments of Health and Human Services and Labor

These proposed rules would add new 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100 requiring plans and issuers to use CARCs and RARCs, as specified in guidance issued by the Departments, or as required under any applicable, adopted standards and operating rules under 45 CFR part 162, on both electronic and paper remittance advice, to communicate information related to whether a claim for an item or service furnished by an entity that does not have a direct or indirect contractual relationship with the plan or issuer for the furnishing of such item or service under the plan or coverage is subject to the provisions of 26 CFR 54.9816 and 54.9817; 29 CFR 2590.716 and 2590.717; or 45 CFR part 149, subpart B, E, or F. The Departments further propose amendments to existing regulations to specify that plans and issuers

must, in the case of air ambulance services, disclose the QPA and certain information about the QPA when cost sharing is calculated using the QPA. These proposed changes would reflect that the term "recognized amount" is not used with respect to air ambulance services and make technical corrections to address omissions where providers of air ambulances were not listed alongside other providers and facilities in the current regulatory text.

The Departments also propose to revise the regulation addressing information to be shared about the QPA to make clear these disclosures are required when the recognized amount (or for air ambulance services, the amount on which cost sharing is based) is the QPA or the amount billed by the provider, facility, or provider of air ambulance services.

The Departments also propose amendments to the content of the statement required under the regulations regarding the information to be shared about the QPA. Specifically, the Departments propose that the required statement specify that the 30-day period for open negotiation is 30 business days; reference providers of air ambulance services (in addition to providers and facilities); specify that a party wishing to initiate open negotiation must provide the required notice within 30 business days of receiving an initial payment or notice of denial of payment; and include language notifying the provider, facility, or provider of air ambulance services that they must notify the Departments and the plan or issuer to initiate the open negotiation period.[194] The Departments also propose to require plans and issuers to disclose the legal business name of the plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the registration number assigned under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, or 45 CFR 149.530, as applicable, if the plan or issuer is registered with the Federal IDR registry.

These proposed rules also would require the party initiating open negotiations to provide an open negotiation notice and supporting documentation to the other party and the Departments

[194] For a description of the proposal to require parties to notify the Departments when they initiate open negotiation, *see* section II.D.1. of this preamble.

via the Federal IDR portal to initiate the open negotiation period. The Departments also propose to require several new content requirements for the open negotiation notice. Furthermore, these proposed rules would require the party in receipt of the open negotiation notice to provide a response to the open negotiation notice, with specified content, and supporting documentation to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period.

In addition, the Departments propose to amend the notice of IDR initiation content requirements to require the initiating party to submit certain additional information in the notice of IDR initiation. The Departments also propose that the non-initiating party must submit a written response to the notice of IDR initiation to the initiating party and to the Departments within 3 business days after the date of IDR initiation. These proposed rules would require the notice of IDR initiation response to include an attestation that the item or service that is the subject of the dispute is a qualified IDR item or service or an assertion that the item or service is not a qualified IDR item or service, and an explanation and documentation to support the assertion. Furthermore, the Departments propose that the non-initiating party would also be required to indicate in the notice of IDR initiation response whether they agree or object to the initiating party's preferred certified IDR entity and provide a statement designating an alternative preferred certified IDR entity if the non-initiating party objects to the initiating party's preferred certified IDR entity.

These proposed rules would require parties furnishing the open negotiation notice, open negotiation response notice, notice of IDR initiation, and notice of IDR initiation response to provide the notices and supporting documentation to the other party and the Departments on the same day via the Federal IDR portal.

The Departments propose that if the party last in receipt of either the notice of IDR initiation response or the notice of certified IDR entity selection received the notice on the third business day after the date of IDR initiation, the Departments would provide the party 2

additional business days to agree or object to other party's alternative preferred certified IDR entity selection. The Departments propose that if the party agrees with the other party's alternative preferred certified IDR entity and notifies the Departments of such agreement, or if the party fails to notify the Departments of its objection by the fifth business day after the date of IDR initiation, the Departments would select the alternative preferred certified IDR entity as the certified IDR entity for the dispute. The Departments propose that if the party notifies the Departments of its objection to the alternative preferred certified IDR entity by the fifth business day after the date of IDR initiation, the Departments would proceed with random selection of the certified IDR entity.

Furthermore, the Departments propose to specify that the date of preliminary selection of the certified IDR entity would be 3 business days after the date of IDR initiation if the parties jointly selected a certified IDR entity, or 6 business days after the date of IDR initiation if the parties fail to agree and jointly select a certified IDR entity, and the Departments randomly select a certified IDR entity. These proposed rules would establish that if a selected certified IDR entity attests to having a conflict of interest, the Departments would randomly select another certified IDR entity, and the date of final selection of the certified IDR entity would be the date the Departments provide notice to the parties that the new certified IDR entity has attested that it meets the conflict-of-interest requirements.

The Departments propose to establish several requirements regarding eligibility determinations. Specifically, the Departments propose that after the selected certified IDR entity attests that it meets the conflict-of-interest requirements, the selected certified IDR entity must review the information provided in the notice of IDR initiation and notice of IDR initiation response, as well as any additional information requested and received, and make an eligibility determination no later than 5 business days after the date of final selection of the certified IDR entity.

These proposed rules would also establish a departmental eligibility review when the Departments, in their discretion, determine that application of the departmental eligibility review is necessary to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process. When the departmental eligibility review is in effect, the Departments would make eligibility determinations, as opposed to the certified IDR entities. The Departments propose to provide reasonable notice before the Departments invoke the departmental eligibility review and before ceasing to use the departmental eligibility review.

The Departments further propose to establish a process for disputes to be withdrawn from the Federal IDR process. Specifically, the Departments propose that a dispute may be withdrawn from the Federal IDR process if: (1) the initiating party provides notification through the Federal IDR portal to the Secretary and the certified IDR entity (if selected) that both parties agree to withdraw the dispute from the Federal IDR process, with signatures from authorized signatories for both parties; (2) the initiating party provides a standard withdrawal request notice to the Departments, the certified IDR entity (if selected), and the non-initiating party and the non-initiating party notifies the Secretary, certified IDR entity (if selected), and initiating party of its agreement to withdraw the dispute within 5 business days of the initiating party's request (or the non-initiating party fails to respond within 5 business days of the initiating party's request); (3) the certified IDR entity or the Departments cannot determine eligibility because both parties are unresponsive to any requests for additional information to determine eligibility; or (4) the certified IDR entity cannot make a payment determination because both parties have failed to submit an offer as described in section II.E.4. of this preamble.

The Departments also propose to amend the batching policies for the Federal IDR process to increase efficiency and create a workable framework for disputing parties and certified IDR entities. Specifically, the Departments propose to allow qualified IDR items and services to be batched if: (1) the items and services were furnished to a single patient during a patient encounter on one or more consecutive dates of service and billed on the same claim form

(single patient encounter); (2) the items and services were furnished to one or more patients and were billed under the same service code, or a comparable code under a different procedural code system; or (3) anesthesiology, radiology, pathology, and laboratory qualified IDR items and services were furnished under service codes belonging to the same Category I CPT code range, as specified in guidance by the Departments. These proposed rules would also require that no more than 25 qualified IDR items and services may be considered jointly as part of one payment determination for the purposes of batched determinations.

The Departments further propose several changes to the collection of the administrative fee. First, in addition to proposing new administrative fee amounts and a revised methodology for calculating such amounts, the Departments propose that the initiating party must pay the administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity. The Departments also propose that the non-initiating party must pay the administrative fee within 2 business days of notice of an eligibility determination by either the certified IDR entity or the Departments, as applicable. Third, the Departments propose to collect the administrative fee directly from the disputing parties. Fourth, the Departments propose to clarify how the Federal IDR process applies when either party fails to timely pay the fees associated with the Federal IDR process. Finally, the Departments propose to charge the disputing parties a reduced administrative fee for low-dollar disputes and to charge the non-initiating party a reduced administrative fee when either the certified IDR entity or the Departments determine the dispute is not eligible for the Federal IDR process.

The Departments also propose to clarify the extenuating circumstances in which the time periods, other than under current 26 CFR 54.9816-8T(c)(4)(ix), 29 CFR 2590.716-8(c)(4)(ix), and 45 CFR 149.510(c)(4)(ix), may be extended. Specifically, the Departments propose that such extenuating circumstances include circumstances that contribute to systematic delays in processing disputes under the Federal IDR process, such as an unforeseen volume of disputes or Federal IDR portal system failures. The Departments also propose that when the Departments

determine that the parties or certified IDR entities cannot meet applicable timeframes due to systemic delays in processing disputes, the Departments would post a public notice regarding any extension of time periods due to such extenuating circumstances. These proposed rules would also establish that such extenuating circumstances would include, for a specific dispute, when the Departments determine that the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of one or both parties or the certified IDR entity, or for other good cause. Further, the Departments propose that a certified IDR entity may submit a request for an extension due to extenuating circumstances to the Departments through the Federal IDR portal.

Finally, the Departments propose requiring plans and issuers that are subject to the Federal IDR process to register with the Federal IDR portal and submit certain information to the Departments. Under these proposed rules, initial registration would be required to be completed by the later of 30 business days after the effective date of the final rule or if plans and issuers begin offering coverage subject to the Federal IDR process after the effective date of the final rule, they would be required to complete their initial registration on the date the plan or issuer begins offering coverage subject to the Federal IDR process.

The Departments have examined the effects of these proposed rules as required by Executive Order 13563 (76 FR 3821, January 21, 2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993, Regulatory Planning and Review); the Regulatory Flexibility Act (Pub. L. 96–354, enacted September 19, 1980, Pub. L. 96–354); section 1102(b) of the Social Security Act (42 U.S.C. 1302(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4); and Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism).

B. Executive Orders 12866, 13563, and 14094 – Departments of Health and Human Services and Labor

Executive Orders 12866, 13563, and 14094 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 entitled "Modernizing Regulatory Review" amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for rules deemed significant under section 3(f)(1). Based on the Departments' estimates, OMB's OIRA has determined these rules are significant under section 3(f)(1). Therefore, the Departments have prepared an RIA that to the best of their ability presents the costs and benefits of these rules. OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Need for Regulatory Action – Departments of Health and Human Services and Labor

As discussed in section II.B. of this preamble, gaps in communication between plans and issuers and providers, facilities, and providers of air ambulance services have resulted in confusion around issues such as whether an item or service is eligible for resolution in the Federal IDR process; how cost sharing and out-of-network rates must be determined (that is, through an All-Payer Model Agreement, specified State law, or Federal rules); how and with whom to initiate open negotiations; and which eligible items and services can be batched or bundled into one dispute. Additionally, a higher-than-expected number of disputes have been submitted to the Federal IDR process for resolution, with many found to be ineligible,[195] contributing to inefficiencies in resolving disputes in the Federal IDR process.

These proposed rules would require plans and issuers to use CARCs and RARCs, as specified in guidance issued by the Departments, or as required under any applicable, adopted standards and operating rules under 45 CFR part 162, to communicate information related to whether a claim for an item or service furnished by an entity that does not have a direct or indirect contractual relationship with the plan or issuer for the furnishing of the item or service under the plan or coverage is subject to the provisions of 26 CFR 54.9816 and 54.9817; 29 CFR 2590.716 and 2590.717; or 45 CFR part 149, subparts B, E, or F.

The July 2021 interim final rules require plans and issuers to disclose the QPA and certain other information regarding the QPA for an item or service furnished by a provider, facility, or provider of air ambulance services, and specific information regarding the initiation of the Federal IDR process. These requirements were later amended by the August 2022 final rules. As discussed in section II.C. of this preamble, the Departments propose to amend regulations at 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) to specify

[195] In the first full year of Federal IDR process operations, approximately 37 percent of disputes were determined ineligible for the Federal IDR process. *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury. *Federal Independent Dispute Resolution Process – Status Update*. April 27, 2023. *https://www.cms.gov/files/document/federal-idr-processstatus-update-april-2023.pdf*.

that plans and issuers must disclose the QPA and certain information about the QPA not only when the recognized amount (or for air ambulance services, the amount on which cost sharing is based) is the QPA but also when the recognized amount is the amount billed by the provider, facility, or provider of air ambulance services as these items and services would also be eligible for the Federal IDR process (provided all other eligibility criteria are satisfied).

In addition, the Departments propose amendments to the statement required to be provided by plans and issuers regarding the initiation of open negotiation and availability of the Federal IDR process. The Departments also propose amendments to the content of the statement to refer to providers of air ambulance services (as well as providers and facilities), and to specify that the open negotiation period is counted in business days and that a party wishing to initiate open negotiation must provide the required notice within 30 business days of receiving an initial payment or notice of denial of payment. Furthermore, the Departments propose that the statement must also note that the provider, facility, or provider of air ambulance services must notify the Departments, as applicable, to initiate open negotiations. To ensure payment disputes are directed to the correct parties, the Departments propose requiring plans and issuers to disclose the legal business name of the plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the registration number to be assigned under 26 CFR 54.9816-9, 29 CFR 2590.716-9, or 45 CFR 149.530, as applicable, if the plan or issuer is registered with the Federal IDR registry.

As discussed in section II.D.1. of this preamble, interested parties generally report that disputing parties are not negotiating with each other during the required open negotiation period to the extent expected by the Departments. To encourage effective use of the open negotiation period, the Departments propose to require the party initiating open negotiations to use a standardized open negotiation notice form, which includes an enumerated list of information, and to send supporting documentation to the other party and the Departments to initiate the open negotiation period. Furthermore, the party in receipt of the open negotiation notice would be

required to provide a response to the open negotiation notice to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period. The Departments are of the view that this proposal would create more certainty regarding whether and when the initiating party began open negotiations by ensuring that start and end dates are documented in the Federal IDR portal. This proposal also may reduce the number of ineligible disputes initiated by requiring the exchange of eligibility information during open negotiation.

As discussed in section II.D.2. of this preamble, to accelerate dispute processing and reduce the burden on certified IDR entities, the Departments propose to require the initiating party to provide an enumerated list of additional information in the notice of IDR initiation, including the claim number, an attestation that the item or service under dispute is a qualified IDR item or service and the basis on which the party believes it is so, and a statement describing the elements of the claim that serve as the basis for initiating the Federal IDR process. Similarly, the Departments propose to require the non-initiating party to provide a response to the notice of IDR initiation that must also include an enumerated list of information, including an agreement to the preferred certified IDR entity identified in the notice of IDR initiation or an alternate preferred certified IDR entity selection, an attestation that the item or service under dispute is a qualified IDR item or service, and for each item or service that the non-initiating party asserts is not a qualified IDR item or service, an explanation and documentation to support the assertion. The Departments are of the view that these additional elements would assist in determining if the item or service is a qualified IDR item or service that is eligible for the Federal IDR process, allow for a streamlined process to track the initiation of the Federal IDR process, enhance communication among the parties, and facilitate a more efficient Federal IDR process.

As discussed in section II.E.1.a. of this preamble, since the implementation of the Federal IDR process, the Departments have identified potential areas to improve upon and provide additional clarity with respect to the process for selecting a certified IDR entity. In the

Departments' experience implementing this process, when a non-initiating party waits until the third business day after the date of IDR initiation to select an alternative preferred certified IDR entity, the initiating party lacks sufficient time to agree or object to the alternative preferred certified IDR entity. To provide the parties sufficient opportunity to agree or object to the alternative preferred certified IDR entity, the Departments propose to amend the process for selecting a certified IDR entity when the parties fail to jointly agree on a certified IDR entity. Specifically, the Departments propose that if the party last in receipt of either the notice of IDR initiation response or the notice of certified IDR entity selection received the notice on the third business day after the date of IDR initiation and did not agree to the other party's alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Departments would provide the party 2 additional business days to agree or object to other party's preferred certified IDR entity selection.

To provide clarity and to codify the process and timeframes for selecting a certified IDR entity, the certified IDR entity's conflict-of-interest review, and the date the certified IDR entity selection is considered finally selected, the Departments propose to establish a process that includes both preliminary selection of the certified IDR entity and final selection of the certified IDR entity. The Departments are of the view that the conflict-of-interest review by the certified IDR entity should not cut into the time periods for either the disputing parties to submit their offers or for the certified IDR entity to make a payment determination. For this reason, the Departments propose requirements that would provide for a certified IDR entity conflict-of-interest review process that must be conducted before a preliminary selection of the certified IDR entity is considered to be a final selected certified IDR entity. Under these proposed rules, final selection of the certified IDR entity would trigger the timeframes for conducting an eligibility review, accepting offers of an out-of-network payment amount, and making a payment determination.

As discussed in section II.E.1.b. of this preamble, eligibility determinations have proven to be complex, time-consuming, resource-intensive, and often uncompensated activities that impede timely payment determinations. To support eligibility determinations during a period of systemic delay or other extenuating circumstances, the Departments propose to implement a departmental eligibility review. When this departmental eligibility review is in effect, the Departments would make eligibility determinations instead of the certified IDR entities. The Departments are of the view that these changes are necessary to ensure certified IDR entities are able to spend the majority of their time and resources on making payment determinations for eligible IDR items and services, prevent certified IDR entities from temporarily suspending their acceptance of new disputes, ensure participation in the Federal IDR process remains financially sustainable for certified IDR entities, and prevent disparate outcomes.

As discussed in section II.E.1.d.ii. of this preamble, the Departments have identified potential areas to improve upon and provide additional clarity with respect to the process for disputes to be withdrawn from the Federal IDR process. Currently, there is no clear uniform process for parties, the certified IDR entity, or the Departments to withdraw a dispute from the Federal IDR process. To establish a process for withdrawals, the Departments propose four conditions in which a dispute may be withdrawn from the Federal IDR process by the initiating party, the Departments, or the certified IDR entity before a payment determination is made. Specifically, the Departments propose that a dispute may be withdrawn from the Federal IDR process if: (1) the initiating party provides notification through the Federal IDR portal to the Departments and the certified IDR entity (if selected) that both parties agree to withdraw the dispute from the Federal IDR process, with signatures from authorized signatories for both parties; (2) the initiating party provides a standard withdrawal request notice to the Departments, the certified IDR entity (if selected), and the non-initiating party, and the non-initiating party notifies the Secretary, certified IDR entity (if selected), and initiating party of its agreement to withdraw within 5 business days of the initiating party's request (or the non-initiating party fails

to respond within 5 business days of the initiating party's request); (3) the certified IDR entity or the Departments cannot determine eligibility because both parties to the dispute are unresponsive to any requests for additional information to determine eligibility; or (4) the certified IDR entity cannot make a payment determination because both parties to the dispute have failed to submit an offer as described in section II.E.4. of this preamble. The Departments are of the view that these proposals would strike a balance between fairness to the disputing parties and efficiency of the Federal IDR process by generally requiring mutual agreement by the disputing parties to withdraw the dispute and providing that a dispute would be withdrawn in the event the parties are nonresponsive within the required timeframes.

As discussed in section II.E.2. of this preamble, in response to the Departments' experiences with batched determinations and operationalizing the Federal IDR process, as well as consideration of interested parties' feedback, the Departments propose batching policies for the Federal IDR process to increase efficiency and create a workable framework for disputing parties and certified IDR entities. The Departments propose to implement batching provisions that would allow parties the flexibility to batch qualified IDR items and services (or "line items") that relate to the treatment of similar conditions, with necessary limitations to encourage efficiency. Specifically, the policy would allow all qualified IDR items and services within the following groupings to be batched together: (1) the items and services were furnished to a single patient during a patient encounter on one or more consecutive dates of service and billed on the same claim form (single patient encounter); (2) the items and services were furnished to one or more patients and billed under the same service code, or a comparable code under a different procedural code system; or (3) anesthesiology, radiology, pathology, and laboratory qualified IDR items and services were furnished under service codes belonging to the same Category I CPT code range, as specified in guidance by the Departments. The Departments are of the view that this approach would appropriately balance several objectives of the Federal IDR process, including: encouraging efficiency (including minimizing costs) within the Federal IDR process

without unreasonably impeding payers' or providers' access to the Federal IDR process and considering relative costs and administrative burden; providing a framework to expedite processing of the backlog of Federal IDR disputes by simplifying the Federal IDR process while avoiding creating new operational complexities; and ensuring that items and services included in batched determinations have a clear organizing principle that makes for logical and consistent payment determinations across certified IDR entities in order to reduce the chance of disparate outcomes. The Departments also propose to codify the definition of a bundled payment arrangement, as currently set forth in guidance, at proposed 26 CFR 54.9816-3, 29 CFR 2590.716-3, and 45 CFR 149.30.

As discussed in section II.E.3. of this preamble, to implement a fair and efficient Federal IDR process, the Departments propose to amend the certified IDR entity and administrative fee provisions of the Federal IDR process to align financial incentives for disputing parties with the efforts associated with administering the Federal IDR process. The Departments propose to amend the provisions related to the time and manner of fee collection, such that an initiating party would be required to pay the non-refundable administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity, and a non-initiating party would be required to pay the non-refundable administrative fee within 2 business days of being notified of an eligibility determination. The Departments also propose to add flexibility to the process by removing the requirement that certified IDR entities, rather than the Departments, must collect the administrative fee, and propose to directly collect the administrative fee from the parties. The Departments further propose to revise how the Federal IDR process applies when either party fails to timely pay the fees associated with the Federal IDR process. The Departments also propose charging the disputing parties a reduced administrative fee for low-dollar disputes and charging a non-initiating party a reduced administrative fee when either the certified IDR entity or the Departments determine the dispute is not eligible for the Federal IDR process. The Departments are of the view that these fee collection changes would ensure that disputing parties

pay an administrative fee to participate in the Federal IDR process even if the dispute is determined to be ineligible, remove the operational burden from certified IDR entities of processing administrative fees and remitting them to the Departments, improve accessibility of the Federal IDR process for certain types of parties, more fairly allocate the costs associated with ineligible disputes, and help reduce the need for future increases to the administrative fee.

As discussed in section II.E.5. of this preamble, the Departments are proposing to codify a generally applicable extension of time periods when the Departments determine that such extension is necessary due to extenuating circumstances that contribute to systematic delays in processing disputes under the Federal IDR process, such as a high volume of disputes or Federal IDR portal system failures. This would allow the Departments to extend the time periods under the Federal IDR process without requiring a case-by-case analysis of individual extension requests. The Departments are of the view that granting certain extensions in this manner would provide protection for parties engaged in the Federal IDR process from the impact of systematic processing delays and ensure that unforeseen circumstances do not unfairly disadvantage a party or hinder its ability to comply with the Federal IDR process timeframes. This would also provide more transparency into the timing it would take for a dispute to be processed.

As discussed in section II.F. of this preamble, the Departments propose requiring plans and issuers subject to the Federal IDR process to register with the Departments and provide general information on the application of the Federal IDR process to items or services covered by the plan or coverage. Providers, facilities, and providers of air ambulance services report that when they initiate open negotiations prior to initiating the Federal IDR process, it is often difficult to identify the plan or issuer with which they are seeking to initiate a dispute, determine the correct contact information for initiating open negotiation or a dispute, and delineate between different group health plans offered by the same plan sponsor. To address these issues, the Departments propose to make available a registry containing this information, which would help providers, facilities, and providers of air ambulance services initiate open negotiations and the

Federal IDR process with all required information by resolving the aforementioned information-sharing issues between parties.

D. Summary of Impacts and Accounting Table – Departments of Health and Human Services and Labor

The expected benefits and costs of these proposed rules are summarized in Table 6 and discussed in this section of the preamble. In accordance with OMB Circular A–4, Table 6 depicts an accounting statement summarizing the Departments' assessment of the benefits and costs associated with this regulatory action. The Departments are unable to quantify all benefits and costs of these proposed rules but have sought, where possible, to describe these non-quantified impacts. The effects in Table 6 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these proposed rules.

TABLE 6: Accounting Table

Accounting Statement				
Benefits:				
Non-Quantified: ● Reduce wasted effort on inappropriately initiated disputes for certified IDR entities as well as both initiating and non-initiating parties by providing information necessary for dispute initiation in a centralized registry, thus minimizing: (1) open negotiations and/or disputes initiated against the wrong party; (2) disputes over items or services that are actually subject to a specified State law or All-Payer Model Agreement; and (3) incorrectly batched disputes. ● Increase efficiency (including minimizing costs) within the Federal IDR process without unreasonably impeding payers' or providers' access to the Federal IDR process considering potential administrative burden by revising the batching policies in order to reduce the chance of disparate outcomes.				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/Year)	$205.01 million	2023	7 percent	2024-2028
	$206.83 million	2023	3 percent	2024-2028
Quantified Costs: ● Costs to issuers and TPAs of approximately $1,549,606 to make annual changes, beginning in 2024, to their information technology (IT) systems to accommodate the use of CARCs and RARCs related to the No Surprises Act in accordance with guidance issued by the Departments or as required under any applicable adopted standards and operating rules under 45 CFR part 162. ● Costs to issuers and TPAs of approximately $505,567 to make a one-time change in 2024 to their IT systems to change the currently required QPA notification to incorporate the proposed information described in the proposed new 26 CFR 54.9816-6T(d)(1)(v), 29 CFR 2590.716-6(d)(1)(v), and 45 CFR 149.140(d)(1)(v). ● Costs to providers, facilities, and providers of air ambulance services of approximately $22,039,500 in 2024 and $44,079,000 annually beginning in 2025 to submit additional information in the open negotiation notice to the Departments and the other party for an estimated 560,000 disputes entering open negotiations annually. ● Costs to issuers and TPAs of approximately $22,039,500 in 2024 and $44,079,000 annually beginning in 2025 to create and submit open negotiation notice responses to the Departments and the other party for an estimated 560,000 disputes entering open negotiations annually. ● Costs to providers, facilities, and providers of air ambulance services of approximately $16,529,625 in 2024 and $33,059,250 annually beginning in 2025 to submit more information through				

notices of IDR initiation to the Departments and the other party for an estimated 420,000 disputes initiated annually.

- Costs to issuers and TPAs of approximately $16,529,623 in 2024 and $33,059,250 annually beginning in 2025 to submit notice of IDR initiation responses to the Departments and the other party for an estimated 420,000 disputes initiated annually.
- Costs to the Departments of approximately $11,000,000 for a one-time system build in the Federal IDR portal in 2024 to operationalize the proposals in these rules related to submission and exchange of open negotiation, initiation, and certified IDR entity selection notices and information between parties, and the departmental eligibility review.
- Increase in costs of $418,621 annually beginning in 2025 for plans, issuers, providers, and facilities to submit the notice of certified IDR entity selection form.
- If the departmental eligibility review is in effect, ongoing operations and maintenance costs of $463,320 annually beginning in 2025.
- If the departmental eligibility review is in effect, costs to the Departments of approximately $17,199,000 in 2024 and $41,277,600 per year beginning in 2025 for regulatory analysis, outreach, quality assurance, administrative activities, and close coordination among multiple parties related to making eligibility determinations.
- Costs to initiating parties of approximately $372,120 in 2024 and $744,240 annually beginning in 2025 associated with submitting notices of withdrawal request.
- Costs to non-initiating parties of approximately $83,076 in 2024 and $166,152 annually beginning in 2025 associated with submitting notices of withdrawal response.
- Costs to the Departments of approximately $3,000,000 for system and operations development related to administrative fee collection in fiscal year (FY) 2024, and ongoing operations and maintenance costs of approximately $2,500,000 in FY 2025, $1,250,000 in FY 2026, $1,000,000 in FY 2027, and $1,000,000 in FY 2028.
- Annual reduction of $9,257 in reporting and administrative fee processing costs for certified IDR entities associated with collection of the administrative fee by the Departments in lieu of the certified IDR entities beginning in 2025.
- Costs to the parties of approximately $36,198,000 annually beginning in 2025 associated with the administrative fee proposals in these proposed rules.
- Costs to certified IDR entities of approximately $99 in 2024 and $198 annually beginning in 2025 associated with submitting requests for extensions.
- Costs to the Departments of approximately $3,000,000 in 2024 and $150,000 annually beginning in 2025 for system and operations development related to the Federal IDR registry.
- One-time costs to issuers and TPAs in 2024 of approximately $1,575,693 to submit information to register for a permanent IDR registration number, and annual costs beginning in 2025 of approximately $94,252 to update this information in a timely manner.
- Costs to interested parties of $3,307,080 to review and interpret these rules in 2024.

Not Quantified:

- The use of CARCs and RARCs, in accordance with guidance issued by the Departments or as required under any applicable adopted standards and operating rules under 45 CFR part 162, would potentially reduce costs to certified IDR entities by reducing the number of ineligible payment disputes submitted to the Federal IDR process, and would also potentially reduce administrative costs incurred by parties related to initiating and responding to ineligible payment disputes.
- If the departmental eligibility review is in effect, the Departments would be making eligibility determinations for disputes that are ineligible for the Federal IDR process, which would incur a higher level of burden than if the departmental eligibility review is not in effect.
- The broader batching rules would increase the costs to the Departments in 2024 to implement the necessary system updates.

Intermediate effects, leading to benefits and costs:

- Provide standardized information, via CARCs and RARCs, to providers, facilities, and providers of air ambulance services to increase their understanding of whether and how the No Surprises Act applies to claims for out-of-network items and services and determine whether disputes are eligible for the Federal IDR process or are subject to a specified State law or an All-Payer Model Agreement that determines the out-of-network payment amount.
- Improve information sharing among the disputing parties and the Departments and create increased certainty regarding when open negotiations and Federal IDR process initiation begin by: (1) requiring a disputing party to provide an open negotiation notice and supporting documentation to the other party and the Departments to initiate the open negotiation period; (2) requiring a response from the party in receipt of the open negotiation notice; and (3) requiring the non-initiating party to furnish a response to the notice of IDR initiation.

- Increase access to the Federal IDR process and increase equity across the parties using the Federal IDR process, regardless of eligibility, by requiring payment of the administrative fee by the initiating party within 2 business days of the date of preliminary selection of the certified IDR entity and by the non-initiating party within 2 business days of notice of an eligibility determination.
- Streamline the process and increase transparency by clarifying how the Federal IDR process applies when either party fails to timely pay the fees associated with the Federal IDR process.
- Improve accessibility to the Federal IDR process for some disputing parties by reducing the administrative fee for low-dollar disputes.
- Provide a framework to expedite processing of the backlog of Federal IDR disputes by simplifying the Federal IDR process, and ensure items and services included in batched determinations have a clear organizing principle that makes for logical and consistent payment determinations across certified IDR entities by revising the batching policies in order to reduce the chance of disparate outcomes.
- Reduction in the number of ineligible disputes by approximately 50 to 75 percent due to the provisions in these proposed rules.

1. Benefits

These rules seek to maximize benefits to providers, facilities, providers of air ambulance services, plans, and issuers and to reduce burdens on certified IDR entities. The Departments invite comment regarding the assumptions made in this section and any additional benefits that would be associated with the proposals in these rules. The Departments also seek comment from individuals from minority and underserved communities, and providers who serve these individuals, to help address the benefits that would be associated with these proposed rules related to these communities specifically.

a. Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes

The proposed new 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100, which would require plans and issuers to use CARCs and RARCs to convey information related to the No Surprises Act as specified in guidance issued by the Departments or as required under any applicable adopted standards and operating rules under 45 CFR part 162, on electronic and paper remittance advice, would help to ensure plans and issuers provide information to providers, facilities, and providers of air ambulance services in a standardized manner and in standardized language so that they may understand whether and how the No Surprises Act applies to claims for out-of-network items and services and determine whether disputes are eligible for the Federal IDR process or subject to a specified State law or All-Payer Model Agreement for purposes of determining the out-of-network rate. Additionally, the use of CARCs

and RARCs would further reduce the potential for the communication issues discussed in section II.B. of this preamble, and would help providers, facilities, and providers of air ambulance services identify items and services that are not subject to the No Surprises Act's balance billing protections and thus identify items and services that are not eligible for the Federal IDR process.

By ensuring that a plan or issuer communicates information related to whether a claim for an item or service furnished by an entity that does not have a direct or indirect contractual relationship with the plan or issuer for the furnishing of the item or service under the plan or coverage is subject to the prohibitions on balance billing in the No Surprises Act, the proposed CARC and RARC requirements would reduce the number of ineligible payment disputes submitted to the Federal IDR process, as further described in section V.D.1.l. of this preamble. The potential reduction in ineligible Federal IDR disputes could result in faster payment determinations, which in turn would result in providers, facilities, and providers of air ambulance services receiving reimbursements sooner.

b. Information to be Shared About the QPA (26 CFR 54.9816-6T, 29 CFR 2590.716-6, and 45 CFR 149.140)

These proposed rules would revise 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d) to specify that plans and issuers must disclose the QPA and certain information about the QPA when cost sharing is calculated using the QPA or the billed amount (including for air ambulance services, for which the term "recognized amount" is inapplicable). These proposed revisions would provide greater clarity regarding when these disclosures must be provided.

Further, the proposed amendments at 26 CFR 54.9816-6, 29 CFR 2590.716-6, and 45 CFR 149.140 would require plans and issuers to disclose the legal business name (if any) of the plan or issuer; the legal business name of the plan sponsor (if applicable); the registration number assigned under 26 CFR 54.9816-9, 29 CFR 2590.716-9, or 45 CFR 149.530, as applicable, if the plan or issuer is registered with the Federal IDR registry. The proposed

amendments would help ensure that payment disputes are directed to the appropriate parties, facilitate more productive open negotiations, and reduce the number of ineligible disputes ultimately submitted to the Federal IDR process (as further described in section V.D.1.l. of this preamble). Additionally, the required disclosure of the legal business name (if any) of the plan or issuer, the legal business name of the plan sponsor (if applicable), and the registration number would help providers, facilities, and providers of air ambulance services look up plans, plan sponsors, and issuers in the Federal IDR registry that would be established under these proposed rules.

c. Open Negotiation

The Departments propose to amend the open negotiation provisions at 26 CFR 54.9816-8(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1) to require the party initiating open negotiations to provide an open negotiation notice and supporting documentation to the other party and the Departments through the Federal IDR portal to initiate the open negotiation period. The Departments also propose to expand the required information on the open negotiation notice to include new elements. Furthermore, the Departments propose that the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice and supporting documentation to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period. Both of these notice provisions require the parties to provide specific information detailed in the proposed regulatory text.

The Departments propose these changes to improve information sharing among the parties and the Departments. The Departments are of the view that this proposal would create more certainty regarding whether and when a party began open negotiations by recording start and end dates. Furthermore, this proposal may allow the parties to focus negotiations on items or services they believe would ultimately be eligible for the Federal IDR process. This proposal would also create an additional exchange of eligibility-related disclosures between the parties that may reduce the number of ineligible disputes submitted to the Federal IDR process, as

further described in section V.D.1.l. of this preamble. While the Departments have issued guidance to clarify that the use of an issuer's proprietary open negotiation portal is not required by the parties, many issuers currently maintain their own open negotiation portals and encourage parties to submit notices through them. This proposal would benefit providers, facilities, and providers of air ambulance services by creating a centralized location in which they can exchange information for open negotiation, as opposed to using different portals and systems depending on the plan or issuer. These proposed requirements would reduce the number of platforms or vehicles the party submitting the open negotiation notice currently use to furnish the notices and supporting documentation to both the Departments and the other party.

d. Initiating the Federal IDR Process and Notice of IDR Initiation

The Departments propose changes to 26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2). Specifically, the Departments propose to require the initiating party to provide additional elements on the notice of IDR initiation, including expanded information to identify the disputing parties (as well as any third party representing a party) and additional information to identify the item or service subject to the dispute.

Similarly, the Departments propose to require the non-initiating party to provide a response to the notice of IDR initiation that must include an enumerated list of information with additional disclosures, such as either a statement agreeing to the preferred certified IDR entity or an alternative preferred certified IDR entity, and an attestation as to the eligibility of the item or service that is the subject of the dispute. The Departments are of the view that these additional elements would assist in determining whether the item or services is eligible for the Federal IDR process, allow for a streamlined process to track dispute initiation, enhance communication among the parties, and facilitate a more efficient process of IDR initiation. Information about why the non-initiating party believes the dispute is ineligible for the Federal IDR process would assist the Departments or the certified IDR entity in its review of dispute eligibility, thereby streamlining the eligibility review process.

Additionally, by streamlining the submission of these notices through the Federal IDR portal, including the open negotiation notice and open negotiation response notice, the Departments may be able to use information that was submitted for one notice to pre-populate subsequent notices, reducing the burden of providing duplicative information. For instance, if a party that submitted the open negotiation notice through the Federal IDR portal decides to initiate the Federal IDR process after the open negotiation period has ended, the Departments anticipate that the Federal IDR portal may be able to pre-populate the fields in the notice of IDR initiation with the same information that was provided in the open negotiation notice. Furthermore, these proposed requirements would reduce the number of platforms or vehicles the initiating party must use in order to furnish the notice of IDR initiation and supporting documentation to both the Departments and the other party. This administrative streamlining would simplify the burden on initiating parties and would create greater efficiency.

e. Certified IDR Entity Selection

The Departments propose amending 26 CFR 54.9816-8(c)(1), 29 CFR 2590.716-8(c)(1), and 45 CFR 149.510(c)(1) regarding the process for certified IDR entity selection and submission of the notice of certified IDR entity selection. In the Departments' experience implementing the Federal IDR process, when a non-initiating party waits until the third business day after the date of IDR initiation to select an alternative preferred certified IDR entity, the initiating party lacks sufficient time to agree or object to the alternative preferred certified IDR entity. To provide the parties sufficient opportunity to agree or object to an alternative preferred certified IDR entity, the Departments propose that if the party last in receipt of either the notice of IDR initiation response or the notice of certified IDR entity selection received the notice on the third business day after the date of IDR initiation and did not agree to the other party's alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Departments would provide the party 2 additional business days to agree or object to other party's alternative preferred certified IDR entity selection. Further, to provide clarity and

to codify the process and timeframes for selecting a certified IDR entity, the certified IDR entity's conflict-of-interest review, and the date the certified IDR entity selection is considered finally selected, the Departments propose to establish a process that includes both preliminary selection of the certified IDR entity and final selection of the certified IDR entity. The Departments are of the view that the conflict-of-interest review by the certified IDR entity should not cut into the time periods for either the disputing parties to submit their offers or for the certified IDR entity to make a payment determination. For this reason, the Departments propose requirements that would provide for a certified IDR entity conflict-of-interest review process that must be conducted before a preliminary selection of the certified IDR entity is considered a final selected certified IDR entity. Under these proposed rules, the final selection of the certified IDR entity would trigger the timeframes for conducting an eligibility review, accepting offers of an out-of-network payment amount, and making a payment determination. The Departments are of the view that this proposal would streamline the exchange of information between parties, provide clarity on the dates that trigger the timeframes for offer submission and payment determinations, and relieve the time constraints on certified IDR entities by not having the conflict-of-interest review cut into the timeframe for payment determinations.

f. Federal IDR Process Eligibility Determinations

The Departments propose amending 26 CFR 54.9816-8(c), 29 CFR 2590.716-8(c), and 45 CFR 149.510(c) to make Federal IDR process eligibility determinations the responsibility of the Departments in certain circumstances. Under this proposal, when certain criteria are met as discussed in section II.E.1.b. of this preamble, the Departments would determine whether the dispute is eligible and make the eligibility determination for the Federal IDR process (that is, departmental eligibility review). If the dispute is found to be eligible, the Departments would send it to the certified IDR entity to continue the Federal IDR process. If the dispute is found to be ineligible for the Federal IDR process, it would be closed.

When the Departments are conducting eligibility determinations, it would relieve the burden on certified IDR entities of this responsibility and help ensure that they can focus their time and resources on payment determinations in accordance with statutory timeframes.

g. Withdrawals

The Departments propose to add 26 CFR 54.9816–8(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii) to establish a process for disputes to be withdrawn from the Federal IDR process. First, these proposed rules would allow a dispute to be withdrawn from the Federal IDR process if the initiating party provides notification through the Federal IDR portal to the Departments and the certified IDR entity (if selected) that both parties agree to withdraw the dispute, with signatures from authorized signatories for both parties. These proposed rules would also establish that the initiating party could withdraw a dispute by submitting a standard withdrawal request notice to the Departments, the non-initiating party, and the certified IDR entity (if selected) through the Federal IDR portal. In this case, the non-initiating party would then be required to provide the standard withdrawal request response notice within 5 business days indicating agreement or objection to the request for withdrawal. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party would be considered to have agreed to the dispute's withdrawal.

The Departments also propose to establish that the certified IDR entity or the Departments could withdraw a dispute from the Federal IDR process if the certified IDR entity or the Departments cannot determine eligibility because both parties are unresponsive to any requests for additional information to determine eligibility, or if the certified IDR entity cannot make a payment determination because both parties have failed to submit an offer as described in 26 CFR 54.9816–8(c)(5)(i), 29 CFR 2590.716– 8(c)(5)(i), and 45 CFR 149.510(c)(5)(i). The Departments are of the view that these proposals would both create fairness to the disputing parties and encourage efficiency of the Federal IDR process by generally requiring mutual agreement by the disputing parties to withdraw the dispute and providing that the dispute would

be withdrawn in the event the parties are nonresponsive within the required timeframes. The Departments also are of the view that permitting the withdrawal of a dispute in such cases would decrease the number of payment determinations the certified IDR entity is required to adjudicate, improving efficiency of the Federal IDR process.

h. Treatment of Batched Items and Services

The Departments propose to amend the batching polices in response to the Departments' experiences with batched determinations and operationalizing the Federal IDR process, as well as consideration of interested parties' feedback regarding the Federal IDR process. Under this proposal, the Departments would allow parties the flexibility to batch qualified IDR items and services (or "line items") that relate to the treatment of similar conditions with necessary limitations to encourage efficiency. Specifically, the policy would allow all qualified IDR items and services to be batched by: (1) items and services furnished to a single patient during a patient encounter on one or more consecutive dates of service and billed on the same claim form (single patient encounter); (2) items and services were furnished to one or more patients and billed under the same service code, or a comparable code under a different procedural code system; or (3) anesthesiology, radiology, pathology, and laboratory IDR items and services furnished under service codes belonging to the same Category I CPT code range, as specified in guidance by the Departments, in order to address the unique circumstances of certain medical specialties and provider types.

As discussed in section II.E.2. of this preamble, the Departments are of the view this approach would encourage efficiency (including minimizing costs) within the Federal IDR process without unreasonably impeding payers' or providers' access to the Federal IDR process considering relative costs and administrative burden; provide a framework to expedite processing of the backlog of Federal IDR disputes by simplifying the Federal IDR process; and ensure that items and services included in batched determinations have a clear organizing principle that

makes for logical and consistent payment determinations across certified IDR entities to reduce the chance of disparate outcomes.

i. Administrative and Certified IDR Entity Fee Collection

i. Establishment of the Administrative Fee Amount and Methodology

First, the Departments propose revisions to the methodology for setting the administrative fee and propose new reduced administrative fee amounts. The revised methodology and amounts would account for the proposals in these proposed rules, such as the reduced administrative fees for ineligible disputes and low-dollar disputes discussed in sections II.E.3.e. and II.E.3.f. of this preamble, while still complying with the statutory requirement that the Departments set the administrative fee amount such that the total amount of fees paid for such year is estimated to be equal to the amount of expenditures estimated to be made by the Departments for such year in carrying out the Federal IDR process. These proposals would allow the Departments to administer the Federal IDR process and be responsive to the needs of the program by updating the methodology and administrative fee amounts in conjunction with policy and operational improvements to the process.

ii. Time of Collection of Administrative Fee and Certified IDR Entity Fee

Second, the Departments are proposing to amend the provisions related to the time of administrative fee collection such that an initiating party would be required to pay the non-refundable administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity, which occurs before an eligibility determination is complete, and the non-initiating party would be required to pay the non-refundable administrative fee within 2 business days of the non-initiating party receiving notice of an eligibility determination. Specifically, an initiating party would be expected to pay the administrative fee regardless of whether the dispute is determined eligible for the Federal IDR process. Because the administrative fees are currently non-refundable and under the current regulation and associated impact analysis, this benefit is unchanged. The Departments are of the view that the effect of this change in benefits

experienced as a result of this proposal on disputing parties would be minimal.

Overall, the Departments are of the view that this proposal would promote the objective of costs of using the Federal IDR process being proportionately borne by parties to both eligible and ineligible disputes.

iii. Manner of Administrative Fee Collection

Third, the Departments are proposing to directly collect the administrative fee from each party. Because the administrative fees are always non-refundable, the Departments are of the view that the impact of this proposed change would be minimal. The Departments anticipate that direct collection of the administrative fee by the Departments would reduce the burden on certified IDR entities, as it would remove the requirement that certified IDR entities collect this fee and later remit it to the Departments upon dispute closure. This burden is currently approved under OMB control number 1210-0169 and accounts for an average of 18 hours of clerical worker time annually per certified IDR entity, as discussed further in section V.F.7. of this preamble.[196] If this policy is finalized, the Departments anticipate this change would have minimal impact on the certified IDR entities, as certified IDR entities would continue to collect certified IDR entity fees from disputing parties.

iv. Application of Federal IDR Process Requirements in Circumstances Involving a Failure to Pay Certified IDR Entity Fees or Administrative Fees

Fourth, the Departments propose to clarify how the Federal IDR process applies when either party fails to timely pay the fees associated with the Federal IDR process. Specifically, the failure to pay the administrative fee by an initiating party would result in the closure of the dispute due to nonpayment, and failure to pay the certified IDR entity fee by an initiating party would result in the certified IDR entity not considering the initiating party's offer. Nonpayment of the certified IDR entity fee or administrative fee by a non-initiating party would result in the

[196] OMB Control Number: 1210-0169 (No Surprises Act: IDR Process). The burden is estimated as follows: (18 hours x $39.56) = $712.08 per certified IDR entity. A labor rate of $39.56 is used for a clerical worker. The labor rates are applied in the following calculation: (13 x 18 hours x $39.56) = $9,257.

certified IDR entity not considering the non-initiating party's offer. The Departments are of the view that the impact of this change would be minimal. The purpose of this policy is to codify the sub-regulatory guidance that already exists and allow the closure of disputes in which the initiating party does not provide the appropriate administrative fee payment.

v. Administrative Fee Structure for Disputing Parties in Low-Dollar Disputes

Fifth, the Departments propose to charge both parties a reduced administrative fee when the initiating party attests that the highest offer (or aggregate offers for a dispute, whether the dispute is for one item or service, a bundled arrangement, or multiple items and services submitted as part of a batched dispute) made during open negotiation by either disputing party was less than the predetermined threshold. Because a reduction to the administrative fee would only be made in these limited situations, the Departments are of the view that the impact of this change would be minimal for most parties, particularly if the value of disputes increases as intended under the batching policies proposed in these rules, if finalized.

Furthermore, the Departments are of the view that this proposal would have a positive impact on some initiating parties, particularly small providers or providers in rural areas, that may not be able to efficiently access the Federal IDR process even under the batching policies proposed in these rules. Even though the Departments estimate in the Regulatory Flexibility Act analysis later in these proposed rules that there are approximately 66,000 small physicians[197] that may access the Federal IDR process, the Departments lack the data or ability to estimate how many providers would actually initiate the Federal IDR process and how many would or would not be able to efficiently initiate the process under the proposed batching policies in these rules and would therefore be impacted by the proposed reduced administrative fee for low-dollar disputes. The Departments seek comment on data sources or other resources to quantitatively

[197] Based on data from the NAICS Association for NAICS code 62111 (Offices of Physicians), the Departments estimate the percent of businesses within the industry of Offices of Physicians with less than $16 million in annual sales. By this standard, the Departments estimate that 47.2 percent or 66,207 physicians are considered small under the SBA's size standards. *See https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

estimate the benefits to this population and how to estimate the proportion of disputes that would be impacted by this policy.

vi. Administrative Fee Structure for Non-Initiating Parties in Ineligible Disputes

The Departments propose to charge the non-initiating party a reduced administrative fee when either the certified IDR entity or the Departments determine the entire dispute is not eligible for the Federal IDR process. Because a reduction to the administrative fee would be made only in this limited situation and one other situation (for low-dollar disputes), the Departments are of the view that the impact of this change would be minimal, particularly if the volume of ineligible disputes is reduced as anticipated due to the other policies proposed in these rules. The Departments are of the view that system improvements coupled with a reduced administrative fee in ineligible disputes may incentivize non-initiating parties to proactively raise and provide documentation to support eligibility challenges earlier in open negotiation or the Federal IDR process. This may result in a reduction in the volume of ineligible disputes (as further described in section V.D.1.l. of this preamble) and therefore reduce program administrative costs for the Departments overall. The Departments seek comment on the impact of a reduced administrative fee for non-initiating parties in ineligible disputes, including whether bad faith challenges to dispute eligibility may increase burden and whether modifications to the guidance for disputing parties are needed to prevent bad faith challenges to dispute eligibility.

j. Extension of Time Periods for Extenuating Circumstances

The Departments are proposing to amend 26 CFR 54.9816–8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g) to establish at paragraph (g)(1)(i) that the Departments, or at the request of a certified IDR entity or a party, would determine whether an extension is necessary because the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of the certified IDR entity or one or both parties, or for other good cause. Under these proposed rules, the Departments would provide an extension of the time periods if they identify unforeseen or good cause delays on a case-by-case basis, as opposed to solely relying on one of

the parties to submit an extension request. The Departments may detect these issues before either party would, and could immediately grant the necessary extension without having to wait for the submission of a formal request.

The Departments also propose to establish at 26 CFR 54.9816–8(g)(1)(ii), 29 CFR 2590.716-8(g)(1)(ii), and 45 CFR 149.510(g)(1)(ii) to codify a generally applicable extension of time periods when the Departments determine that such extension is necessary due to extenuating circumstances that contribute to systematic delays in processing disputes under the Federal IDR process, such as a high volume of disputes or Federal IDR portal system failures. The Departments would also post a public notice about any generally applicable extensions of time periods. Under these proposed changes, the Departments would extend the time periods under the Federal IDR process without requiring a case-by-case analysis of individual extension requests. The Departments are of the view that granting certain extensions in this manner would provide protection for parties engaged in the Federal IDR process from the impact of systematic processing delays and ensure that unforeseen circumstances do not unfairly disadvantage a party or hinder its ability to comply with the Federal IDR process timeframes. This would also provide more transparency into the time it would take for a dispute to be processed.

k. Registration of Group Health Plans and Health Insurance Issuers

Access to the IDR registry would provide a single, centralized place for initiating parties to find contact information for a plan or issuer, therefore reducing time spent by providers, facilities, and providers of air ambulance services when they initiate open negotiations. The registry would also help reduce wasted effort on inappropriately initiated disputes for certified IDR entities, as well as both initiating and non-initiating parties, by minimizing: (1) disputes initiated against the wrong party; (2) disputes over items or services that are subject to a specified State law or All-Payer Model Agreement; and (3) disputes that are incorrectly batched.

l. Reduction in Ineligible Disputes

The Departments anticipate that provisions of these proposed rules, in particular the proposed use of RARCs and CARCs, the proposed requirements in the open negotiation notice and response and the IDR initiation notice and response, the proposed modifications to batching requirements, the proposal to require the initiating party to pay the non-refundable administrative fee earlier in the initiation process, and the proposed registry for group health plans and health insurance issuers, would reduce the number of ineligible disputes initiated in the Federal IDR process each year. Preliminary internal data indicate that between June 2022 and May 2023, approximately 48,000 disputes were determined to be ineligible by certified IDR entities. Based on this data and the rates of ineligibility attributable to various reasons (for example, State jurisdiction over the dispute or the dispute being initiated against the wrong non-initiating party), the Departments estimate that a total decrease in ineligible disputes of approximately 50 to 75 percent, or 24,000 to 36,000 disputes, could result from the cumulative impact of these proposals each year. The Departments have calculated this estimated range to reflect that the proposals in these rules, while severable, may work in concert with one another to reduce ineligible disputes. Uncertainties in the reduction of ineligible disputes remain, and the Departments note that variables such as the number of disputes initiated have changed over time and may continue to fluctuate. Therefore, it is possible that the number of ineligible disputes ultimately prevented by the proposals in these rules could be outside of the range estimated in this paragraph.

2. Costs

These proposed rules seek to minimize costs to providers, facilities, providers of air ambulance services, plans, and issuers. The Departments seek comments on the assumptions made in this section and any additional costs that would be incurred by affected parties associated with the proposals in these proposed rules. The Departments also seek comment from individuals from minority and underserved communities, and providers who serve these individuals, to help address the costs that would be associated with these proposed rules related to these communities specifically.

a. Required Use of CARCs and RARCs

Plans and issuers would incur costs to comply with the requirements of these proposed rules related to the use of CARCs and RARCs. Plans and issuers would be required to use CARCs and RARCs on both electronic and paper remittance advice, in accordance with guidance issued by the Departments or as required under any applicable, adopted standards and operating rules under 45 CFR part 162. This would be necessary when processing out-of-network claims[198] to communicate information related to whether a claim for an item or service furnished by an entity that does not have a direct or indirect contractual relationship with the plan or issuer for the furnishing of the item or service under the plan or coverage is subject to the No Surprises Act's surprise billing provisions.

The Departments estimate that 1,500 issuers[199] and 205 TPAs[200] would incur costs to automate the process to include the appropriate CARCs and RARCs in the appropriate remittance documents and comply with the proposed provisions. The Departments anticipate that issuers and TPAs would need to make annual changes to their IT systems to accommodate additional No Surprises Act-related CARCs and RARCs that may be required by the Departments in future guidance, or as required under any applicable adopted standards and operating rules under 45 CFR part 162. The Departments estimate that each issuer or TPA would require a computer programmer 8 hours (at an hourly rate of $98.84)[201] to make annual changes to their IT system to allow for the incorporation of newly developed No Surprises Act-related CARCs and RARCs into their remittance documents and an operations manager 1 hour (at an hourly rate of $118.14) to annually verify accuracy and accessibility. The Departments estimate that each issuer or TPA would require a total of 9 hours annually, with an associated cost of

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[198] This requirement would not apply to claims submitted by a participant, beneficiary, or enrollee directly to the plan or issuer for items or services furnished by a nonparticipating provider or nonparticipating facility.
[199] Based on data from MLR annual report for the 2021 MLR reporting year. *See https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*
[200] Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.
[201] Wage rate derived from the BLS May 2022 National Occupational Employment and Wage Estimates for Computer Programmer (occupation 15-1251). Mean hourly rate ($49.42) has been increased by 100 percent to account for the cost of fringe benefits and other indirect costs ($49.42 * 100% = $98.84).

$909. For all issuers and TPAs, the Departments estimate an annual burden of 15,345 hours, with an associated total annual cost of $1,549,606 beginning in 2024.

TABLE 7: Annual IT Costs for Issuers and TPAs Related to CARCs and RARCs

	Estimated Number of Issuers and TPAs	Hours per Issuer/TPA (Hours)	Total Annual (Hours)	Total Estimated Cost
Annual IT Changes	1,705	9.0	15,345	$1,549,606

The Departments anticipate that most issuers and TPAs that are subject to HIPAA Administrative Simplification requirements currently use ERA and therefore are already required to use CARCs and RARCs in their ERAs to providers. However, the Departments recognize that some plans, issuers, and TPAs may not have the capacity to use more than one CARC and RARC per line item or may not currently use CARCs and RARCs when providing paper remittances. These issuers and TPAs would incur a higher burden and cost associated with the proposed provisions, particularly to the extent that an issuer or TPA is required to use multiple CARCs and RARCs per line item. In addition, plans and issuers with narrow networks may incur increased costs, as they would likely process more out-of-network claims to which this proposal would apply. The Departments anticipate that TPAs would, in general, pass on the costs to implement the use of CARCs and RARCs to plan sponsors, which in turn could be passed on to participants in the form of higher premiums or contributions.

The Departments seek comment on these estimates, the number of issuers or TPAs that do not currently have the ability to use CARCs and RARCs on paper remittance documents, what the burden and cost would be, and if any of those costs would be passed on to plan sponsors, to meet the requirements of this proposed provision. The Departments specifically seek comment on whether plans and issuers generally have the ability to use CARCs and RARCs in both paper and electronic remittance advice, or just electronic remittance advice. The Departments recognize that an issuer's or TPA's current IT structure could play a role in their ability to meet the requirements in the proposed provisions and the ability to apply more than one

CARC and RARC combination on a single line item, if required in certain scenarios. The Departments seek comment on issuers' and TPAs' capability to implement new No Surprises Act-specific CARCs and RARCs and to use more than one CARC and RARC combination on a single line item if necessary; what barriers plans, issuers, and TPAs may face in developing and implementing this capability; and what associated burden and cost would be incurred to implement and operationalize this capability for both electronic and paper remittances.

In addition, the use of CARCs and RARCs on both electronic and paper remittance advice would potentially reduce costs to certified IDR entities by reducing the number of ineligible payment disputes submitted to the Federal IDR process, as further described in section V.D.1.l. of this preamble. It would also reduce administrative costs incurred by parties related to initiating and responding to ineligible payment disputes.

b. Information to be Shared About the QPA

As detailed in section V.F.2. of this preamble, the Departments estimate that in the aggregate plans (or their TPAs) and issuers would incur a total one-time cost in 2024 of approximately $505,567 to make changes to the currently required QPA notification to incorporate the additional information described in proposed amendments to paragraphs 26 CFR 54.9816-6(d)(1)(iv) and (v), 29 CFR 2590.716-6(d)(1)(iv) and (v), and 45 CFR 149.140(d)(1)(iv) and (v).

c. Open Negotiation

The Departments propose to amend the open negotiation provisions to require the party initiating open negotiations to provide an open negotiation notice and supporting documentation to the other party and the Departments through the Federal IDR portal to initiate the open negotiation period. The Departments propose to expand the required information on the open negotiation notice to include new elements. Furthermore, the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice within the first 15 business days of 30-business-day open negotiation period.

To implement this proposal and other proposals in these proposed rules impacting the submission of information to the Federal IDR portal (including the proposals pertaining to the notice of IDR initiation and notice of IDR initiation response forms, the notice of certified IDR entity selection form, and the departmental eligibility review), the Departments would need to implement system changes to the Federal IDR portal to ensure parties are able to submit the open negotiation notice through the portal to the other party and the Departments, and to allow for a response from the non-initiating party. The Departments estimate that their costs to implement all portal system changes described in these proposed rules would be approximately $11,000,000 in fiscal year 2024. While some plans or issuers have created their own proprietary portals to facilitate open negotiations, providers, facilities, and providers of air ambulance services are not required to use them, and the Departments are of the view that there would be significant efficiencies in having one central location where providers, facilities, and providers of air ambulance services could initiate open negotiations across all plans and issuers.

The Departments estimate that these proposed rules would increase burden and create burden for the parties submitting the open negotiation notice and the proposed open negotiation response notice.[202] The total burden associated with these new requirements for parties would be 420,000 hours at a cost of $44,079,000 in 2024 and 840,000 hours at a cost of $88,158,000 annually beginning in 2025. The burden associated with this information collection is discussed further in section V.F.3. of this preamble.

The Departments seek comment on these costs and any other burdens interested parties foresee resulting from this proposal.

d. Initiating the Federal IDR Process and Notice of IDR Initiation

The Departments are proposing changes impacting the process for initiating the Federal IDR process and the notice of IDR initiation. The cost associated with updates to the Federal IDR portal for IDR initiation are described in the previous section V.D.2.c. regarding open

[202] OMB Control Number: 1210-0169 (No Surprises Act: IDR Process).

negotiation costs. The Departments are proposing these changes to accelerate dispute processing and reduce the burden on certified IDR entities. Specifically, the Departments propose to require the initiating party to provide additional information and supporting documentation on the notice of IDR initiation. The Departments also propose to require the non-initiating party to provide a response to the notice of IDR initiation within 3 business days of the date of IDR initiation that must include an enumerated list of information with additional disclosures, including a statement agreeing to the preferred certified IDR entity or providing an alternative preferred certified IDR entity, information regarding the eligibility of the item or service subject to the dispute, and supporting documentation. These proposals would increase the administrative burden for parties as they add information requirements that parties must submit at the initiation of the Federal IDR process. The Departments estimate that the total combined burden associated with the new requirements for all parties would be 315,000 hours at a cost of $33,059,250 in 2024 and 630,000 hours at a cost of $66,118,500 annually beginning in 2025. The burden associated with this information collection is discussed further in section V.F.4.a. of this preamble.

e. Certified IDR Entity Selection

The Departments propose to amend the process for the preliminary selection of the certified IDR entity and the submission of the notice of certified IDR entity selection. Specifically, under these proposed rules, the Departments propose that the non-initiating party must agree or object to the preferred certified IDR entity in the notice of IDR initiation response within 3 business days after the date of IDR initiation as discussed in section II.D.2.b. of this preamble. Due to this proposed change, the initiating party would only be required to submit the notice of certified IDR entity selection if the non-initiating party submits an alternative preferred certified IDR entity in the notice of IDR initiation response. The initiating party would submit its notice agreeing or objecting to the non-initiating's alternative preferred certified IDR entity through the Federal IDR portal. The non-initiating party would only be required to submit the notice of certified IDR entity selection if the initiating party provides an alternative preferred

certified IDR entity in the notice of certified IDR entity selection within the 3-business-day period following the date of IDR initiation. As such, the burden associated with this collection would be increased by approximately $418,621 and is described further in section V.F.4.b. of this preamble.

f. Federal IDR Eligibility Determinations

The Departments propose amending 26 CFR 54.9816-8(c)(1)(v), 29 CFR 2590.716-8(c)(1)(v), and 45 CFR 149.510(c)(1)(v) to make Federal IDR process eligibility determinations the responsibility of the Departments in certain circumstances, at the discretion of the Departments. Under this proposal to invoke a departmental eligibility review when certain criteria are met as discussed in section II.E.1.b. of this preamble, following IDR initiation, the Departments would evaluate whether the dispute is eligible for the Federal IDR process and make an eligibility determination. If the dispute is found to be eligible, the Departments would send it to the certified IDR entity to continue the Federal IDR process. If the dispute is found to be ineligible for the Federal IDR process, it would be closed.

By assuming the responsibility for Federal IDR process eligibility determinations, the Departments would incur costs that have thus far been incurred primarily by certified IDR entities. Therefore, it is important to note that these costs generally represent a transfer of costs (from certified IDR entities to the Departments) rather than actual new costs associated with the Federal IDR process. It is equally important to note that the Departments cannot quantify the full extent of these costs as they are now being incurred by certified IDR entities, and the Departments are not privy to their finances. As such, these estimates should be considered as the Departments' best approximations based on limited information.

These costs would vary depending on whether the departmental eligibility review for Federal IDR process eligibility determinations is in effect or not and may also vary considerably based on Federal IDR process dispute volume. When the departmental eligibility review is not in effect, the Departments would incur fewer costs, as they would not be responsible for Federal

IDR process eligibility determinations. The Departments estimate that they would incur a one-time "startup" cost for system and operations development in the first year beginning when these proposed rules are finalized and go into effect, which is included in the cost of the overall Federal IDR portal build described in section V.D.2.c. of this preamble, and ongoing operations and maintenance costs of $463,320 annually thereafter. When the departmental eligibility review is in effect, the Departments would be making eligibility determinations for disputes submitted to the Federal IDR process, which would incur a much higher level of burden, including responsibilities such as regulatory analysis, outreach, quality assurance, administrative activities, and close coordination among multiple parties. The Departments estimate that this would cost approximately $17,199,000 in 2024 and $41,277,600 per year beginning in 2025. The Departments wish to reiterate the draft nature of these estimates and their strong dependency on Federal IDR process volume, which is highly challenging to predict. As such, the Departments encourage comment and feedback.

g. Withdrawals

The Departments propose to add 26 CFR 54.9816–8(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii) to establish a process for disputes to be withdrawn from the Federal IDR process. If the withdrawal is not agreed upon by both parties, these proposed rules would require the initiating party to submit a withdrawal request to the Departments and the non-initiating party through the Federal IDR portal. The non-initiating party would then be required to provide a response within 5 business days indicating agreement or objection to the request for withdrawal. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party would be considered to have agreed to the dispute's withdrawal. This new collection would result in a cost to the parties of $455,196 in 2024 ($372,120 for initiating parties and $83,076 for non-initiating parties) and $910,392 ($744,240 for initiating parties and $166,152 for non-initiating parties) annually beginning in 2025, as discussed further in section V.F.6. of this preamble.

h. Treatment of Batched Items and Services

The Departments propose to amend the batching policies in response to the Departments' experiences with batched determinations and operationalizing the Federal IDR process, as well as consideration of interested parties' feedback regarding the Federal IDR process. Under this proposal, the Departments would allow parties the flexibility to batch qualified IDR items and services (or "line items") that relate to the treatment of a similar condition with necessary limitations to encourage efficiency. Specifically, the policy would allow all qualified IDR items and services to be batched by: (1) items and services furnished to a single patient during a patient encounter on one or more consecutive dates of service and billed on the same claim form (single patient encounter); (2) items and services furnished to one or more patients and billed under the same service code, or a comparable code under a different procedural code system; or (3) anesthesiology, radiology, pathology, and laboratory IDR items and services furnished under service codes belonging to the same Category I CPT code range, as specified in guidance by the Departments, in order to address the unique circumstances of certain medical specialties and provider types.

To implement this proposal, the Departments would need to implement system changes to the Federal IDR portal to ensure that the ability to batch under the new rules is operationalized. The total cost to implement system changes associated with submitting information through the portal, including those related to batching, is described in the open negotiation cost section of these proposed rules (section V.D.2.c. of this preamble). While the Federal IDR portal currently has batching capabilities, these proposed rules would allow for additional permissible mechanisms of batching which would need to be collected and captured in the Federal IDR portal.

i. Administrative Fee Collection

i. Establishment of the Administrative Fee Amount and Methodology

The Departments propose revisions to the methodology for setting the administrative fee and propose new reduced administrative fee amounts. If the IDR Process Fees proposed rules are finalized as proposed, the administrative fee in effect in calendar year 2024 would be $150 per party per dispute.[203] Based on internal Federal IDR process data and estimating the impact of *TMA IV*'s vacatur of the batching regulations at 26 CFR 54.9816-8T(c)(3)(i)(C), 29 CFR 2590-716-8(c)(3)(i)(C), and 45 CFR 149.510(c)(3)(i)(C), the Departments estimate that approximately 225,000 disputes are closed per year. Therefore, if the administrative fee as proposed in the IDR Process Fees proposed rule, if finalized, were to remain applicable, disputing parties would pay approximately $67,500,000 in administrative fees annually (225,000 disputes x 2 parties per dispute x $150 per party).

In these proposed rules, the Departments are proposing an administrative fee of $150 per party per dispute, a reduced administrative fee of $75 for both parties in low-dollar disputes, and a reduced administrative fee of $30 for non-initiating parties in ineligible disputes for disputes initiated on or after January 1, 2025. The Departments are also proposing to collect the administrative fee directly from the parties closer to the time of initiation rather than the time a dispute is closed.

The Departments project a total of 420,000 disputes would be initiated annually based on internal data, which includes 65,520 disputes for which both parties would pay the reduced administrative fee for low-dollar disputes, 18,480 disputes for which the initiating party would pay the reduced administrative fee for low-dollar disputes and the non-initiating party would pay the reduced administrative fee for ineligible disputes, 73,920 disputes for which the initiating party would pay the full administrative fee and the non-initiating party would pay the reduced administrative fee for ineligible disputes, and 262,080 disputes for which both parties would pay the full administrative fee. Thus, based on this data and assuming the number of disputes remains

[203] Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges proposed rules, 88 FR 65888 (September 26, 2023).

stable year over year and the administrative fee amounts are not subsequently changed through notice and comment rulemaking, the Departments estimate that disputing parties would pay approximately $103,698,000 in administrative fees annually beginning in 2025.[204] Therefore, the costs associated with this proposal would be approximately $36,198,000 annually beginning in 2025 ($103,698,000 if this proposal is finalized - $67,500,000 if the baseline condition under the IDR Process Fees proposed rules, if finalized, were to continue).

The Departments seek comment on these estimates and assumptions.

ii. Time of Collection of Administrative Fee and Certified IDR Entity Fee

The Departments are proposing to amend the provisions related to the time of administrative fee collection such that an initiating party would be required to pay the non-refundable administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity, and the non-initiating party would be required to pay the non-refundable administrative fee within 2 business days after a notice of an eligibility determination. Because initiating parties are not required to pay the administrative fee until offer submission under current guidance, some initiating parties fail to pay this fee for ineligible disputes. Although the Departments anticipate that this proposal would result in all initiating parties paying their administrative fee because the administrative fees are always non-refundable and incurred when preliminary selection of the certified IDR entity is complete, the Departments are of the view that the impact of this proposed change would be minimal on initiating parties, as compared to the existing regulation, associated burden analysis, and approved Paperwork Reduction Act Supporting Statement, which provide for all administrative fees to be non-refundable and to be paid in every dispute submitted. Under these proposed rules, if an initiating party fails to pay the required administrative fee within 2 business days of preliminary selection of the certified IDR

[204] This is calculated as follows: (65,520 disputes x 2 parties per dispute x $75 per party) + {18,480 disputes x [(1 party per dispute x $75 per party) + (1 party per dispute x $30 per party)]} + {73,920 disputes x [(1 party per dispute x $150 per party) + (1 party per dispute x $30 per party)]} + (262,080 disputes x 2 parties per dispute x $150 per party) =$103,698,000.

entity, the dispute would be closed and neither disputing party would owe the administrative fee; thus, a dispute opened by an initiating party that fails to timely pay the administrative fee is treated as a provisional dispute that does not proceed through the full Federal IDR process. Further, the Departments anticipate that this proposal would result in almost all non-initiating parties paying their administrative fee because of associated penalties for nonpayment, including that their offer would not be considered received, the non-initiating party would still be responsible for paying the administrative fee, and the unpaid administrative fee would be subject to Federal debt collection procedures.

Currently, approximately 40 percent of non-initiating parties do not pay the administrative fee. Under these proposed changes, the Departments estimate a total of 420,000 disputes would be initiated annually. However, the Departments are of the view that extrapolating a 40 percent cost increase to non-initiating parties would not be appropriate. Specifically, the combination of policies proposed in these rules, including attestation of eligibility during open negotiation and requiring the initiating party to pay the administrative fee at preliminary selection of the certified IDR entity, are designed to reduce the number of ineligible disputes submitted (as further described in section V.D.1.l. of this preamble), which are the disputes for which parties are often not paying the associated administrative fees. This proposal would be implemented in tandem with the requirements that non-initiating parties respond to the notice of IDR initiation, and the estimated amount of time for the non-initiating party to submit payment would be included in the estimated amount of time for the non-initiating party to submit the notice of IDR initiation response proposed in these rules. This amount of time is discussed further in section V.F.4.a. of this preamble.

The Departments are of the view that, if these proposed rules are finalized, initiating parties would submit fewer ineligible disputes, which would decrease the expenses incurred by the Departments and certified IDR entities to review eligibility information. In addition, parties would pay the required administrative fees in a higher percentage of disputes. However, at the

same time, there would be fewer disputes to review, so fewer administrative fees would be collected. Overall, the Departments are of the view that this proposal would ensure that the costs of using the Federal IDR process are being equitably allocated to both eligible and ineligible disputes.

iii. Manner of Administrative Fee Collection

The proposal for the Departments to directly collect the administrative fee from disputing parties would increase the activities required to be accounted for in the administrative fee, as the Departments' costs associated with this collection would need to be included in that fee. The Departments estimate that there would be an implementation cost of approximately $3,000,000 for system and operations development related to administrative fee collection in FY 2024, and ongoing operations and maintenance costs of approximately $2,500,000 in FY 2025, $1,250,000 in FY 2026, $1,000,000 in FY 2027, and $1,000,000 in FY 2028. Because the Federal IDR process is intended to be self-sustaining, once the administrative fee calculation is adjusted, there would be no financial impact to the Federal Government. Although the Departments are of the view that requiring disputing parties to pay the administrative fee directly to the Departments, instead of to certified IDR entities, would not impose an additional administrative burden on disputing parties, the Departments acknowledge that any increased fee that could potentially result from this proposal could impact disputing parties. The Departments seek comment on these assumptions, including any burden increase associated with this process and whether that potential burden would be offset by a reduction of the administrative fee based on a higher collection rate of the administrative fee from disputing parties.

iv. Application of Federal IDR Process Requirements in Circumstances involving a Failure to Pay Certified IDR Entity Fees or Administrative Fees

The Departments propose to clarify how the Federal IDR process applies when either party fails to timely pay the fees associated with the Federal IDR process. Specifically, the failure to pay the administrative fee by an initiating party would result in the closure of the

dispute, and nonpayment of the certified IDR entity fee by the initiating party would result in the certified IDR entity not considering the initiating party's offer. Nonpayment of the certified IDR entity or administrative fee by a non-initiating party would result in the certified IDR entity not considering the non-initiating party's offer. The Departments are of the view that the impact of this change would be minimal for the parties, as the purpose of this policy is to clarify the sub-regulatory guidance that already exists and allow closure of disputes in which the initiating party does not provide the appropriate administrative fee payment. Further, the Departments are of the view that it would take a *de minimis* amount of time for the initiating and non-initiating parties to include their taxpayer identification numbers, which would be required to link debts owed by the disputing parties to the Departments, on the notice of IDR initiation and the notice of IDR initiation response.

v. Administrative Fee Structure for Disputing Parties in Low-Dollar Disputes

The Departments propose to charge the parties a reduced administrative fee when the initiating party attests that the highest offer made during open negotiation by either party was less than the predetermined threshold as discussed further in section II.E.3.e. of this preamble. Because a reduction of the administrative fee would be applied to both parties when a low-dollar dispute is initiated, the Departments are of the view that the impact of this change would be minimal for most parties when combined with the proposal to expand batching, because these policies combined would result in fewer single low-dollar disputes being initiated. Furthermore, this proposal would reduce costs for certain parties to participate in the process, namely parties that provide low-dollar items or services and are unable to batch a sufficient number of items and services together to benefit from the batching proposals in these rules.

This proposal would require initiating parties to attest (for example, by checking a box) in the Federal IDR portal that no offer made by either party during open negotiation exceeded a predetermined threshold. The Departments are of the view that this action would only take a *de minimis* amount of time for the initiating party to complete, perhaps a minute, and therefore

would result in negligible costs. This amount of time is minimal and is captured in the total time it takes to initiate the dispute – 2.25 hours, as discussed further in the PRA package for the Federal IDR process (OMB control number: 1210-0169). This proposal may also increase the burden on the Federal Government due to the costs to complete system updates to account for this proposal, but the Departments anticipate that these costs would be incurred in tandem with changes to the other system build costs discussed in these proposed rules; thus, those costs are included in the cost estimates for the proposed changes related to open negotiation in section V.D.2.c. of this preamble. Furthermore, the Departments are of the view that the benefit of making the Federal IDR process more accessible to all types of providers, such as providers of low-dollar services, outweighs the limited costs to HHS to modify its system build.

vi. Administrative Fee Structure for Non-Initiating Parties in Ineligible Disputes

Additionally, the Departments propose to charge the non-initiating party a reduced administrative fee when either the certified IDR entity or the Departments determine the entire dispute is not eligible for the Federal IDR process. Because a reduction of the administrative fee would be applied to the non-initiating party when a dispute is ineligible for the Federal IDR process, the Departments are of the view that the impact of this change would be minimal for two reasons. First, under the current process, certified IDR entities often do not collect the administrative fee in these disputes; however, non-paying parties have been on notice that this fee was due even if they did not pay at the appropriate time. Second, policies such as requiring an attestation of eligibility during open negotiation and requiring the initiating party to pay the administrative fee at preliminary selection of the certified IDR entity are designed to reduce the number of ineligible disputes (as further described in section V.D.1.l. of this preamble) such that non-initiating parties would be assessed an administrative fee in fewer ineligible disputes. Because this process may incentivize non-initiating parties to timely challenge dispute eligibility during open negotiation, this may better capture the costs associated with the parties.

Further, the burden on disputing parties is dependent on whether the administrative fee is increased or decreased, which is a byproduct of estimated total annual expenditures by the Departments. In the event of a substantial change in payment of the administrative fee based on the volume of ineligible disputes or associated expenditures, which would impact the calculation of the administrative fee, the parties may incur an increased or decreased administrative fee to cover the costs to carry out the Federal IDR process. The Departments seek comment on potential impacts to disputing parties and certified IDR entities of any change in burden from this policy, including any modifications to internal operating procedures that may be required to implement this fee structure.

j. Extension of Time Periods for Extenuating Circumstances

The Departments propose to establish that the Departments, or at the request of a certified IDR entity or a party, would determine whether an extension is necessary because the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of the certified IDR entity or one or both parties, or for other good cause. The process for requesting an extension due to extenuating circumstances would remain the same as when this process was established in the October 2021 interim final rules, and entities would continue to submit the Request for Extension due to Extenuating Circumstances form through the Federal IDR portal. However, based on the proposed changes to this policy, the Departments estimate that the number of respondents would increase due to the addition of certified IDR entities, thus slightly increasing the total burden associated with this collection. The Departments estimate that the costs associated with certified IDR entity requests for the extension would be $99 in 2024 and $197.80 annually beginning in 2025. This cost is explained in further detail in section V.F.8. of this preamble.

k. Registration of Group Health Plans and Health Insurance Issuers

Establishing the Federal IDR registry would impose a cost on the Departments by requiring them to develop and build the registry. The Departments anticipate incurring a cost of

approximately $3,000,000 to develop and build the Federal IDR registry in FY 2024, with annual ongoing costs to maintain the registry of $150,000 on average thereafter. Additionally, enrolling in the Federal IDR registry would impose a cost on issuers and plans by requiring them to submit information to the Departments. These costs amount to $1,573,693 in 2024 and $94,252 annually beginning in 2025 and are further described in section V.F.9. of this preamble.

3. Uncertainties

While the Departments are of the view that the majority of issuers and TPAs have the capability to use single CARC and RARC combinations on ERA transactions, the Departments are uncertain about the current level of use within the industry and whether issuers and TPAs have the capability to incorporate this information on paper remittance advice. Further, the Departments are uncertain about the current capability or percentage of issuers and TPAs that have the ability to use multiple CARC and RARC combinations for individual line items, including on electronic and paper remittance advice; what barriers and challenges issuers and TPAs would face to implement and operationalize this capability; and whether substantial system changes would need to be implemented to effectuate this proposed policy.

It is unclear whether the Federal IDR process would experience the same operating conditions, such as the number of ineligible disputes submitted or the number of disputes that would be closed for nonpayment of the administrative fee, if all or some of the policies proposed in these proposed rules are finalized and implemented. While these factors would have a direct impact on the expenditures made by the Departments to carry out the Federal IDR process, it is difficult to project the impact that may result to the administrative fee amount charged to the parties. It is also uncertain how many disputes would be considered low-dollar disputes in the future, which would impact how many parties would be charged the proposed reduced administrative fee for low-dollar disputes, and it is uncertain how many disputes would be determined ineligible if the proposals in these rules are finalized, which would impact how many

non-initiating parties would be charged the proposed reduced administrative fee for ineligible disputes.

Furthermore, it is unclear if or when the proposed departmental eligibility review, which would allow the Departments to make eligibility determinations rather than certified IDR entities, may need to be invoked. The departmental eligibility review would impact dispute processing times and overall certified IDR entity operations; further, these factors may impact what percentage of disputes are settled or withdrawn after initiation but before offer submission.

The economies of scale that may be realized by batching qualified IDR items and services are uncertain, including whether there would be a reduction in the amount of fees each party has to pay since parties would generally be allowed to batch more items and services in a single dispute than under the vacated provisions (discussed in section II.E.2. of this preamble). The specific provisions of the batching proposal may have differing effects on the trends in dispute initiation overall. For example, the increased flexibility to batch based on a single patient encounter may increase initiation of batched disputes, while the proposed cap on the number of line items within a batch may require parties that previously submitted batches with a high number of line items to divide the claims across multiple batched disputes. Further, the Departments are of the view that the increased batching flexibilities in concert with the reduced administrative fee for low-dollar disputes, if finalized, could lead to an increase in disputes initiated, since these policies may result in the Federal IDR process becoming more accessible to providers and payers. For these reasons, the Departments recognize the uncertainty in estimating the potential impact on the number of disputes submitted, and thus the fees collected, due to the proposed batching provisions. Further, it is uncertain if increased batching would lead to decreased collection of funds by the Departments if fewer administrative fees are paid.

It is uncertain how much time would be needed for plans, issuers, carriers, and TPAs to collect the registration information that they would be required to provide under these proposed rules. Furthermore, it is unclear how many group health plans would choose to self-register for

the proposed IDR registry, rather than relying on a TPA or other third party to register on their behalf. If a significant number of group health plans self-register, this may increase the burden to industry as well as the operational burden to the Departments to create and maintain the registry.

Although the Departments have analyzed the last 12 months of Federal IDR process data available to inform their projections, it is uncertain if the trends in this data will remain applicable for two reasons. First, the Federal IDR process is still in an early phase of implementation and has not yet achieved the stabilization that occurs with long-term uptake of the process. Initially, the Departments estimated that approximately 22,000 disputes would be submitted to the process each year;[205] uptake of the process, however, has rapidly outpaced that estimate as dispute initiations have grown exponentially since implementation, and analysis has revealed an estimated number closer to 420,000 annual disputes [206] would have been more accurate.

Second, although each of the proposed provisions could be implemented separately and is severable, when reviewed holistically, implementation of these proposed policies would create comingled impacts, including on the number and type of disputes initiated, such that it is uncertain what the overall collective impact of these proposed policies would be. For example, although the Departments project a 50 to 75 percent decrease in the number of ineligible disputes as discussed further in section V.D.1.l. of this preamble, other policies such as expanded batching and the reduced administrative fee for low-dollar disputes are anticipated to increase access to the Federal IDR process, such that the total number of disputes initiated yearly may increase overall. Additionally, the proposed framework for administrative fees that, if finalized, would result in a reduced administrative fee for some disputing parties when a dispute is ineligible or low-dollar complicates the analysis of what types of disputes would be initiated

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[205] In the regulatory impact analysis of the October 2021 interim final rules, the Departments estimated that 17,333 disputes involving non-air ambulance services and 4,899 disputes involving air ambulance services would be submitted to the Federal IDR process during the first year of implementation, totaling 22,232 anticipated disputes.
[206] Federal Independent Dispute Resolution Process – Status Update. Centers for Medicare & Medicaid Services. April 27, 2023. *https://www.cms.gov/files/document/federal-idr-processstatus-update-april-2023.pdf*.

under these proposed rules. Further, the policies designed to increase communication between the disputing parties, such as the registry, open negotiation, and dispute initiation provisions, are anticipated to reduce the number of ineligible disputes initiated and increase the number of disputes resolved through open negotiation. However, the Departments are uncertain whether additional parties will utilize the Federal IDR process due to these process improvements, which would ultimately bring more disputes into the process.

Overall, some of the proposed policies may reduce the number of disputes while others may increase the number of disputes initiated. Additionally, whether there will be a reduction in costs to the disputing parties is also uncertain under these collective proposals. For example, a provider that previously felt that the nature of their practice made it infeasible to initiate a dispute due to financial concerns may find the Federal IDR process more financially accessible under the proposed reduced administrative fee framework, thus incurring the associated cost and administrative fees and increasing the annual dispute number.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on entities, such as the time needed to read and interpret rules, regulatory agencies should estimate the total cost associated with regulatory review. Based on comments received for the July 2021 interim final rules and October 2021 interim final rules, the Departments estimate that more than 2,100 entities will review these proposed rules, including 1,500 issuers, 205 TPAs, and at least 395 other interested parties (for example, State insurance departments, State legislatures, industry associations, advocacy organizations, and providers and provider organizations). The Departments acknowledge that this assumption may understate or overstate the number of entities that will review these proposed rules.

Using the mean hourly wage rate from the Bureau of Labor Statistics for a Lawyer (Code 23-1011) to account for average labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs), the Departments estimate that the cost of reviewing

these proposed rules would be $157.48 per hour.[207] The Departments estimate, based on an average reading speed of 200 to 250 words per minute, that it would take each reviewing entity approximately 10 hours to review these proposed rules, with an associated cost of approximately $1,574.80 (10 hours x $157.48 per hour). Therefore, the Departments estimate that the total burden to review these proposed rules will be approximately 21,000 hours (2,100 reviewers x 10 hours per reviewer), with an associated cost of approximately $3,307,080 (2,100 reviewers x $1,574.80 per reviewer).

The Departments welcome comments on this approach to estimating the total burden and cost for interested parties to read and interpret these proposed rules.

E. Regulatory Alternatives – Departments of Health and Human Services and Labor

In developing these proposed rules, the Departments considered various alternative approaches.

1. Required Use of CARCs and RARCs

The Departments considered applying the proposed requirement to use CARCs and RARCs under new 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100 only to claims subject to the surprise billing protections of the No Surprises Act. However, the Departments have become aware that providers, facilities, and providers of air ambulance services have sought to initiate open negotiations or the Federal IDR process for a sizeable number of claims that are not subject to the No Surprises Act. Therefore, the Departments have concluded that it would be helpful for plans and issuers to communicate information regarding the applicability of the No Surprises Act for all out-of-network claims, and that a narrower application would be less impactful. Thus, the proposed approach may reduce the number of ineligible claims submitted, as further described in section V.D.1.l. of this preamble.

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[207] Centers for Medicare & Medicaid Services. (May 1, 2022). *May 2022 National Occupational Employment and Wage Estimates*. *https://www.bls.gov/oes/current/oes_nat.htm.*

The Departments considered specifying in regulation which CARCs and RARCs must be used, rather than providing this information in guidance. The Departments are working to understand and address the current backlog of disputes slowing down the Federal IDR process. The Departments have concluded that retaining the flexibility to identify the CARCs and RARCs to be used in specified scenarios in guidance rather than through notice and comment rulemaking would provide greater ability to quickly address communication gaps that are contributing to this backlog and future implementation challenges, as the Departments better understand these gaps. This also mirrors the current approach for required CARC and RARC code combinations that must be used by HIPAA-covered entities in business scenarios, as specified in guidance.

The Departments also considered continuing to support the voluntary use of No Surprises Act-specific RARCs. The Departments recognize the additional burden that requiring certain RARCs may place on small entities that may have fewer dedicated IT and coding staff. However, since the RARC Committee approved a set of RARCs for optional use, effective March 1, 2022, providers, facilities, and providers of air ambulance services and plans and issuers have continued to report communication challenges and to request more standardized mechanisms for communicating information. The Departments concluded that requiring certain CARCs and RARCs in specific circumstances, as well as continuing to permit the use of voluntary RARCs at the discretion of plans and issuers, would provide a more effective means of standardizing communication and better achieve a number of aims, including improving information flow between plans and issuers and providers, facilities, and providers of air ambulance services and consequently reducing the submission of ineligible claims to the Federal IDR process.

2. Open Negotiation Provision Changes (26 CFR 54.9816-8(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1))

The Departments propose to amend the open negotiation provisions at 26 CFR 54.9816-8(b)(1)(i), 29 CFR 2590.716-8(b)(1)(i), and 45 CFR 149.510 (b)(1)(i) to require the party

initiating open negotiations to provide an open negotiation notice and supporting documentation to the other party and the Departments to initiate the open negotiation period. Furthermore, the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period.

The Departments considered alternative ways for the party initiating open negotiation to notify the Departments of the initiation of open negotiations instead of submitting the notice through the Federal IDR portal. The Departments considered having the party submitting the open negotiation notice notify the Departments via mail or email but decided that the portal would provide a more logical place for the notice to be provided, as this is where Federal IDR process information is stored. The Departments also considered taking no action and maintaining the current process in which parties initiating open negotiation do not inform the Departments directly of the initiation of open negotiations. However, the Departments are of the view that these changes are necessary to make it explicitly clear to the Departments when open negotiations are initiated in order to best track the flow of Federal IDR process dispute initiations. The Departments are of the view that these proposals would create more certainty regarding whether and when the party initiating open negotiation begins open negotiations by ensuring that start and end dates are documented in the Federal IDR portal, which is the official place of record for the Federal IDR process. Further, the Departments acknowledge the additional burden that small entities may face in meeting the requirements of the Federal IDR process since they may not have dedicated staff to perform all the functions necessary to meet the requirements. However, the Departments are of the view that the proposed policy to centralize the submission of open negotiation notices through the Federal IDR portal would alleviate burden on small entities as it would reduce the number of channels they previously submit these notices through.

The Departments also considered alternatives to requiring the party in receipt of the open negotiation notice to provide a response to the open negotiation notice within the 30-business-day open negotiation period. The Departments considered maintaining the status quo of not requiring this response, but are of the view that creating this requirement would be the better alternative, because this proposal would create an additional exchange of eligibility-related disclosures between the parties and foster better communication between the parties to improve the Federal IDR process.

The Departments also propose to require that the open negotiation notice contain additional specific information and be in a specific format as discussed in section II.D.1.c. of this preamble. The Departments further propose to require that the open negotiation response notice must be provided, using the standard form developed by the Departments, no later than the 15th business day of the 30-business-day open negotiation period, and the party in receipt of the open negotiation notice must provide the open negotiation response notice through the Federal IDR portal resulting in receipt by the party initiating open negotiation and the Departments on the same day. The Departments considered maintaining the status quo and not requiring the additional information, the specific format, or timing, but determined that this proposal would create an additional exchange of information necessary to help the Federal IDR process be successful, allow certified IDR entities to make more informed decisions, and improve communication between the parties.

3. Changes to the Initiation of the Federal IDR Process and the Notice of IDR Initiation (26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2))

The Departments propose to amend the IDR initiation provisions of 26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2) to accelerate dispute processing and reduce the burden on certified IDR entities. Specifically, the Departments propose to require the initiating party to provide an enumerated list of additional information on the notice of IDR initiation, including a statement describing the aspects of the claim, such as patient acuity or

level of training, any payment discussed by the parties during open negotiation, whether the reasons for initiating the Federal IDR process are different from the aspects of the claim discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process.

Similarly, the Departments propose to require the non-initiating party to provide a response to the notice of IDR initiation, within 3 business days after the date of IDR initiation, that must include an enumerated list of information, including an agreement or disagreement that the dispute is eligible for the Federal IDR process, supporting documentation if the non-initiating party believes a dispute is not eligible, and an agreement to the preferred certified IDR entity identified in the notice of IDR initiation or an alternate preferred certified IDR entity selection.

The Departments propose to require these notices to be provided to the other party and the Departments electronically through the Federal IDR portal.

The Departments considered alternatives to these notices and the information they are required to contain, including contemplating notices that contained less required information. Recognizing the increased administrative burden of providing this additional information within the specified timeframe, particularly for small entities that may regularly engage with the IDR process and may not have staff dedicated to perform this function, the Departments also considered maintaining the status quo, but instead determined that these notices are necessary to address processing and communication issues caused by the lack of information. These new requirements would provide information to the certified IDR entities that is frequently missing under the status quo.

Each of the new required elements would provide specific information needed by the certified IDR entities to successfully conduct the Federal IDR process. The lack of these information elements creates a burden on the certified IDR entities, as they are currently required to undertake concerted efforts to obtain the information from the parties or other sources. This has resulted in additional time and effort for the certified IDR entities and caused the process to

move at a slower pace than is desired. The Departments are of the view that requiring the parties to provide these notices and the information contained in them within the timeframes and in the manner proposed would result in a reduction in this burden on the certified IDR entities and would result in greater efficiency of the Federal IDR process overall. Additionally, the Departments are of the view that these additional elements would assist in determining whether the items or services associated with the dispute are eligible for the Federal IDR process, allow for a streamlined process to track dispute initiation, enhance communication between the parties, and facilitate a more efficient process of IDR initiation.

4. Certified IDR Entity Selection (26 CFR 54.9816-8(c)(1), 29 CFR 2590.716-8(c)(1), and 45 CFR 149.510(c)(1))

The Departments propose to establish a process for the preliminary selection of the certified IDR entity and final selection of the certified IDR entity at 26 CFR 54.9816-8(c)(1), 29 CFR 2590.716-8(c)(1), and 45 CFR 149.510(c)(1). Specifically, the Departments propose amending the preliminary selection of the certified IDR entity process to establish that if the party last in receipt of either the notice of IDR initiation response or the notice of certified IDR entity selection received the notice on the third business day after the date of IDR initiation and did not agree to the other party's alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Departments would provide the party 2 additional business days to agree or object to other party's alternative preferred certified IDR entity selection. Further, the Departments propose to clarify that the date of preliminary selection of the certified IDR entity would be 3 business days after the date of IDR initiation if the parties jointly selected a certified IDR entity, or 6 business days after the date of IDR initiation if the parties fail to jointly select a certified IDR entity and the Departments select a certified IDR entity either based on the agreement (or failure to respond) of the party in receipt of the last notice (either the notice of IDR initiation response or the notice of certified IDR entity selection) or through random selection. Lastly, the Departments propose to establish the process for

finalizing selection of the certified IDR entity at 26 CFR 54.9816-8(c)(1)(iv), 29 CFR 2590.716-8(c)(1)(iv), and 45 CFR 149.510(c)(1)(iv), which would establish that the date of final selection of the certified IDR entity is the date the Departments provide notice to the parties that the preliminarily selected certified IDR entity attests that it meets the conflict-of-interest requirements.

The Departments considered alternatives to this proposal. The Departments considered maintaining the status quo and not modifying the process of selecting a certified IDR entity. However, given that the current rules allow the conflict-of-interest review to coincide with the eligibility review, the Departments are of the view that creating a finalization stage of certified IDR entity selection in the Federal IDR process would improve efficiency and reduce confusion when completing certified IDR entity selection. The Departments are of the view that this proposed policy would not increase burden for disputing parties, including small entities, as the time period requirement for disputing parties to jointly select a certified IDR entity is not changing. The Departments are of the view that the certified IDR entity must be considered preliminarily selected until it is determined that the certified IDR entity has no conflict of interest, and that the conflict-of-interest review should not cut into the time periods for either disputing party to submit their offers or for the certified IDR entity to make a payment determination.

5. Federal IDR Eligibility Determinations (26 CFR 54.9816-8(c)(1)(v), 29 CFR 2590.716-8(c)(1)(v), and 45 CFR 149.510(c)(1)(v))

The Departments propose to amend 26 CFR 54.9816-8(c), 29 CFR 2590.716-8(c), and 45 CFR 149.510(c) regarding Federal IDR eligibility determinations to make the Federal IDR process eligibility reviews the responsibility of the Departments under certain circumstances. Under this proposal, when a departmental eligibility review is in effect, the Departments would determine whether the dispute is eligible for the Federal IDR process. If the dispute is found to

be eligible, the Departments would send it to the certified IDR entity to continue the Federal IDR process. If the dispute is found to be ineligible for the Federal IDR process, it would be closed.

The Departments considered being more involved in the entire eligibility review process on a permanent basis; however, once the Federal IDR process arrives at a steadier operational state, the Departments are of the view that the majority of eligibility work—in particular eligibility determinations—should be conducted by certified IDR entities, particularly if the other proposed policies in these proposed rules and non-regulatory improvements are successful in improving throughput. The Departments also considered maintaining the status quo of certified IDR entities performing the full scope of the eligibility determination process, but the burden of making these eligibility determinations has proven to be complex and time-consuming for certified IDR entities, and the statute only affords certified IDR entities the ability to collect the certified IDR entity fee when a payment determination is made. A payment determination can only be made for eligible disputes, so certified IDR entities are not able to keep any portion of their fee for disputes they determine are ineligible. This situation results in certified IDR entities being uncompensated for eligibility determination work on ineligible disputes. The Departments do not anticipate that this policy, if finalized as proposed, would have a differential impact on small entities. Therefore, the Departments are proposing this provision in a manner that provides the Departments with the flexibility to move the responsibility for Federal IDR eligibility determinations between the Departments and certified IDR entities, as appropriate and with appropriate notice to interested parties.

6. Withdrawals (26 CFR 54.9816-8(c)(3), 29 CFR 2590.716-8(c)(3), and 45 CFR 149.510(c)(3))

The Departments propose to add 26 CFR 54.9816–8(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii) to establish a process for disputes to be withdrawn from the Federal IDR process. Specifically, the Departments propose that a dispute may be withdrawn from the Federal IDR process if: (1) the initiating party provides notification through the Federal IDR portal to the Secretary and the certified IDR entity (if selected) that both parties agree to

withdraw the dispute from the Federal IDR process, with signatures from authorized signatories for both parties; (2) the initiating party provides a standard withdrawal request notice to the Departments, the certified IDR entity (if selected), and the non-initiating party, and the non-initiating party notifies the Secretary, certified IDR entity (if selected), and initiating party of its agreement to withdraw within 5 business days of the initiating party's request (or the non-initiating party fails to respond within 5 business days of the initiating party's request); (3) the certified IDR entity or the Departments cannot determine eligibility because both parties to the dispute are unresponsive to any requests for additional information to determine eligibility; or (4) the certified IDR entity cannot make a payment determination because both parties to the dispute have failed to submit an offer as described in 26 CFR 54.9816–8(c)(5)(i), 29 CFR 2590.716–8(c)(5)(i), and 45 CFR 149.510(c)(5)(i).

The Departments considered alternatives to this proposal. The Departments considered maintaining the status quo and not formalizing the process for disputes to be withdrawn. The Departments recognize that the withdrawal process may place particular burden on resource constrained small entities, that may face greater challenges meeting the timetables described in this proposal. However, given that the current rules do not establish a clear uniform process for disputes to be withdrawn, the Departments are of the view that these proposals would encourage efficiency by creating a centralized process for the parties to request a withdrawal of a dispute and requiring that the dispute would be withdrawn in the event the parties are nonresponsive within the required timeframes. Further, the Departments also are of the view that permitting the withdrawal of a dispute in these cases would decrease the number of payment determinations the certified IDR entity is required to adjudicate.

7. Treatment of Batched Items and Services (26 CFR 54.9816-8(c)(4), 29 CFR 2590.716-8(c)(4), and 45 CFR 149.510(c)(4))

After considering feedback from interested parties, the Departments are of the view that the batching rules should be amended to capture additional efficiencies and expand access to the

Federal IDR process, while avoiding combinations of unrelated claims in a single dispute that could unnecessarily complicate an IDR payment determination and operate to reduce efficiency. The Departments also anticipate that these batching policies, if finalized as proposed, would be particularly beneficial to small entities. By offering greater flexibility, these policies will improve the economic cost of the Federal IDR process and reduce the burden on small entities' billing and coding staff.

The Departments considered different approaches to expand the batching rules at proposed 26 CFR 54.9816–8(c)(4), 29 CFR 2590.716–8(c)(4), and 45 CFR 149.510(c)(4) for determining whether the items or services are related to treatment of a similar condition. In particular, the Departments considered approaches that relied on existing code sets that would capture a wider range of items and services than those under the current regulations, including the vacated provisions (discussed in section II.E.2. of this preamble). The rationale underlying batching based on code sets (or subsets of those code sets) is that based on the manner in which these code sets were built (by medical and coding professionals and others), the code sets present a reasonable basis upon which to conclude that certain sections (or subsections) of those code sets describe items and services that are related to the treatment of a similar condition.

The broadest potentially workable standard the Departments considered for determining whether the items or services are related to treatment of a similar condition is the Berenson-Eggers Type of Service (BETOS) codes. The BETOS coding system was originally developed for analyzing the growth in Medicare expenditures and is not utilized for the purposes of billing.[208] The Restructured BETOS Classification System (RBCS) includes HCPCS Level I codes (commonly referred to as "CPT codes") and HCPCS Level II codes (commonly referred to as "HCPCS codes") and groups CPT and HCPCS procedural codes into a few very broad categories: (1) anesthesia, (2) evaluation and management, (3) procedures, (4) imaging, (5) tests,

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[208] Centers for Medicare & Medicaid Services. (October 20, 2022). *Restructured BETOS Classification System. https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system.*

(6) durable medical equipment, (7) treatment, and (8) other. However, this could theoretically offer unlimited batching of services furnished by specialty providers and, accordingly, result in batches that would be difficult for certified IDR entities to adjudicate in a timely manner. While this coding system is stable over time and is relatively immune to minor changes in technology or practice patterns, this approach would require parties and certified IDR entities to learn and become familiar with a new framework for categorizing items and services for the specific purpose of engaging with the Federal IDR process. The Departments are of the view that this would result in confusion and an exacerbation of backlog issues.

The Departments also considered allowing initiating parties to batch all items and services with the same ICD-10 diagnosis code. Every medical claim includes at least one ICD-10 diagnosis code, including a primary diagnosis code and optional secondary diagnosis codes. There are approximately 68,000 ICD-10 diagnosis codes that cover a wide variation in patient diagnoses. Given the wide variation in diagnoses and the fact that a single ICD-10 diagnosis code can cover a wide range of individual items or services, it is conceivable that diagnosis codes are not a reasonable basis upon which to determine that items or services provided to different patients sufficiently relate to treatment of a similar condition. Furthermore, the Departments are of the view that this level of variation could create complexity for disputing parties and certified IDR entities and increase the risk of inconsistent batching determinations.

In addition to batching based on code sets, the Departments considered specific recommendations from interested parties on creating additional batching flexibilities for determining whether the items or services are related to treatment of a similar condition. As discussed in section II.E.2. of this preamble, anesthesiologists have advocated for batching by conversion factor since contracting practices for anesthesiology items and service focus on conversion factor rates. The Departments are of the view that this approach would undermine the Departments' efforts to increase efficiency in the Federal IDR process. Because conversion factors would be identical for every out-of-network service furnished by an anesthesiologist

provider or provider group, the "same conversion factor" requirement results in the provider or provider group being able to batch every out-of-network service it furnishes that otherwise satisfies the requirements of the batching rules at proposed 26 CFR 54.9816–8(c)(4), 29 CFR 2590.716–8(c)(4), and 45 CFR 149.510(c)(4). Instead, the Departments are of the view that batching based on CPT code categories would lead to greater efficiency, would more closely align with the interpretation of treatment of a similar condition, and would lead to less risk in the variability among the items and services and factual circumstances that certified IDR entities must consider.

Additionally, the Departments considered feedback provided by emergency physicians, who stated that the nature of emergency care makes it difficult for them to batch claims under the current rules and suggested that the batching rules should allow for the most common evaluation and management CPT codes (99281-99285) to be batched together. However, the Departments have concluded that in the context of emergency care, the acuity of a patient may vary substantially in these circumstances. This means that certified IDR entities would need to review complex and disparate factual conditions for each item or service in a batch pertaining to emergency care, which would be extremely time consuming. Batching in these circumstances would therefore exacerbate payment determination delays and compound the backlog of disputes.

Similarly, the Departments considered allowing batching of all items and services within one of the six major sections of the CPT code book: (1) evaluation & management, (2) anesthesiology, (3) surgery, (4) radiology, (5) pathology and laboratory, and (6) medicine. This could allow batching of the services most often provided by emergency physicians, anesthesiologists, radiologists, pathologists, and other specialty providers. Due to the breadth of CPT codes relevant to surgery and radiology services, the Departments considered further limiting providers' batching ability to the specific services represented by the code spans relevant to each row in Table 8 that correlates to surgery or radiology services. While these

delineations could serve as straightforward guidelines that may result in consistent application of a batching standard across certified IDR entities, the Departments are of the view that variations in these services within a batched dispute could present challenges to certified IDR entities' efficient resolution of disputes due again to the fact-specific and time intensive nature of reviewing information specific to each item or service within a batch.

TABLE 8: CPT Level I HCPCS Codes Groupings

CPT Level I HCPCS Codes (CPT) Code Span	Description
99202 – 99499	Evaluation and Management
00100 – 01999	Anesthesia
10004 – 19499	Surgery/Integumentary System
20100 – 29999	Surgery/Musculoskeletal System
33016 – 39599	Surgery/Cardiovascular System
40490 – 49999	Surgery/Digestive System
50010 – 53899	Surgery/Urinary System
54000 – 55980	Surgery/Male Genital System
56405 – 58999	Surgery/Female Genital System
60000 – 60599	Surgery/Endocrine System
61000 – 64999	Surgery/Nervous System
65091 – 68899	Surgery/Eye and Ocular Adnexa
69000 – 69979	Surgery/Auditory System
70010 – 77092	Radiology/Diagnostic Radiology/Diagnostic Ultrasound
77261 – 79999	Radiology/Radiation Oncology/Nuclear Medicine
80047 – 89398 0001U – 0284U	Pathology and Laboratory/Proprietary Laboratory Analysis
90281 – 99607	Medicine

The Departments are of the view that specific, narrower ranges within CPT Category I sections could mitigate this risk, more closely relate to the treatment of a similar condition, and encourage efficiencies of the Federal IDR process. Further, the Departments are of the view that batching based on CPT code categories would lead to greater efficiency, would more closely align with the interpretation of treatment of a similar condition, and would lead to less risk in the variability among the items and services and factual circumstances that certified IDR entities must consider. Thus, in balancing the need to create a workable batching rule for all parties and encouraging efficiency (including minimizing costs) to the Federal IDR process, the Departments determined that it would be appropriate to propose amendments to allow qualified IDR items and services to be batched by: (1) items and services furnished to a single patient

during a patient encounter on one or more consecutive dates of service and billed on the same claim form (single patient encounter); (2) items and services furnished to one or more patients and billed under the same service code, or a comparable code under a different procedural code system; or (3) anesthesiology, radiology, pathology, and laboratory IDR items and services furnished under service codes belonging to the same Category I CPT code range, as specified in guidance by the Departments, in order to address the unique circumstances of certain medical specialties and provider types.

Because these proposed rules would potentially allow batching of an unlimited number of qualified IDR items or services, the Departments also considered different approaches to mitigate the risk of large batches that may require certified IDR entities to review the eligibility for each line item, the acuity of each patient and/or other payment determination factors for each line item in the batch. First, the Departments considered modifying regulations related to the certified IDR entity fee to permit certified IDR entities to charge per line item. However, the Departments are of the view that a per line-item charge would present cost challenges for providers with lower dollar-value claims when utilizing the Federal IDR process. The Departments subsequently considered modifying the IDR entity fee structure such that the certified IDR entity could charge per unique service code, so that certified IDR entities would be able to be adequately compensated for the time and work involved in payment determinations, while allowing for flexibility to batch a greater number of line items per dispute. However, given the Departments' experience in managing the Federal IDR process, the Departments are of the view that such a modification to the certified IDR entity fee structure would still necessitate a line-item limit to ensure certified IDR entities are able to make payment determinations within the required 30-business-day period. It is the Departments' understanding that a per service code charge and line-item limit combined may unnecessarily restrict access to the Federal IDR process.

The Departments also considered limiting a batched dispute to more than 25 different payment offers. For line items in which the payment offers are equal, the certified IDR entity could resolve all such line items through its review of a single set of facts and documentation. A few certified IDR entities noted that it is easier to resolve payment determinations if the QPA is the same across codes. However, to accommodate batching of more than 25 qualified IDR items and services with equal payment offers, the initiating party would need to provide the offer for each line item or service earlier in the process such as during open negotiation or in the notice of IDR initiation as opposed to only at the time of the notice of offer. The Departments are of the view that this option would prove challenging because it would raise the issue of how to handle the limit of unique payment offers if the non-initiating party disagrees with the amount of unique payment offers. Further, under this approach, if the Departments would require offer information at the time of IDR initiation, the initiating party would only have 4 days to determine their offer following the end of the open negotiation period.

Lastly, the Departments considered imposing line-item limits to mitigate the risk of unwieldy batches. Specifically, the Departments considered proposing a limit of no more than 50 qualified IDR items or services in a batched determination. As of June 6, 2023, the average number of line items per batched dispute was 9 line items from April 2022 to June 2023. The Departments considered that while the average number of line items per batched dispute is much lower than the 50-line-item limit, this data is reflective of the number of line items a party can submit under the same service code, or a comparable code under a different procedural code system, and that there may likely be a higher average with the additional proposed batching flexibilities. Further, the Departments considered that 50 line items might, in some cases, still allow certified IDR entities to resolve payment determinations within the required 30-business-day period. However, based on their experience making payment determinations under the current batching rule, many certified IDR entities stated that batched determinations with more than 25 line items would be difficult to render payment determinations within the 30-business-

day period if the Departments proposed additional batching flexibilities. To ensure operational efficiency for certified IDR entities as they make their payment determinations and given the average number of line items in a batched dispute, the Departments propose to require that no more than 25 qualified IDR items and services may be considered jointly as part of one payment determination for the purposes of batched determinations.

8. Administrative and Certified IDR Entity Fee Collection (26 CFR 54.9816-8T(d), 29 CFR 2590.716-8(d), and 45 CFR 149.510(d))

The Departments considered maintaining the current policy that both the administrative fee and the certified IDR entity fee are due at the same time, later in the Federal IDR process. The Departments, however, determined that requiring a uniform 2-business-day requirement for the administrative fee to be paid by the parties was appropriate. The Departments are of the view that requiring payment by an initiating party within 2 business days of the date of preliminary selection of the certified IDR entity and by a non-initiating party within 2 business days of a notice of an eligibility determination by either the certified IDR entity or the Departments would substantially accelerate dispute throughput in the Federal IDR process and ensure that the costs of using the Federal IDR process are being allocated to both eligible and ineligible disputes.

Further, the Departments considered requiring the initiating party to pay the administrative fee within 1 business day of the date of preliminary selection of the certified IDR entity. The Departments considered whether the initiating party, by virtue of being the party that brings the dispute into the Federal IDR process, takes a more active role from the outset, and it should therefore be aware that it would be required to pay the administrative fee soon after initiating the dispute. In contrast, the Departments considered whether it was appropriate to allow the non-initiating party an additional business day from the date of notice of an eligibility determination to pay the administrative fee, because the non-initiating party neither controls when the dispute is initiated nor when eligibility is determined. On balance, the Departments determined a uniform 2 business day deadline from the date the administrative fee amount is

determined (which is at preliminary selection of the certified IDR entity for the initiating party and at notification of an eligibility determination for the non-initiating party) was appropriate to allow equitable payment timeframes for both disputing parties.

Further, the Departments considered requiring the non-initiating party to pay the administrative fee within 2 business days of preliminary selection of the certified IDR entity. However, because the Departments propose in these proposed rules that the non-initiating party may receive a reduced administrative fee for an ineligible dispute, the Departments determined requiring payment within 2 business days of notification of the eligibility determination was more appropriate. In making this determination, the Departments considered the additional burden associated with an overcharge to non-initiating parties for ineligible disputes, including the hold of additional administrative fees while eligibility is determined and operational costs to effectuate refunds to overcharged non-initiating parties.

The Departments considered maintaining the status quo of certified IDR entities collecting the administrative fee on behalf of the Departments. However, collection of the administrative fee by the certified IDR entities is inefficient, increases the burden of uncompensated work to certified IDR entities when the volume of ineligible disputes is high, and has historically resulted in low collection rates for ineligible disputes partially due to the existing administrative fee collection timing. The Departments also considered direct collection of both the administrative fee and certified IDR entity fee. The Departments are of the view that direct payment of the fee by the parties to the organization to which payment is ultimately owed (the Departments for the administrative fee and the certified IDR entity for the certified IDR entity fee) is more appropriate, especially in light of the different timing of these fee collections.

The Departments also considered only pursuing collection actions from all non-paying parties instead of moving up the timing of the fee collection. This option was counterbalanced by the expense associated with collection proceedings and the need to implement a policy that appropriately accounts for the financial burden of ineligible disputes.

The Departments considered allowing disputes to be placed on a temporary hold while fees are paid. However, ensuring all appropriate Federal IDR process fees are paid was counterbalanced by the need to implement an efficient Federal IDR process to determine out-of-network rates between providers, facilities, and providers of air ambulance services and plans, issuers, and FEHB carriers. The Departments are also of the view that a hold would not incentivize non-responsive parties to take action to challenge eligibility and further participate in open negotiation and the Federal IDR process, which are some of the goals of this proposal.

The Departments also considered charging only the initiating party a reduced administrative fee for low-dollar disputes and charging the non-initiating party the full administrative fee; however, the Departments determined this may be unnecessarily punitive to non-initiating parties in low-dollar disputes. Before proposing the highest offer from a disputing party during open negotiation as the proper metric to determine whether a dispute is low-dollar, the Departments considered setting the threshold for low-dollar disputes based on several metrics including the QPA, billed charge amount, and submitted offer. The Departments are of the view that the QPA is inappropriate because interested parties have expressed concerns about relying on the QPA as a determinative factor in the Federal IDR process. Similarly, billed charge amount was discarded as an option because it is a statutorily prohibited factor in payment determinations; thus, including it as an anchoring point for the administrative fee amount in the Federal IDR portal may lead disputing parties to believe the billed charge amount would be improperly considered by the certified IDR entity in making the final payment determination. Additionally, it would be inappropriate to utilize the final offer amount for two reasons. First, the parties may not know their offer amount when the certified IDR entity is selected and the administrative fee is billed. Second, utilizing the initiating party's offer amount may result in the non-initiating party having insight into the final offer of the initiating party, which may afford a negotiating advantage to non-initiating parties.

The Departments also considered creating an administrative fee that would be scaled based on the value of the dispute initiated, such as charging each disputing party an administrative fee that was 20 percent of the value of the dispute submitted. The Departments, however, are of the view that this approach is not appropriate for two reasons. First, the value of disputes can have a wide range, such as a $5 million dispute for a NICU inpatient hospital stay compared to a $500 outpatient service. This example structure would result in parties to the former dispute paying a $1 million administrative fee and parties to the latter dispute paying a $100 administrative fee. Second, the Departments recognize that resolving a dispute generally costs the Departments the same amount regardless of whether the dispute involves low-dollar or high-dollar items or services, and the Federal IDR process is intended to streamline resolution of payment disputes between plans or issuers and providers or facilities. Further, the nature of estimating the administrative fee based on the expenditures made by the Departments in a given year means the administrative fee is not particularized to an individual dispute. This makes a sliding scale impractical to apply to the wide range of disputes subject to the Federal IDR process. Finally, the Departments considered maintaining a flat administrative fee applicable to all disputes but determined that the impact of a flat administrative fee amount on parties seeking to initiate low-dollar disputes could make the Federal IDR process cost prohibitive for some initiating parties.

The Departments considered applying a standardized administrative fee to all parties in all disputes regardless of eligibility. After considering a uniform application, the Departments determined that a framework that better accounts for eligibility costs based on the role of the disputing party and the eligibility of the dispute was a more appropriate distribution of the Departments' expenditures which the administrative fee is designed to recoup. The Departments also had concerns that non-initiating parties could be penalized by paying for an ineligible dispute if an initiating party indiscriminately submitted disputes; however, given that an initiating party must pay the administrative fee for a dispute to be considered fully submitted and

for the fee to be assessed to both parties, the Departments are of the view that there are sufficient safeguards in place. Further, the Departments also considered not charging non-initiating parties for ineligible disputes; however, because the statute indicates that each party to a dispute is responsible for the administrative fee, and even in ineligible disputes the non-initiating party is benefiting from Federal IDR process safeguards such as access to the proposed registry and open negotiation, the Departments are of the view that a payment of a reduced administrative fee for non-initiating parties is appropriate, even in disputes that are not eligible for the Federal IDR process. The Departments recognize that the timelines described in this proposed policy may place additional burden on resource constrained small entities. However, the Departments believe that any additional burden to small entities will be significantly outweighed by the additional benefits to small entities from the proposed policies regarding low dollar and ineligible disputes..

9. Extension of Time Periods for Extenuating Circumstances (26 CFR 54.9816-8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g))

Under the proposed amendments to 26 CFR 54.9816-8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g), the Departments would provide an extension of the time periods associated with the Federal IDR process if they identify unforeseen or good cause delays on a case-by-case basis, as opposed to solely relying on one of the parties to submit an extension request. Further, the Departments also propose to codify a generally applicable extension of time periods when the Departments determine that such extension is necessary due to extenuating circumstances that contribute to systematic delays in processing disputes under the Federal IDR process, such as an unforeseen high volume of disputes or Federal IDR portal system failures.

The Departments considered alternatives to these proposals, including maintaining the status quo and not proposing to modify the ability of the Departments to provide extensions on a case-by-case basis or for generally applicable extensions of time periods. Additionally, the Departments considered only proposing the former, and not proposing to codify generally

applicable extensions. However, the Departments are of the view that both proposed pathways to granting extensions of time periods for extenuating circumstances are relevant and necessary for the parties and entities participating in the Federal IDR process. In particular, the Departments are of the view that the ability to grant generally applicable extensions of time periods due to extenuating circumstances that contribute to systematic delays would provide protection for parties engaged in the Federal IDR process from the impact of systematic processing delays and ensure that unforeseen circumstances do not unfairly disadvantage a party or hinder its ability to comply with the Federal IDR process timeframes. Furthermore, the Departments believe that these additional protections may be especially beneficial to small entities, which may face difficulty in complying with the timelines proposed in this rulemaking. This proposed policy may partially offset the additional timeframe compliance burden placed on small entities, as described throughout this section, by providing greater flexibility in obtaining extensions in extenuating circumstances.

10. Registration of Group Health Plans and Health Insurance Issuers (26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530)

These proposed rules would require plans and issuers to submit certain information to the Departments within 30 business days after the effective date of the final rules through an IDR registration process, and would make the resulting registry of plans and issuers available to parties initiating open negotiation requests or disputes through the Federal IDR portal. The Departments also recognize that this proposed policy may impose additional burden on resource constrained small entities by requiring them to submit additional information to the Departments. The Departments considered limiting registration information to a plan's or issuer's contact information and plan type (for example, fully-insured, self-insured, etc.). However, the Departments are of the view that this limited set of information would be insufficient to allow providers, facilities, and providers of air ambulances to initiate open negotiation and disputes correctly. For example, if a plan submitted information that it was self-insured but did not submit

information showing that it had opted into a specified State law, a provider might incorrectly initiate a payment dispute in the Federal IDR process rather than the relevant State process. The Departments also considered requiring more comprehensive registration information, including a list of items and services that the plan covers which would be subject to a specified State law or All-Payer Model Agreement. The Departments are of the view that this level of detail would be overly burdensome on plans and issuers. Additionally, since States regularly modify the requirements of their specified State laws and All-Payer Model Agreements, the information contained in the registry would frequently be out-of-date. The Departments also considered allowing plans and issuers a period of one year following the rules' effective date to register; however, the Departments are of the view that since plans and issuers are already required to disclose most of the proposed registration information, requiring registration by 30 business days after the rules' effective date would not be unduly burdensome.

F. Paperwork Reduction Act—Department of Health and Human Services, Department of Labor, and Department of the Treasury

Under the Paperwork Reduction Act of 1995 (PRA), the Departments are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments solicit comment on the following issues:

● The need for information collection and its usefulness in carrying out the proper functions of the Departments.

● The accuracy of the Departments' estimate of the information collection burden.

● The quality, utility, and clarity of the information to be collected.

● Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

1. Wage Estimates

To derive wage estimates, the Departments generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the information collection requirements (ICRs).[209] Table 9 presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage from the May 2022 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*).

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers and because methods of estimating these costs vary widely across studies.

TABLE 9: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hour)	Fringe Benefits and Overhead ($/hour)	Adjusted Hourly Wage ($/hour)
Computer Programmers	15-1251	$49.42	$49.42	$98.84
General and Operations Manager	11-1021	$59.07	$59.07	$118.14
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	$20.87	$20.87	$41.74
Compensation and Benefits Manager	11-3111	$68.82	$68.82	$137.64
Medical and Health Services Manager	11-9111	$61.53	$61.53	$123.06
Office Clerk	43-9061	$19.78	$19.78	$39.56

2. ICRs Regarding Information to be Shared About the QPA (26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d))

The July 2021 interim final rules, as updated by the August 2022 final rules, require plans and issuers to provide certain information regarding the QPA to providers, facilities, and providers of air ambulance services when making an initial payment or notice of denial of payment when the QPA is the recognized amount (or, for air ambulance services, the amount on which cost sharing is based).

[209] *Id.*

These proposed rules would require plans and issuers to disclose the legal business name of the group health plan (if any) or issuer; the legal business name of the plan sponsor (if applicable); and the assigned Federal IDR registration number (if the plan or issuer is registered with the Federal IDR registry). In addition, these proposed rules would amend the statement required under 26 CFR 54.9816-6(d)(1)(iv), 29 CFR 2590.716-6(d)(1)(iv), and 45 CFR 149.140(d)(1)(iv) to make technical and conforming changes to the content of the statement.

The Departments assume that TPAs would provide this information on behalf of the self-insured plans they administer. The Departments assume that issuers and TPAs would automate the process of preparing and providing this information to providers, facilities, and providers of air ambulance services. The Departments anticipate that issuers and TPAs would need to make a one-time change to their IT systems to make changes to the currently required QPA notification to incorporate the proposed information described in the proposed new paragraph (d)(1)(v) and paragraph (d)(1)(iv). The Departments estimate that for each plan and issuer, on average, it would take a computer programmer 3 hours (at an hourly rate of $98.84) to add fillable fields to disclose the legal business name (if any) of the group health plan or issuer; the legal business name of the plan sponsor (if applicable) and the assigned Federal IDR registration number (if the plan or issuer is registered with the Federal IDR registry); to add information notifying the provider, facility, or provider of air ambulance services of the proposed requirement to notify the Departments to initiate open negotiation; and to replace the phrase "amount of total payment" with the term "out-of-network rate" and the term "determination" with the phrase "agreement on the amount of payment" in the statement about initiating open negotiation. The Departments estimate that the one-time burden for each plan or issuer, to be incurred in 2024, would be 3 hours on average, with an equivalent cost of approximately $297. The Departments estimate a total one-time burden, for all issuers and TPAs, of 5,115 hours, with an associated cost of approximately $505,567. As the Departments share jurisdiction, HHS would account for 50 percent of the total burden, or approximately 2,558 burden hours, with an equivalent cost of

approximately $252,783. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 1,279 burden hours, with an equivalent cost of approximately $126,392. The Departments seek comment on these burden estimates.

In addition, the Departments propose to revise the regulation addressing information to be shared about the QPA to make clear these disclosures are required when the recognized amount (or for air ambulance services, the amount on which cost sharing is based) is the QPA or the amount billed by the provider, facility, or provider of air ambulance services. The Departments anticipate that this is not a common occurrence and therefore would not result in an increase in burden for plans and issuers.

TABLE 10: One-Time IT Burden and Cost for Plans and Issuers to Incorporate Information Related to QPA to Providers, Facilities, and Providers of Air Ambulance Services

Year	Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
2024	HHS	853	853	3	2,557.5	$252,783
	Labor	426	426	3	1,278.8	$126,392
	Treasury	426	426	3	1,278.8	$126,392

The Departments would revise the information collection currently approved under OMB control number 0938-1401 to account for this new burden.[210]

3. ICRs Regarding Open Negotiation (26 CFR 54.9816-8(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1))

The Departments propose to require a party to provide an open negotiation notice containing additional required elements and supporting documentation to the other party and the Departments to initiate the open negotiation period. The October 2021 interim final rules established that the initiating party must provide an open negotiation notice to the other party which must include information sufficient to identify the items or services subject to negotiation,

[210] OMB Control Number: 0938-1401 (CMS-10780, Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in).

including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice. The provisions in these proposed rules would expand the required information in an open negotiation notice to include 12 new content additions to the existing required elements. The expanded content requirements would include: (1) information sufficient to identify the provider, facility or provider of air ambulance services, including name and current contact information (including the legal business name, email address, phone number, and mailing address) and the National Provider Identifier (NPI); (2) the plan's or issuer's registration number as required under 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 (if the plan or issuer is not registered under 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, an attestation by the party submitting the open negotiation notice that the plan or issuer was not registered by the date it submitted the open negotiation notice), the legal business name of the plan or issuer as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment), and if the party submitting the open negotiation notice is a plan or issuer, the plan type (for example, self-insured or fully-insured); (3) the name and contact information including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation notice and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation; (4) information sufficient to identify the item or service, including, but not limited to: the date(s) the item or service was furnished and the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer; the type of item or service (including, whether the item or service is an emergency service as defined in 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716–4(c)(2), and 45 CFR 149.110(c)(2), non-emergency times and services as described in 26 CFR 54.9816-5T(b), 29 CFR 2590.716-5(b), and 45 CFR

149.120(b); or an air ambulance service as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30; whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information sufficient to identify the location the item of service was furnished (such as place of service code or bill type); (5) the initial payment amount (including $0 if, for example, payment is denied); (6) the QPA if provided with the initial payment or denial of payment; (7) an offer of an out-of-network rate for each item or service; (8) if the party submitting the open negotiation notice is a plan or issuer, the amount of cost sharing imposed for the item or service; (9) if the party submitting the open negotiation notice is a provider or facility, a statement that the patient who received the item or service did not receive notice or provide consent as described in 45 CFR 149.410(b) or 149.420(c) through (i) to be treated by a nonparticipating provider or nonparticipating emergency facility; (10) a statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished; (11) general information listed in the standard open negotiation notice developed by the Departments describing the open negotiation period and the Federal IDR process (including a description of the purpose of the open negotiation period and Federal IDR process and key deadlines in the open negotiation period and Federal IDR process); and (12) a copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1) for the item or service.

Furthermore, the Departments propose that the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice through the Federal IDR portal no later than the 15th business day of the 30-business-day open negotiation period. The proposed open negotiation response notice would require the following categories of information, beginning with the same information as specified in proposed 26 CFR 54.9816-

8(b)(1)(ii)(A)(*1*) through (*3*), 29 CFR 2590.716-8(b)(1)(ii)(A)(*1*) through (*3*), and 45 CFR 45 CFR 149.510(b)(1)(ii)(A)(*1*) through (*3*) related to the requirements to provide contact information for the provider, facility, or provider of air ambulance services, and the plan or issuer that is a party to the open negotiation, and any third party representing a party in the open negotiation. It would also include (4) information sufficient to identify each item or service included in the open negotiation notice, including the date(s) the item or service was furnished and the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer and the claim number; (5) if the party in receipt of the open negotiation notice is a plan or issuer, a statement as to whether the party in receipt of the open negotiation notice agrees that the initial payment amount (including $0 if, for example, payment is denied) and the QPA reflected in the open negotiation notice is accurate for the item or service, and if not, or if the open negotiation notice indicated that the initial payment amount or qualifying payment amount was not communicated by the plan or issuer with the initial payment or notice of denial of payment or other remittance advice, the initial payment amount (including $0 if, for example, payment is denied) and/or QPA amount it believes to be correct and documentation to support the statement; (6) if the party in receipt of the open negotiation notice is a plan or issuer, the amount of cost sharing imposed for the item or service; (7) a counteroffer of an out-of-network rate for the item or service or an acceptance of the other party's offer; (8) if the party in receipt of the open negotiation notice is a provider or facility, a statement that the patient who received the item or service did not receive notice or provide consent to be treated by a nonparticipating provider or nonparticipating emergency facility as described in 149.410(b) or 149.420(c) through (i); (9) with respect to each item or service, either a statement and supporting documentation that notes why the item or service is ineligible for the Federal IDR process or a statement agreeing that the item or service is eligible for the Federal IDR process; (10) a statement as to whether any of the information provided in the open negotiation notice is inaccurate and the basis for the assertion;

and (11) a statement confirming that the initial payment or notice of denial of payment or other remittance advice provided with the open negotiation notice is accurate, and if inaccurate, a copy of the initial payment or notice of denial of payment or other remittance advice that are required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), for the item or service.

In addition to the paperwork costs for the Federal IDR process previously accounted for in the July 2021 interim final rules and October 2021 interim final rules, the Departments estimate that it would take a compensation and benefits manager 30 minutes (at an hourly rate of $137.64) and an office clerk 15 minutes (at an hourly rate of $39.56) on average to prepare and submit the additional information for open negotiation for each plan, issuer, or FEHB carrier and provider or facility initiating open negotiation. This results in a cost of $78.71 per party per open negotiation notice. Similarly, the Departments estimate that it would take a compensation and benefits manager 30 minutes (at an hourly rate or $137.64) and an office clerk 15 minutes (at an hourly rate of $39.56) on average to prepare and submit the proposed open negotiation response notice for each party in receipt of the open negotiation notice, resulting in a cost of $78.71 per party per open negotiation response notice. In the October 2021 interim final rules, the Departments originally estimated that 25 percent of disputes would be resolved in open negotiation before entering the Federal IDR process.[211] The Departments request data or comments on whether this assumption has been proven correct. Accordingly, the Departments estimate that 560,000 disputes per year would go through open negotiation, requiring 560,000 initiating parties to prepare and submit the additional materials proposed for the open negotiation notice and 560,000 non-initiating parties to prepare and submit the additional materials proposed for the open negotiation notice response notice. At a cost of $78.71 ($68.82 for 30 minutes by the compensation and benefits manager and $9.89 for 15 minutes by the office clerk, or a combined hourly rate of $104.95) per party per dispute, this results in a total annual hour burden of 840,000

[211] 86 FR 56056.

hours with an equivalent cost of approximately $88,158,000 for 560,000 disputes annually beginning in 2025.[212] As the Departments and OPM share jurisdiction, HHS would account for 45 percent of the total burden, or approximately 378,000 burden hours, with an equivalent cost of approximately $39,671,100. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 210,000 burden hours, with an equivalent cost of approximately $22,039,500. OPM would account for 5 percent of the total burden, or approximately 42,000 burden hours, with an equivalent cost of approximately $4,407,900. The Departments seek comment on these assumptions.

TABLE 11: Annual Burden and Cost for Open Negotiation

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	472,500	472,500	0.75	378,000	$39,671,100
Labor	262,500	262,500	0.75	210,000	$22,039,500
Treasury	262,500	262,500	0.75	210,000	$22,039,500
OPM	52,500	52,500	0.75	42,000	$4,407,900

The Departments would revise the information collection currently approved under OMB control number 1210-0169 to account for this new burden.[213]

4. ICRs Regarding Initiating the Federal IDR Process and the Notice of IDR Initiation (26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2))

a. Notice of IDR Initiation and Notice of IDR Initiation Response

To initiate the Federal IDR process, the initiating party must submit a written notice of IDR initiation to the non-initiating party and to the Departments (using the standard form developed by the Departments) during the 4-business-day period beginning on the first business day after the close of the 30-business-day open negotiation period. The Departments propose to add additional required elements under the 8 categories to the existing required information in

[212] As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 420,000 hours with an equivalent cost of $44,079,000.
[213] OMB Control Number: 1210-0169 (No Surprises Act: IDR Process).

the written notice of IDR initiation: (1) information sufficient to identify the initiating party, including the TIN, the NPI of the provider, facility, or provider of air ambulance services (if available), the plan's or issuer's registration number, if the plan or issuer is registered under 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, and if the initiating party is a plan or issuer, the plan type; (2) the name and contact information for any third party representing the initiating party and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process; (3) information sufficient to identify whether the dispute being initiated includes batched or bundled qualified IDR items or services; (4) information sufficient to identify the item or service included in the notice of IDR initiation, including the date(s) the item or service was furnished. If the initiating party is a provider, facility, or provider of air ambulances, the date(s) the provider, facility, or air ambulance provider received the initial payment or denial of payment, the date the open negotiation period began, the type of item or service, whether the service is a professional or service or facility-based service, the State where the item or service was furnished, the claim number, service code and information to identify the location the service was furnished (including place of service or bill type code); (5) if the non-initiating party is a plan or issuer, a statement that the provider, facility, or air ambulance provider was a nonparticipating provider, facility, or air ambulance provider; (6) an attestation that the item or service is a qualified IDR item or service and the basis for the attestation; (7) a copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service; and (8) a statement describing the key aspects of the claim, such as patient acuity or level of training of the provider, facility, or provider of air ambulance services that furnished the qualified IDR item or service, discussed by the parties during open negotiation that relate to the payment for the disputed claim, whether the reasons for initiating the Federal IDR process are different from the

aspects of the claim discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process.

The Departments also propose that the non-initiating party must submit a written response to the notice of IDR initiation to the initiating party and to the Departments during the 3-business-day period beginning on the day after the notice of IDR initiation is received by the Departments. This proposed IDR initiation response notice would require the following information: (1) information sufficient to identify the provider, facility, or provider of air ambulance services, including name and current contact information (including the legal business name, email address, phone number, and mailing address), the TIN, the NPI of the provider, facility, or provider of air ambulance services, (2) information sufficient to identify the plan or issuer including the plan's or issuer's registration number, as required under 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 or an attestation from the non-initiating party that the plan or issuer was not registered prior to the date that it submitted the notice, the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the notice of IDR initiation response is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor); (3) the name and contact information for any third party representing the non-initiating party and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process; (4) information sufficient to identify each item or service (including the date(s) the item or service was furnished, if the non-initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number); (5) if the non-initiating party is a plan or issuer, a statement as to whether the non-initiating party agrees that the initial payment (including $0 if, for example,

payment is denied) and the QPA reflected in the notice of IDR initiation is accurate and if not, an assertion of the correct initial payment amount and/or the QPA that was disclosed with the initial payment or notice of denial of payment for the item or service and documentation to support the assertion; (6) if the non-initiating party is a plan or issuer, the amount of cost sharing imposed for the item or service; (7) if the non-initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at CFR 149.410(b) or 149.420 (c); (8) for each item or service subject to the dispute, an attestation that the item or service that is the subject of the dispute is a qualified IDR item or service, and for each item or service that the non-initiating party attests is not a qualified IDR item or service, an explanation and supporting documentation; (9) a statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the initiating party under paragraph (b)(2)(ii)(A)(*12*) is accurate, and if inaccurate, a copy of the remittance advice or other documentation required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service; (10) a statement as to whether any of the information provided in the notice of IDR initiation is inaccurate and the basis for the statement as well as any supporting documentation; and (11) a statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity and if the party objects, an alternative preferred certified IDR entity.

In addition to the paperwork costs for the Federal IDR process, the Departments estimate that it would take a compensation and benefits manager 30 minutes (at an hourly rate of $137.64) and an office clerk 15 minutes (at an hourly rate of $39.56) on average to prepare and submit the additional statements proposed for the notice of IDR initiation for each initiating party, resulting in a cost of $78.71 per party per notice of IDR initiation. Similarly, the Departments estimate that it would take a compensation and benefits manager 30 minutes (at an hourly rate of $137.64) and an office clerk 15 minutes (at an hourly rate of $39.56) on average to prepare and submit the

proposed notice of IDR initiation response for each non-initiating party, resulting in a cost of $78.71 per party per notice of IDR initiation response. The Departments estimate that 420,000 disputes would be initiated, requiring work by 840,000 disputing parties. At a per party cost of $78.71 ($68.82 for 30 minutes by the compensation and benefits manager at $137.64 per hour and $9.89 for 15 minutes by the office clerk at $39.56 per hour, or a combined hourly rate of $104.95) per party, this results in a total estimated annual hour burden of 630,000 hours or an equivalent cost burden of $66,118,500 for 420,000 disputes, which includes 315,000 estimated annual burden hours or an equivalent annual cost burden of $33,059,250 each for initiating and non-initiating parties, respectively, beginning in 2025.[214] As the Departments and OPM share jurisdictions, HHS would account for 45 percent of the total burden, or approximately 283,500 burden hours, with an equivalent cost of approximately $29,753,325. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 157,500 burden hours, with an equivalent cost of approximately $16,529,625. OPM would account for 5 percent of the total burden, or approximately 31,500 burden hours, with an equivalent cost of approximately $3,305,925. The Departments seek comment on these assumptions.

TABLE 12: Annual Burden and Cost for Notice of IDR Initiation

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	378,000	378,000	0.75	283,500	$29,753,325
DOL	210,000	210,000	0.75	157,500	$16,529,625
Treasury	210,000	210,000	0.75	157,500	$16,529,625
OPM	42,000	42,000	0.75	31,500	$3,305,925

The Departments would revise the information collection currently approved under OMB control number 1210-0169 to account for the new burden.[215]

[214] As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 315,000 hours with an equivalent cost of $33,059,250.
[215] OMB Control Number: 1210-0169 (No Surprises Act: IDR Process).

b. Preliminary Selection of the Certified IDR Entity

The Departments anticipate that the amendments to the process for the preliminary selection of the certified IDR entity would reduce the overall burden associated with collecting information through the notice of certified IDR entity selection. In these proposed rules, the Departments propose that the non-initiating party must agree or object to the preferred certified IDR entity in the notice of IDR initiation response. Accordingly, the initiating party would only be required to submit the notice of certified IDR entity selection if the non-initiating party objects to the initiating party's preferred certified IDR entity and submits an alternative preferred certified IDR entity in the notice of IDR initiation response, thus limiting the frequency with which the Departments expect the initiating party to submit this information. Similarly, the non-initiating party would only be required to use the notice of certified IDR entity selection if the non-initiating party objected to the initiating party's alternative preferred certified IDR entity included in the initiating party's notice of certified IDR selection form. The content submitted through the notice would also be streamlined to only reflect information confirming the party's agreement or objection, preferred alternative to other party's alternative preferred certified IDR entity, and if applicable, an explanation of the conflict of interest with the alternative preferred certified IDR entity.

Under the current rules and currently approved PRA package (OMB control number 1210-0169), the Departments assume that all disputes require the submission of the notice of certified IDR entity selection, and that each notice corresponds to approximately 1.25 burden hours, with an equivalent cost of $119.[216] Across all disputes, the Departments assume an annual burden of approximately 21,794 hours at a cost of approximately $2,156,635 for parties to submit the notice of certified IDR entity selection. However, based on these proposed rules, the

[216] The Departments assume that it will take 1 hour for a medical and health services professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice at a wage rate of $109.03 per hour for the medical and health services manager and a wage rate of $58.66 per hour for the clerical worker.

Departments anticipate that the frequency and content of this collection would change, thus impacting the currently estimated burden.

Under these proposed rules, this information collection would be limited to those disputes in which either party does not agree to the other party's preferred alternative certified IDR entity. For this subset of disputes, the initiating party would be required to submit the notice of certified IDR entity selection to indicate agreement or objection to the non-initiating party's alternate preferred certified IDR entity selection as indicated in the notice of IDR initiation response, and both parties would have the ability to submit the notice back-and-forth during the 3-day period after the date of IDR initiation until an agreed upon entity is identified or the parties fail to jointly agree. The content of the collection would be revised to only require a party to indicate their agreement or objection and if applicable an explanation of the conflict of interest, and identification of an alternate preferred certified IDR entity and thus the Departments anticipate that it would take a respondent much less time to submit this information than previously estimated.

Based on internal data, in approximately 29 percent of disputes, the non-initiating party objects to the certified IDR entity selected by the initiating party. Further, out of the 29 percent of disputes in which the non-initiating party objected to the certified IDR entity selected by the initiating party, the majority of those disputes (93 percent, or 27 percent of all disputes) the initiating party agreed to the alternate preferred certified IDR entity selected by the non-initiating party. In a very small percentage (approximately 2 percent) of disputes, the non-initiating party and initiating party engage in a back-and-forth by objecting to each other's preferred certified IDR entities multiple times. Based on the number of disputes submitted from June 2022 through June 2023, the Departments estimate that approximately 113,400 disputes would require the initiating party to submit a notice of certified IDR entity selection form a single time. The Departments estimate that it would take an office clerk 30 minutes (at an hourly rate of $39.56) on average to prepare and submit the notice indicating agreement or objection to the alternate

preferred certified IDR entity and selecting an alternative entity, if applicable. This would result in a cost of $19.78 per dispute. For the approximately 113,400 disputes that would require this collection, the total annual hourly burden would be 56,700 hours, with an equivalent annual cost of approximately $2,243,052.[217]

In addition, the Departments expect that, for a small proportion of disputes, the initiating party and the non-initiating party would exchange the notice of certified IDR entity selection multiple times within the proposed timeframe before reaching agreement and jointly selecting or defaulting to random selection. To reflect the additional burden associated with disputes requiring multiple notices, the Departments estimate that approximately 8,400 disputes would require the provision of two total rounds of notice exchange[218] by the initiating party and non-initiating party before either jointly selecting a certified IDR entity or defaulting to selection by the Departments. This would result in a cost of $39.56 per dispute, and a total annual hourly burden of 8,400 hours with an equivalent cost of $332,304.[219]

The Departments estimate that in total for disputes requiring this collection, including both the 113,400 disputes that the Departments anticipate would require a single submission of the notice of certified IDR entity selection form and the 8,400 disputes requiring multiple submissions of the form, the average burden per response would be approximately 0.53 hours[220] with an equivalent cost of approximately $21.14 per response.[221] Therefore, the total annual

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[217] The is calculated as follows: 113,400 disputes x 0.5 hours = 56,700 burden hours. 56,700 burden hours x $39.56 hourly rate = $2,243,052 total annual cost.

[218] Internal data show that the highest number of times a certified IDR entity was selected for a single dispute was five. Since these proposed rules would amend the frequency of use of the notice of certified IDR entity selection by transferring one of the selection instances to the notice of IDR initiation, five unique selections would correspond to four exchanges of the notice of certified IDR entity selection. However, the Departments anticipate that four exchanges would be quite rare based on internal data, so the Departments are using two exchanges of the notice of certified IDR entity selection in these estimates. The Departments seek comment on these assumptions.

[219] This is calculated as follows: 8,400 disputes x 0.5 hours x 2 exchanges = 8,400 burden hours. 8,400 burden hours x $39.56 hourly rate = $332,304 total annual cost.

[220] The precise unrounded number for the weighted average time per response is 0.53448 hours. This unrounded number is used to calculate the total annual burden across the disputes requiring the submission of a certified IDR entity selection notice. The calculation is as follows: 0.53448 weighted average time per response x 121,800 disputes = 65,100 total annual burden hours

[221] This is calculated as follows: 0.53 hours x $39.56 hourly rate = $21.14 cost per response.

burden would be 65,100 hours, with an equivalent cost of $2,575,356.[222] As the Departments and OPM share jurisdiction, HHS would account for 45 percent of the total burden, or approximately 29,295 burden hours, with an equivalent cost of approximately $1,158,910. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 16,275 burden hours each, with an equivalent cost of approximately $643,839 each. OPM would account for 5 percent of the total burden, or approximately 3,255 burden hours, with an equivalent cost of approximately $128,768.

However, as discussed earlier in this section, as the current information collection assumes a burden per respondent of 1.25 hours and a total cost burden of $2,156,635, the Departments estimate a total increase in costs of approximately $418,621[223] due to the proposed changes to the requirement to submit this notice. The Departments seek comment on these assumptions.

TABLE 13: Annual Burden and Cost for Notice of Certified IDR Entity Selection Form

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	44,370	44,370	0.53	29,295	$1,158,910
Labor	24,650	24,650	0.53	16,275	$643,839
Treasury	24,650	24,650	0.53	16,275	$643,839
OPM	4,930	4,930	0.53	3,255	$128,768

The Departments would revise the information collection currently approved under OMB control number 1210-0169 to account for this revised burden.

5. ICRs Regarding Federal IDR Eligibility Determinations (26 CFR 54.9816-8(c), 29 CFR 2590.716-8(c), and 45 CFR 149.510(c))

The Departments anticipate no change or nominal change in burden related to the proposed departmental eligibility review provision. This information collection is approved

[222] As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 32,550 hours with an equivalent cost of $1,287,678.
[223] This is calculated as follows: $2,156,635 - $2,575,256 = -$418,621.

under OMB control number 1210-0169. The same type and quantity of information would continue to be collected from disputing parties to determine eligibility under these proposed rules. When the departmental eligibility review is in effect, the Departments would be collecting information related to Federal IDR dispute eligibility. When the departmental eligibility review is not in effect, the Departments and the certified IDR entities would be collecting this information. Therefore, the Departments are of the view that there is no change in burden associated with changing to whom the parties are submitting eligibility information. The Departments seek comment on these assumptions.

6. ICRs Regarding Withdrawals (26 CFR 54.9816–8(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii))

The Departments propose to add 26 CFR 54.9816–8(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), and 45 CFR 149.510(c)(3)(ii) to establish a process for disputes to be withdrawn from the Federal IDR process. The proposed withdrawal process would require the creation of a new collection of information and increase burden on the initiating and non-initiating parties required to submit the proposed notice. These proposed rules would require the initiating party to submit a withdrawal request to the Departments and the non-initiating party through the Federal IDR portal. The non-initiating party would then be required to provide a response within 5 business days indicating agreement or objection to the request for withdrawal. Each dispute would therefore require a collection from both the initiating (requesting) and the non-initiating (responding) parties in order to withdraw. If the non-initiating party fails to respond, the non-initiating party would be considered to have agreed to the dispute's withdrawal. The Departments expect that dispute withdrawals would be relatively rare: Based on internal data, the Departments anticipate that approximately 4 percent of disputes (or 16,800 disputes) would be withdrawn annually.

The Departments estimate that it would take a compensation and benefits manager 15 minutes (at an hourly rate of $137.64) and an office clerk 15 minutes (at an hourly rate of

$39.56) for the initiating party to prepare and submit the notice of request for withdrawal to the non-initiating party and the Departments through the Federal IDR portal, resulting in a time of 30 minutes and cost of $44.30 per dispute for the initiating party.[224] For the anticipated 16,800 withdrawn disputes annually, initiating parties would incur a total of 8,400 burden hours with an equivalent cost burden of $744,240 to submit withdrawal requests annually.[225] Because the notice of withdrawal response would have fewer data elements and would require a lower amount of time and labor burden to submit, the Departments estimate that it would take an office clerk approximately 15 minutes (at an hourly rate of $39.56) on average for the non-initiating party to submit the notice of withdrawal response to the initiating party and the Departments through the Federal IDR portal, resulting in a cost of $9.89 per response.[226] For the anticipated 16,800 withdrawn disputes annually, the non-initiating party would incur a total of 4,200 burden hours or an equivalent cost burden of $166,152 to submit withdrawal responses annually.[227] This results in a total estimated annual burden of 12,600 hours or an equivalent cost burden of $910,392 across both the initiating and non-initiating parties.[228]

As the Departments and OPM share jurisdictions, HHS would account for 45 percent of the total burden, or approximately 5,670 burden hours, with an equivalent cost of approximately $409,676. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 3,150 burden hours, with an equivalent cost of approximately

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[224] This is calculated as follows: 0.25 hours per response x $137.64 hourly rate for a compensation and benefits manager = $34.41 per response. 0.25 hours per response x $39.56 hourly rate for an office clerk = $9.89 per response. $34.41 + $9.89 = $44.30 total per response.

[225] This is calculated as follows: 16,800 disputes x 0.5 labor hours per dispute = 8,400 total burden hours. 16,800 disputes x $44.30 per dispute = $744,240 total cost. As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 4,200 hours with an equivalent cost of $372,120.

[226] This is calculated as follows: 0.25 hours pe response x $39.56 hourly rate for an office clerk = $9.89 per response.

[227] This is calculated as follows: 16,800 disputes x 0.25 labor hours per dispute = 4,200 total burden hours. 16,800 disputes x $9.89 = $166,152 total cost. As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 2,100 hours with an equivalent cost of $83,076.

[228] This is calculated as follows: 8,400 total initiating party burden hours + 4,200 total non-initiating party burden hours = 12,600 overall total burden hours. $744,240 total initiating party cost + $166,152 total non-initiating party cost = $910,392 overall total cost. As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 6,300 hours with an equivalent cost of $455,196.

$227,598. OPM would account for 5 percent of the total burden, or approximately 630 burden hours, with an equivalent cost of approximately $45,520. The Departments seek comment on these assumptions.

TABLE 14: Annual Burden and Costs for Withdrawals

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	7,560	7,560	0.75	5,670	$409,676
Labor	4,200	4,200	0.75	3,150	$227,598
Treasury	4,200	4,200	0.75	3,150	$227,598
OPM	840	840	0.75	630	$45,520

The Departments would revise the information collection currently approved under OMB control number 1210-0169 to account for this proposed burden.

7. ICRs Regarding Administrative and Certified IDR Entity Fee Collection (26 CFR 54.9816-8(d), 29 CFR 2590.716-8(d), and 45 CFR 149.510(d))

The Departments propose to allow for the administrative fee due from each party for participating in the Federal IDR process to be paid to the Departments. The burden currently associated with this requirement is the time and effort for a certified IDR entity to track payments made by disputing parties and submit the administrative fees to HHS upon invoice. In the No Surprises Act: IDR Process PRA package,[229] the Departments estimated that tracking payments made by disputing parties and submitting the administrative fees to HHS upon invoice would take a clerical worker (a secretary or administrative assistant, not including legal, medical, or executive) approximately 18 hours annually (at a rate of $39.56 per hour). The Departments estimated that each certified IDR entity would incur a burden of 18 hours annually at a cost of approximately $711 per certified IDR entity to comply with the administrative fee reporting and submission requirements.

[229] OMB Control Number: 1210-0169 (No Surprises Act: IDR Process). The burden is estimated as follows: (18 hours x $39.56) = $712.08 per certified IDR entity. A labor rate of $39.56 is used for a clerical worker (a secretary or administrative assistant, not including legal, medical, or executive). The labor rates are applied in the following calculation: (13 certified IDR entities x 18 hours x $39.56) = $9,257.04.

Since this proposal would eliminate the requirement that certified IDR entities collect the administrative fee on behalf of the Departments, the Departments propose to rescind this information collection. The burden associated with this information collection estimated above would be removed if this proposal is finalized, since certified IDR entities would no longer be collecting the administrative fee moving forward.

The Departments estimate a total burden reduction, for 13 certified IDR entities, of 234 hours, with an associated cost reduction of approximately $9,257 beginning in 2025. As the Departments share jurisdiction, HHS would account for 45 percent of the total burden reduction, or a reduction of approximately 108 burden hours, with an equivalent cost reduction of approximately $4,272. The Departments of Labor and the Treasury would each account for 25 percent of the total burden reduction, or approximately 54 burden hours each, with an equivalent cost reduction of approximately $2,136. OPM would account for 5 percent of the total burden reduction, or approximately 18 burden hours, with an equivalent cost reduction of approximately $712. The Departments seek comment on these assumptions.

TABLE 15: Annual Burden and Cost for Administrative Fee Collection

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	6	6	(18)	(108)	($4,272)
Labor	3	3	(18)	(54)	($2,136)
Treasury	3	3	(18)	(54)	($2,136)
OPM	1	1	(18)	(18)	($712)

This information collection is approved under OMB control number 1210-0169, and if this proposal is finalized, the Departments would rescind this information collection under OMB control number 1210-0169 accordingly. The Departments seek comment on this proposed burden reduction.

The Departments also propose to collect one new information collection element in the Federal IDR portal associated with the administrative fee. The Departments propose to require

the initiating party to attest (for example, by checking a box) in the portal that no offer made by either party during open negotiation exceeded a predetermined threshold discussed in section II.E.3.f. of this preamble, to determine whether the parties should be charged the reduced administrative fee for low-dollar disputes. The Departments are of the view that checking this box would take a *de minimis* amount of time in the context of the total time it takes for the initiating party to initiate a dispute – 2.25 hours, as discussed further in the PRA package for the Federal IDR process (OMB control number: 1210-0169). The Departments will add this information collection element to the information collection currently approved under OMB control number 1210-0169. The Departments seek comment on this proposed information collection.

Although the Departments would now be collecting the administrative fee directly from the disputing parties, rather than the certified IDR entities collecting the fee on the Departments' behalf, generally, the information collected from disputing parties and associated with this step in the Federal IDR process would not change; the parties would be submitting this information to the Departments rather than to the certified IDR entities. Therefore, the Departments are of the view that there is no additional information collection burden associated with this proposal. The Departments seek comment on this assumption.

8. ICRs Regarding Extension of Time Periods for Extenuating Circumstances (26 CFR 54.9816-8(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g)

The Departments anticipate that codifying the ability of certified IDR entities to submit case-by-case extension requests in the same manner as parties would slightly increase the estimated burden associated with collecting requests for extensions. In general, the Departments maintain the expectation that requests for extensions due to extenuating circumstances would be relatively limited, and do not expect that certified IDR entities would submit a high volume of requests for extensions, particularly since these proposed rules also propose to codify the Departments' ability to grant case-by-case extensions of their own initiative without a prior

request from certified IDR entities or parties. Based on internal data, the Departments anticipate that certified IDR entities would submit approximately 20 such requests for extensions annually.

The Departments estimate that it would take an office clerk approximately 15 minutes (at an hourly rate of $39.56) on average to prepare and submit the Request for Extension due to Extenuating Circumstances form. Based on internal data reflecting the number of extension requests submitted by certified IDR entities, the Departments estimate that approximately 20 extensions requests would be submitted by certified IDR entities annually. Accordingly, the Departments estimate that the burden associated with the submission of the extension request notice by certified IDR entities would result in a total annual burden of 5 hours with an equivalent cost of approximately $197.80[230] across all certified IDR entities in addition to the existing burden estimate for extension requests submitted by plans, issuers, FEHB carriers, providers, facilities, and air ambulance services providers already approved under OMB 1210-0169. As the Departments and OPM share jurisdictions, HHS would account for 45 percent of the total burden, or approximately 2.25 burden hours, with an equivalent cost of approximately $89.01. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 1.25 burden hours each, with an equivalent cost of approximately $49.45 each. OPM would account for 5 percent of the total burden, or approximately 0.25 burden hours, with an equivalent cost of approximately $9.89. The Departments seek comment on these assumptions.

[230] This is calculated as follows: 20 annual requests x 0.25 hours = 5 annual burden hours. 5 annual burden hours x $39.56 hourly rate = $197.80 total annual cost. As the Departments do not anticipate these proposed rules would be finalized and effective before July 1, 2024, the burden for 2024 would be prorated to 50 percent, or 2.5 hours with an equivalent cost of $99.

TABLE 16: Annual Burden and Cost for Extension Requests Submitted by Certified IDR Entities

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	9	9	0.25	2.25	$89
Labor	5	5	0.25	1.25	$49
Treasury	5	5	0.25	1.25	$49
OPM	1	1	0.25	0.25	$10

The Departments would revise the information collection currently approved under OMB control number 1210-0169 to account for this additional burden.

9. ICRs Regarding Registration of Group Health Plans and Health Insurance Issuers (26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530)

These proposed rules would require plans and issuers that are subject to the Federal IDR process to register and submit certain information to the Departments.

The Departments assume that TPAs would register on behalf of most self-insured plans. The Departments estimate that a total of 1,705 issuers and TPAs would incur a burden to comply with this provision. The Departments estimate that for each issuer and TPA, an administrative assistant would spend 8 hours (at an hourly rate of $41.74), a compensation and benefits manager would spend 2 hours (at an hourly rate of $137.64), and a lawyer would spend 2 hours (at an hourly rate of $157.48), to communicate with plans, gather the necessary information, and prepare the registration, resulting in a combined hourly rate of $77.01. The estimated total burden for each issuer or TPA would be 12 hours with an equivalent cost of approximately $924.16. The estimated total cost for initial registration and submission of information would be 20,460 hours, with an equivalent cost of approximately $1,575,693. As the Departments and OPM share jurisdictions, HHS would account for 45 percent of the total burden, or approximately 9,207 burden hours, with an equivalent cost of approximately $709,062. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 5,115 burden hours, with an equivalent cost of approximately $393,923. OPM

would account for 5 percent of the total burden, or approximately 1,023 burden hours, with an equivalent cost of approximately $78,785.

The proposed regulation would also require that plans update the information associated with their registration no later than 30 days after such information changes or at least annually. The Departments estimate that for each issuer and TPA, an administrative assistant would spend 30 minutes (at an hourly rate of $41.74), and a compensation and benefits manager would spend 15 minutes (at an hourly rate of $137.64) to update information in a timely way when such information changes, resulting in a combined hourly rate of $73.71. The estimated total burden for each issuer or TPA would be 0.75 hours with an equivalent cost of approximately $55.28. The Departments estimate that updating information in a timely way would incur a total cost for all issuers and TPAs of approximately 1,279 hours with an equivalent cost of approximately $94,252 beginning in 2025. As the Departments and OPM share jurisdictions, HHS would account for 45 percent of the total burden, or approximately 575 burden hours, with an equivalent cost of approximately $42,414. The Departments of Labor and the Treasury would each account for 25 percent of the total burden, or approximately 320 burden hours, with an equivalent cost of approximately $23,563. OPM would account for 5 percent of the total burden, or approximately 64 burden hours, with an equivalent cost of approximately $4,713.

TABLE 17: One-Time Burden and Cost for Plans and Issuers for Initial Registration and Submission of Certain Information to the Departments

Year	Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
2023	HHS	767	767	12	9,207	$709,062
	Labor	426	426	12	5,115	$393,923
	Treasury	426	426	12	5,115	$393,923
	OPM	85	85	12	1,023	$78,785

TABLE 18: Annual Burden and Cost for Plans and Issuers to Register and Submit Certain Information to the Departments

Department	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
HHS	767	767	0.75	575	$42,414
DOL	426	426	0.75	320	$23,563
Treasury	426	426	0.75	320	$23,563
OPM	85	85	0.75	64	$4,713

The Departments would revise the information collection currently approved under OMB control number 1210-0169 to account for this new burden. [231] The Departments seek comment on these burden estimates.

The information collections are summarized as follows:

TABLE 19: Annual Recordkeeping and Reporting Requirements

Regulation Section	OMB Control Number	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting	Total Labor Cost of Reporting
45 CFR 149.510(b)(1)	1210-0169	*HHS:* 472,500 *Labor:* 262,500 *Treasury:* 262,500 *OPM:* 52,500	*HHS:* 472,500 *Labor:* 262,500 *Treasury:* 262,500 *OPM:* 52,500	*HHS:* 0.75 *Labor:* 0.75 *Treasury:* 0.75 *OPM:* 0.75	*HHS:* 378,000 *Labor:* 210,000 *Treasury:* 210,000 *OPM:* 42,000	*HHS:* $104.95 *Labor:* $104.95 *Treasury:* $104.95 *OPM:* $104.95	*HHS:* $39,671,100 *Labor:* $22,039,500 *Treasury:* $22,039,500 *OPM:* $4,407,900
45 CFR 149.510(b)(2)	1210-0169	*HHS:* 378,000 *Labor:* 210,000 *Treasury:* 210,000 *OPM:* 42,000	*HHS:* 378,000 *Labor:* 210,000 *Treasury:* 210,000 *OPM:* 42,000	*HHS:* 0.75 *Labor:* 0.75 *Treasury:* 0.75 *OPM:* 0.75	*HHS:* 283,500 *Labor:* 157,500 *Treasury:* 157,500 *OPM:* 31,500	*HHS:* $104.95 *Labor:* $104.95 *Treasury:* $104.95 *OPM:* $104.95	*HHS:* $29,753,325 *Labor:* $16,529,625 *Treasury:* $16,529,625 *OPM:* $3,305,925
45 CFR 149.510(c)(1)	1210-0169	*HHS:* 44,370 *Labor:* 24,650 *Treasury:* 24,650 *OPM:* 4,930	*HHS:* 44,370 *Labor:* 24,650 *Treasury:* 24,650 *OPM:* 4,930	*HHS:* 0.53 *Labor:* 0.53 *Treasury:* 0.53 *OPM:* 0.53	*HHS:* 29,295 *Labor:* 16,275 *Treasury:* 16,275 *OPM:* 3,255	*HHS:* $39.56 *Labor:* $39.56 *Treasury:* $39.56 *OPM:* $39.56	*HHS:* $1,158,910 *Labor:* $643,839 *Treasury:* $643,839 *OPM:* $128,767

[231] OMB Control Number: 0938-1401 (CMS-10780, Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in).

Regulation Section	OMB Control Number	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting	Total Labor Cost of Reporting
45 CFR 149.510(c)(3)	1210-0169	*HHS:* 7,560 *Labor:* 4,200 *Treasury:* 4,200 *OPM:* 840	*HHS:* 7,560 *Labor:* 4,200 *Treasury:* 4,200 *OPM:* 840	*HHS:* 0.75 *Labor:* 0.75 *Treasury:* 0.75 *OPM:* 0.75	*HHS:* 5,670 *Labor:* 3,150 *Treasury:* 3,150 *OPM:* 630	*HHS:* $72.25 *Labor:* $72.25 *Treasury:* $72.25 *OPM:* $72.25	*HHS:* $409,676 *Labor:* $227,598 *Treasury:* $227,598 *OPM:* $45,520
45 CFR 149.510(d)	1210-0169	*HHS:* 6 *Labor:* 3 *Treasury:* 3 *OPM:* 1	*HHS:* 6 *Labor:* 3 *Treasury:* 3 *OPM:* 1	*HHS:* (18) *Labor:* (18) *Treasury:* (18) *OPM:* (18)	*HHS:* (108) *Labor:* (54) *Treasury:* (54) *OPM:* (18)	*HHS:* $39.56 *Labor:* $39.56 *Treasury:* $39.56 *OPM:* $39.56	*HHS:* ($4,272) *Labor:* ($2,136) *Treasury:* ($2,136) *OPM:* ($712)
45 CFR 149.510(g)	1210-0169	*HHS:* 9 *Labor:* 5 *Treasury:* 5 *OPM:* 1	*HHS:* 9 *Labor:* 5 *Treasury:* 5 *OPM:* 1	*HHS:* 0.25 *Labor:* 0.25 *Treasury:* 0.25 *OPM:* 0.25	*HHS:* 2.25 *Labor:* 1.25 *Treasury:* 1.25 *OPM:* 0.25	*HHS:* $39.56 *Labor:* $39.56 *Treasury:* $39.56 *OPM:* $39.56	*HHS:* $89 *Labor:* $49 *Treasury:* $49 *OPM:* $10
45 CFR 149.530	1210-0169	*HHS:* 767 *Labor:* 426 *Treasury:* 426 *OPM:* 85	*HHS:* 767 *Labor:* 426 *Treasury:* 426 *OPM:* 85	*HHS:* 0.75 *Labor:* 0.75 *Treasury:* 0.75 *OPM:* 0.75	*HHS:* 575 *Labor:* 320 *Treasury:* 320 *OPM:* 64	*HHS:* $73.71 *Labor:* $73.71 *Treasury:* $73.71 *OPM:* $73.71	*HHS:* $42,414 *Labor:* $23,563 *Treasury:* $23,563 *OPM:* $4,713
Total		*HHS:* 525,212 *Labor:* 291,784 *Treasury:* 291,784 *OPM:* 58,357 *Overall:* 1,167,137[232]	*HHS:* 903,212 *Labor:* 501,784 *Treasury:* 501,784 *OPM:* 100,357 *Overall:* 2,007,137		*HHS:* 673,310 *Labor:* 374,067 *Treasury:* 374,067 *OPM:* 74,086 *Overall:* 1,496,249		*HHS:* $68,551,798 *Labor:* $38,084,569 *Treasury:* $38,084,569 *OPM:* $7,616,630 *Overall:* $152,337,567

10. Submission of PRA-Related Comments

The Departments have submitted a copy of these proposed rules to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

[232] 840,000 respondents are duplicated between the open negotiation and Federal IDR process initiation information collections because these respondents must complete open negotiations to be a party to an initiated dispute; therefore, the total number of respondents has been reduced to reflect an accurate total of respondents.

To obtain copies of the supporting statement and any related forms for the proposed collections for control number 0938-1401, please visit CMS's website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*. To obtain copies of the supporting statement for control number 1210-0169, please go to *https://www.RegInfo.gov* or email the request to ebsa.opr@dol.gov and reference control number 1210-0169. The Departments invite public comment on these potential information collection requirements. Commenters may send their views on the Departments' PRA analysis in the same way they send comments in response to these proposed rules as a whole (for example, through the *https://www.regulations.gov* website), including as part of a comment responding to the broader proposed rules.

If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of these proposed rules and identify the rule (CMS–9897–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq*.) requires agencies to analyze options for regulatory relief of small entities to prepare an initial regulatory flexibility analysis to describe the impact of these proposed rules on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." The Departments use a change in revenues of more than 3 to 5 percent as its measure of significant

economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdiction.

1. Need for Regulatory Action, Objectives, and Legal Basis

This proposed rulemaking authorized by the No Surprises Act is intended to address specific issues that are critical to ensuring the timely rendering of payment determinations and to address feedback from interested parties and certified IDR entities to improve the functioning of the Federal IDR process. These proposed rules are intended to address some of the common communication issues between disputing parties stemming from a lack of clarity as to whether items and services are qualified IDR items and services covered by the No Surprises Act. These proposed rules would impose requirements and create incentives for parties to engage with one another during the open negotiation period, which would help reduce the volume of ineligible disputes being submitted. Specifically, these proposed rules would make changes to the information that plans, issuers, providers, facilities, and providers of air ambulance services must share before initiating the Federal IDR process by including proposals at 26 CFR 54.9816-6A, 29 CFR 2590.716-6A, and 45 CFR 149.100 to require plans and issuers to provide CARCs and RARCs when providing any paper or electronic remittance in response to a claim for payment for health care items or services furnished by an entity with which it does not have a direct or indirect contractual relationship. Additionally, the Departments propose amendments at 26 CFR 54.9816-6, 29 CFR 2590.716-6, and 45 CFR 149.140 to the information that must be disclosed about the QPA. These proposed rules would also establish new requirements at 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, which would require plans and issuers to register with the Federal IDR portal to better enable a provider, facility, or provider of air ambulance services to identify the appropriate plan or issuer with which it has a dispute and determine whether its coverage of an item or service is subject to a specified State law, an All-Payer Model Agreement, or the Federal IDR process for determining the out-of-network rate.

To further facilitate communication and improve open negotiations, these proposed rules would amend the open negotiation process that precedes the Federal IDR process. Specifically, at 26 CFR 54.9816-8(b)(1), 29 CFR 2590.716-8(b)(1), and 45 CFR 149.510(b)(1), these proposed rules would amend the content requirements of the standard open negotiation notice, would establish requirements related to an open negotiation response notice, and would clarify the timing for when the open negotiation period begins. These proposed rules would also amend the process for initiating the Federal IDR process. Specifically, at 26 CFR 54.9816-8(b)(2), 29 CFR 2590.716-8(b)(2), and 45 CFR 149.510(b)(2), these proposed rules would amend the content of the notice of IDR initiation and establish new requirements for a notice of IDR initiation response from the non-initiating party. At 26 CFR 54.9816-8T(b)(3), 29 CFR 2590.716-8(b)(3), and 45 CFR 149.510(b)(3), these proposed rules would also establish a new manner for providing notices to the other party and the Departments.

These proposed rules would also provide additional clarity regarding timeframes within the Federal IDR process. The No Surprises Act includes certain timeframes by which certain steps of the Federal IDR process must be conducted. For example, disputing parties must jointly select a certified IDR entity not later than the last day of the 3-business-day period following the date of the initiation of the Federal IDR process, and if the parties fail to jointly select a certified IDR entity, the Departments must select a certified IDR entity not later than 6 business days after the date of IDR initiation.[233] While the No Surprises Act also provides detailed timeframes for certain other steps in the process, the steps that must be conducted before a payment determination can be issued are not as clearly defined, such as when a certified IDR entity must conduct a conflict-of-interest review and must determine whether an item or service is a qualified IDR item or service, as defined in 26 CFR 54.9816-8T(a)(2)(xi), 29 CFR 2590.716-8(a)(2)(xi), and 45 CFR 149.510(a)(2)(xi), and eligible for the Federal IDR process. Therefore, the provisions in these proposed rules would adjust certain steps and establish associated timeframes

[233] Section 9816(c)(4)(F) of the Code, section 716(c)(4)(F) of ERISA, and section 2799A-1(c)(4)(F) of the PHS Act.

(see Table 1). These include provisions related to establishing a process for preliminary selection of the certified IDR entity and final selection of the certified IDR entity as set out in 26 CFR 54.9816-8(c)(1), 29 CFR 2590.716-8(c)(1), and 45 CFR 149.510(c)(1), in order to account for the time it takes certified IDR entities to confirm that they do not have a conflict of interest with either party. To allow more time for certified IDR entities to conduct eligibility reviews, these proposed rules would include proposed amendments to the Federal IDR process eligibility review proposed in 26 CFR 54.9816-8T(c)(2), 29 CFR 2590.716-8(c)(2), and 45 CFR 149.510 (c)(2). As discussed in section I.H. of this preamble, eligibility reviews have proven to be complex and time consuming. In extenuating circumstances, such as when dispute volume is high, it may be more appropriate for the Departments, rather than certified IDR entities, to conduct eligibility reviews to facilitate quicker dispute processing. Therefore, these proposed rules would establish a Departmental eligibility review process in proposed paragraph 26 CFR 54.9816-8(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510 (c)(2)(ii). Further, to support eligibility determinations, conflict-of-interest reviews, and payment determinations, the Departments propose requirements for the submission of additional information from the disputing parties at 26 CFR 54.9816-8(c)(2)(iii), 29 CFR 2590.716-8(c)(2)(iii), and 45 CFR 149.510(c)(2)(iii). To clarify and establish a standard process for disputes to be withdrawn from the Federal IDR process, the Departments propose four conditions in which a dispute may be withdrawn at 26 CFR 54.9816-8(c)(3)(i), 29 CFR 2590.716-8(c)(3)(i), and 45 CFR 149.510(c)(3)(ii). To further adjust timeframes and processes associated with the Federal IDR process, these proposed rules would include proposed amendments related to submission of offers and payment determination and notification at 26 CFR 54.9816-8(c)(5), 29 CFR 2590.716-8(c)(5), and 45 CFR 149.510(c)(5); the collection of the certified IDR entity fee at 26 CFR 54.9816-8(d)(1), 29 CFR 2590.716-8(d)(1), and 45 CFR 149.510(d)(1); and the collection of the administrative fee, including a process for setting a reduced administrative fee for low-dollar amount disputes and for non-initiating parties in cases of ineligible disputes, at 26 CFR

54.9816-8(d)(2), 29 CFR 2590.716-8(d)(2), and 45 CFR 149.510(d)(2). These proposed rules also include provisions to expand upon situations in which Federal IDR process timeframes may be waived due to extenuating circumstances at 26 CFR 54.9816-8T(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g).

Lastly, to address concerns regarding the vacated batching provision at 26 CFR 54.9816-8(c)(3)(i)(C), 29 CFR 2590.716-8(c)(3)(i)(C), and 45 CFR 149.510(c)(3(i)(C) and to create more efficiencies in the process, these proposed rules at 26 CFR 54.9816-8(c)(4), 29 CFR 2590.716-8(c)(4), and 45 CFR 149.510(c)(4) include provisions that would allow for more flexibility in batching multiple items or services in a single dispute.

It is the Departments' intention that the implementation of the proposed provisions in these proposed rules, if finalized, would lead to a more efficient Federal IDR process and more timely payment determinations.

2. Small Entities Regulated

The provisions in these proposed rules would affect plans (or their TPAs), health insurance issuers offering group or individual health insurance coverage, certified IDR entities, and providers, facilities, and providers of air ambulance services.

For purposes of analysis under the RFA, the Departments consider an employee benefit plan with fewer than 100 participants to be a small entity.[234] The basis of this definition is found in section 104(a)(2), which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Under the authority of section 104(a)(3), DOL has previously issued simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, which cover fewer than 100 participants and satisfy

[234] The Department of Labor consulted with the Small Business Administration Office of Advocacy in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c) in a memo dated June 4, 2020.

certain requirements.[235] While some large employers have small plans, small plans are generally maintained by small employers. Thus, the Departments are of the view that assessing the impact of these proposed rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of a small entity considered appropriate for this purpose differs, however, from a definition of a small business based on size standards issued by the SBA[236] in accordance with the Small Business Act.[237]

In 2021, there were 1,500 issuers in the U.S. health insurance market[238] and 205 TPAs.[239] Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[240] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from MLR annual report submissions for the 2021 MLR reporting year, approximately 87 out of 483 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[241] However, it should be noted that also based on MLR data, over 77 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies, are likely to have non-health lines of business that would result in their revenues exceeding $47 million. The Departments are of the view that the same assumptions also apply to TPAs that would be affected by these proposed rules.[242] To produce a conservative estimate, for the purposes of this analysis, the Departments assume 4.1 percent, or 62 health

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[235] *See* 29 CFR 2520.104-20, 2520.104-21, 2520.104-41, 2520.104-46, and 2520.104b-10.
[236] 13 CFR 121.201 (2011).
[237] 15 U.S.C. 631 *et seq*. (2011).
[238] Centers for Medicare and Medicaid Services. (2022). *Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr*. There are 483 issuers of health insurance coverage nationwide and 1,500 issuer-State combinations.
[239] Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.
[240] United States Small Business Administration. (March 17, 2023). *Table of Size Standards. https://www.sba.gov/document/support--table-size-standards.*
[241] Centers for Medicare and Medicaid Services. (2022). *Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*
[242] The Departments are of the view that most TPAs are also issuers.

insurance issuers and 8 TPAs, of the total of 1,500 health insurance issuers and 205 TPAs across the country, are considered small entities.[243] The Departments seek comment on this assumption.

These proposed rules would also affect health care providers due to the proposed requirements for the initiating party to submit the open negotiation notice to the non-initiating party and the Departments, among other proposals.[244] The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis. The number of small physicians is estimated based on the SBA's size standards. The size standard applied for providers is NAICS 62111 (Offices of Physicians), for which a business with less than $16 million in receipts is considered to be small. By this standard, the Departments estimate that 47.2 percent or 66,207 physicians are considered small under the SBA's size standards.[245] These proposed rules are also expected to affect non-physician providers who bill on an out-of-network basis. The Departments lack data on the number of non-physician providers who would be impacted.

The Departments do not have the same level of data for the air ambulance sub-sector. In 2020, the total revenue of providers of air ambulance services was estimated to be $4.2 billion, with 1,114 air ambulance bases.[246] This results in an industry average of $3.8 million per air ambulance base. Based on a 2020 USC-Brookings Schaeffer report on air ambulance services,[247] by 2017, large private equity firms controlled roughly two-thirds of the air ambulance market. The Departments seek comment on the number of small entities in the air ambulance market.

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[243] These numbers are calculated as follows: 77 percent of small companies belong to larger holding groups, so 23 percent do not and would be small entities. 87 issuers x 0.23 = 20. 20 / 483 = 4.1 percent. Applying the 4.1 percent to 1,500 issuers and 205 TPAs total = 62 small issuers and 8 small TPAs.

[244] Historically, less than 1 percent of disputes for emergency and non-emergency services have been submitted by group health plans, health insurance issuers, or FEHB carriers. *See* U.S. Department of Labor, U.S. Department of the Treasury, and U.S. Department of Health and Human Services. (December 15, 2022) *Initial Report on the Federal Independent Dispute Resolution (IDR) Process, April 15 – September 30, 2022. https://www.cms.gov/files/document/initial-report-idr-april-15-september-30-2022.pdf.*

[245] Based on data from the NAICS Association for NAICS code 62111, the Departments estimate the percent of businesses within the industry of Offices of Physicians with less than $16 million in annual sales. *See https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[246] ASPE Office of Health Policy. (September 10, 2021). *Air Ambulance Use and Surprise Billing. https://aspe.hhs.gov/sites/default/files/2021-09/aspe-air-ambulance-ib-09-10-2021.pdf.*

[247] Adler, L., Hannick, K., and Lee, S. High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers. USC-Brookings Schaffer Initiative for Health Policy. October 13, 2020.

Although based on the Departments' experience operating the Federal IDR process, significantly fewer than 66,207 small providers have accessed the process to date, and the vast majority of disputes are initiated by 10 large revenue cycle management companies or provider groups,[248] the Departments lack adequate data to better inform the number of small providers impacted by these proposed rules. The Departments are also aware that many providers are subject to a specified State law or All-Payer Model Agreement, rather than the Federal IDR process, and therefore would not have reason to access the Federal IDR process or need to review these proposed rules.[249] Therefore, although the Departments acknowledge that 66,207 small providers is likely a significant overestimate of the number of small providers impacted by these proposed rules, the Departments use this number of small providers in this analysis to be conservative. The Departments seek comment on this assumption.

Additionally, as discussed in the *Partial Report on the Federal Independent Dispute Resolution (IDR) Process, October 1 – December 31, 2022*, the top 10 initiating parties initiate approximately 85 percent of disputes, and the top 10 non-initiating parties are initiated against in approximately 95 percent of disputes.[250] These top 10 parties are large provider groups or revenue cycle management groups and large insurance companies or their representatives. Therefore, for purposes of this analysis, the Departments assume that only 15 percent of all disputes involve small providers. The 5 percent of all disputes that do not involve the top 10 non-initiating parties could involve any of the 1,695 issuers and TPAs that are not the top 10 non-initiating parties (1,500 issuers and 205 TPAs total – 10 top non-initiating parties = 1,695 remaining issuers and TPAs). The Departments assume that the same proportion of small issuers and TPAs to all issuers and TPAs also applies to the number of disputes each issuer or TPA is

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[248] *See* U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury, *Partial Report on the Federal Independent Dispute Resolution (IDR) Process, October 1 – December 31, 2022*. (n.d.). *https://www.cms.gov/files/document/partial-report-idr-process-octoberdecember-2022.pdf.*
[249] *See Chart for Determining the Applicability for the Federal Independent Dispute Resolution (IDR) Process* (n.d.). *https://www.cms.gov/files/document/caa-federal-idr-applicability-chart.pdf.*
[250] *Id.*

involved in, as small issuers and TPAs cover fewer enrollees than large issuers and TPAs. The Departments seek comment on this assumption.

3. Compliance Requirements

The proposed policies that would result in an increased burden to small entities are described below.

The Departments propose to require that plans and issuers use CARCs and RARCs to convey information related to the No Surprises Act, on electronic and paper remittance advice. The annual burden per issuer/TPA associated with this proposal is $909. For more details, please refer to section V.D.2.a. of this preamble.

The Departments also propose to amend the information plans and issuers must provide related to the QPA with an initial payment or notice of denial of payment. The one-time burden per issuer/TPA associated with this proposal is $297. For more details, please refer to V.F.2 of this preamble.

Additionally, the Departments propose to require the party to provide an open negotiation notice and supporting documentation to the other party and the Departments to initiate the open negotiation period. Furthermore, the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice that is provided to the other party and the Departments within the first 15 business days of the 30-business-day open negotiation period. The annual burden per small provider associated with this proposal is $79,[251] and the annual burden per small issuer/TPA associated with this proposal is $1,338.[252] For more details, please refer to section V.F.3. of this preamble.

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[251] 560,000 disputes in open negotiations – 85 percent (476,000) disputes entered into open negotiations by the top 10 initiating parties = 84,000 disputes entered into open negotiations by other initiating parties. 84,000 disputes / 66,207 small providers = approximately 1 dispute initiated per small provider annually. 1 dispute x $78.71 per dispute = $79 per small provider.

[252] 560,000 disputes in open negotiations – 95 percent (532,000) disputes entered into open negotiations against the top 10 non-initiating parties = 28,000 disputes entered into open negotiations against other non-initiating parties. 28,000 disputes / 1,695 issuers/TPAs = 17 disputes per issuer/TPA. 17 disputes x $78.71 per dispute = $1,338 per small issuer/TPA.

Furthermore, the Departments propose to continue requiring the initiating party to submit a written notice of IDR initiation to the non-initiating party and to the Departments. The Departments also propose that the non-initiating party must submit a written response to the notice of IDR initiation to the initiating party and to the Departments. The annual burden per small provider associated with this proposal is $79,[253] and the annual burden per small issuer/TPA associated with this proposal is $945.[254] For more details, please refer to section V.F.4.a. of this preamble.

Additionally, the Departments propose to revise the content in the notice of certified IDR entity selection form to reflect that this notice would only be used in situations in which the non-initiating party disagrees with the initiating party's preferred certified IDR entity identified in the notice of IDR initiation form. The annual burden per small provider associated with this proposal is $21,[255] and the annual burden per small issuer/TPA associated with this proposal is $85.[256] For more details, please refer to section V.F.4.b. of this preamble.

Moreover, the Departments propose to establish a process for disputes to be withdrawn from the Federal IDR process, including the creation of new notice of withdrawal and notice of withdrawal response forms. The annual burden per small provider associated with this proposal is $44,[257] and the annual burden per small issuer/TPA associated with this proposal is $10.[258] For more details, please refer to section V.F.6. of this preamble.

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[253] 420,000 disputes initiated – 85 percent (357,000) disputes initiated by the top 10 initiating parties = 63,000 disputes initiated by other initiating parties. 63,000 disputes / 66,207 small providers = approximately 1 dispute initiated per small provider annually. 1 dispute x $78.71 per dispute = $79 per small provider.

[254] 420,000 disputes initiated – 95 percent (399,000) disputes initiated against the top 10 non-initiating parties = 21,000 disputes initiated against other non-initiating parties. 21,000 disputes / 1,695 issuers/TPAs = 12 disputes per issuer/TPA annually. 12 disputes x $78.71 per dispute = $945 per small issuer/TPA.

[255] 120,200 disputes for which a notice of certified IDR entity selection is required – 85 percent (102,170) disputes initiated by the top 10 initiating parties = 18,030 disputes for other initiating parties. 18,030 disputes / 66,207 small providers = less than 1 dispute per small provider annually. 1 dispute x $21.14 = $21 per small provider.

[256] 120,200 disputes for which a notice of certified IDR entity selection is required – 95 percent (114,190) disputes initiated against the top 10 non-initiating parties = 6,010 disputes for other non-initiating parties. 6,010 disputes / 1,695 issuers/TPAs = 4 disputes per issuer/TPA annually. 4 disputes x $21.14 = $85 per small issuer/TPA.

[257] 16,800 disputes withdrawn – 85 percent (14,280) disputes withdrawn by the top 10 initiating parties = 2,520 disputes withdrawn by other initiating parties. 2,520 disputes / 66,207 small providers = less than 1 dispute withdrawn per small provider annually. 1 dispute x $44.30 per dispute = $44 per small provider.

[258] 16,800 disputes withdrawn – 95 percent (15,960) disputes withdrawn against the top 10 non-initiating parties = 840 disputes withdrawn against other non-initiating parties. 840 disputes / 1,695 issuers/TPAs = less than 1 dispute withdrawn per issuer/TPA annually. 1 dispute x $9.89 per dispute = $10 per small issuer/TPA.

Additionally, for disputes initiated on or after January 1, 2025, the Departments propose to establish the administrative fee amount at $150 per party per dispute, a reduced administrative fee amount for both parties in low-dollar disputes of $75 per party per dispute, and a reduced administrative fee for non-initiating parties in ineligible disputes of $30 per party per dispute. The annual burden per small provider associated with this proposal is $150,[259] and the annual burden per small issuer/TPA is $1,290.[260] For more details, please refer to section V.D.2.i.i. of this preamble.

Finally, the Departments propose to require plans and issuers to submit information to the Departments to receive a registration number. The initial (one-time) burden per issuer/TPA associated with this proposal is $924, and the annual burden per issuer/TPA associated with this proposal is $55. For more details, please refer to section V.F.9. of this preamble.

The Departments estimate the one-time cost to review the rule would be $1,575 per entity. For more details, please refer to section V.D.4. of this preamble.

Thus, the per-entity estimated annual cost for each small issuer/TPA is $4,632, and the per-entity estimated annual cost for each small provider is $373. The total annual cost for small issuers and TPAs is $324,240, and the total annual cost for small providers is $24,695,211. The per-entity estimated one-time cost for each small issuer/TPAs is $2,796, and the per-entity estimated one-time cost for each small provider is $1,575. The total one-time cost for small issuers and TPAs is $195,720, and the total one-time cost for small providers is $622,125. See Tables 20, 21, 22, and 23.

TABLE 20: Detailed Annual Costs for Small Entities

Description of Cost	Annual Cost per Small Issuer/TPA	Annual Cost per Small Provider

[259] 420,000 disputes initiated – 85 percent (357,000) disputes initiated by the top 10 initiating parties = 63,000 disputes initiated by other initiating parties. 63,000 disputes / 66,207 small providers = approximately 1 dispute initiated per small provider annually. 1 dispute x $150 per dispute = $150 per small provider.

[260] 420,000 disputes initiated – 95 percent (399,000) disputes initiated against the top 10 non-initiating parties = 21,000 disputes initiated against other non-initiating parties. 21,000 disputes / 1,695 issuers/TPAs = 12 disputes per small issuer/TPA annually. Of those 12 disputes, issuers/TPAs would pay a $75 administrative fee for 16 percent (or 2 disputes), a $30 administrative fee for 22 percent (or 3 disputes), and a $150 administrative fee for 62 percent (or 7 disputes). (2 disputes x $75 per dispute) + (3 disputes x $30 per dispute) + (7 disputes x $150 per dispute) = $1,290.

Description of Cost	Annual Cost per Small Issuer/TPA	Annual Cost per Small Provider
CARCs and RARCs	$909	N/A
Open Negotiation	$1,338	$79
Initiation	$945	$79
Certified IDR Entity Selection	$85	$21
Withdrawal	$10	$44
Administrative Fees	$1,290	$150
Registration	$55	N/A
Total	$4,632	$373

TABLE 21: Aggregate Annual Costs for Small Entities

Affected Entity	Affected Small Entities	Annual Cost per Entity	Aggregate Annual Cost for Small Entities
Issuer/TPA	70	$4,632	$324,240
Provider	66,207	$373	$24,695,211

TABLE 22: One-Time Costs for Small Entities

Description of Cost	One-Time Cost per Small Issuer/TPA	One-Time Cost per Small Provider
QPA Disclosures	$297	N/A
Registration	$924	N/A
Regulatory Review	$1,575	$1,575
Total	$2,796	$1,575

TABLE 23: Aggregate One-Time Costs for Small Entities

Affected Entity	Affected Small Entities	One-Time Cost per Entity	Aggregate One-Time Cost for Small Entities
Issuer/TPA	70	$2,796	$195,720
Provider	395	$1,575	$622,125

The annual cost per small provider of $373 is approximately 0.03 percent of the average annual receipts per small provider. The Departments anticipate that small providers would be unlikely to initiate disputes and thereby incur these costs unless they anticipate prevailing in the dispute and receiving payment from issuers or TPAs that exceed the costs incurred to initiate the dispute. The Departments therefore are of the view that small providers could experience an increase in receipts commensurate or larger than the increase in costs. The annual cost per small issuer/TPA of $4,632 is approximately 0.25 percent of the average annual receipts per small issuer/TPA. The Departments anticipate that small issuers/TPAs could pass on these increased

costs to consumers in the form of higher premiums (or for TPAs, higher administration fees), resulting in an increase in receipts commensurate with the increase in costs. However, the Departments are of the view that the actual increase in costs and subsequent impact on revenue is de minimis and likely to decrease due to the proposals in these rules, as many proposals are anticipated to result in increased efficiency and fewer dispute initiations, as discussed further in section V.D.1.l. of this preamble. Additionally, the Departments anticipate that by batching qualified IDR items and services, there may be a reduction in the per-service cost of the Federal IDR process, and potentially the aggregate administrative costs, because the Federal IDR process is likely to exhibit at least some economies of scale.[261] The Departments seek comment on these assumptions.

Thus, the Departments do not anticipate that these proposed rules would have a significant impact on a substantial number of small entities, based on the HHS threshold of 3 to 5 percent change in revenue. The Departments seek comment on this analysis and seek information on the number of small issuers, TPAs, or providers that may be affected by the provisions in these proposed rules, as well as any additional costs associated with these proposed rules that could have a significant economic impact on a substantial number of small entities.

4. Duplication, Overlap, and Conflict with Other Rules and Regulations

The Departments do not anticipate any duplication, overlap, or conflict with other rules and regulations associated with these proposed rules. These proposed rules revise current regulations and add new regulations to continue to implement the No Surprises Act and improve the Federal IDR process. The Departments seek comment on any duplication, overlap, or conflict with other rules and regulations identified by interested parties.

5. Significant Alternatives

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[261] Fielder, M., Adler, L., Ippolito, B. (March 16, 2021). *Recommendations for Implementing the No Surprises Act.* U.S.C.-Brookings Schaeffer on Health Policy. *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

The regulatory alternatives considered in developing these proposed rules are discussed in section V.E. of this preamble. The Departments are of the view that none of these alternatives would both achieve the policy objectives and goals of these proposed rules as previously stated and be less burdensome to small entities. For example, although the proposals pertaining to the open negotiation notice and response, initiation notice and response, selection form and response, and withdrawal form and response may impose costs on small entities, these proposals are critical to ensure the exchange of information between the parties in a standardized time and format, in order to reduce wasted effort for the parties at other stages of the Federal IDR process due to inappropriately or incorrectly initiated open negotiations or Federal IDR process disputes. Although the Departments recognize that the less stringent timetables considered in certain regulatory alternatives described in section V.E. of this preamble may account for the resources available to small entities, they would be contrary to the policy objectives of these proposed rules. Alternative timelines for small entities for any of the policy proposals described in these rules were not considered. The Departments did not identify any alternatives to these proposals that would be less burdensome to small entities while still achieving the objectives of these proposed rules. In addition, the proposals pertaining to the administrative fee may impose costs on small entities, but the proposed $150 administrative fee amount in these proposed rules for disputes initiated on or after January 1, 2025 is the same as the proposed administrative fee amount for disputes initiated on or after January 1, 2024,[262] and these proposed rules further propose to reduce the administrative fee amount for both parties in low-dollar disputes and non-initiating parties in ineligible disputes. Therefore, although some of the regulatory alternatives considered may have led to minor reduction in burden to small entities, we believe they would ultimately undermine the proposals to reduce the cost to initiate a Federal IDR process dispute for small entities in certain situations, which we believe will confer a far greater benefit to small

[262] See *Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges* proposed rules. 88 FR 65888 (September 26, 2023).

entities.

For a more detailed discussion of the regulatory alternatives considered, please reference section V.E. of this preamble.

6. Small Rural Hospitals

In addition, section 1102(b) of the Social Security Act requires the Departments to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. The Departments have determined that these proposed rules will not affect small rural hospitals and that these proposed rules are not subject to section 1102(b) of the Act. Therefore, the Secretary certifies that these proposed rules will not have a significant economic impact on a substantial number of small rural hospitals.

H. Special Analyses – Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

I. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule or any final rule for which a general notice of proposed rulemaking was published that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars,

updated annually for inflation. That threshold is approximately $177 million in 2023. As discussed earlier in the RIA, plans, issuers, TPAs, certified IDR entities, and providers, facilities, and providers of air ambulance services would incur costs to comply with the proposed provisions of these proposed rules. The Departments estimate the combined impact on State, local, or tribal governments and the private sector would not be above the threshold.

J. Federalism

Executive Order 13132 outlines the fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have "substantial direct effects" on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies issuing regulations that have these federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to these proposed rules.

The Departments do not anticipate that these proposed rules would have any federalism implications or limit the policy-making discretion of the States in compliance with the requirement of Executive Order 13132. The Departments recognize that at least one State (and possibly more) currently require the use of CARCs and RARCs to communicate information related to the applicability of State balance billing laws. In these instances, these proposed rules would not infringe upon the State's ability to continue to specify its requirements related to using CARCs and RARCs.

State and local government health plans may be subject to the Federal IDR process where a specified State law or All-Payer Model Agreement does not apply. The No Surprises Act authorizes States to enforce the new requirements, including those related to balance billing, for issuers, providers, facilities, and providers of air ambulance services, with HHS enforcing only in cases where the State has notified HHS that the State does not have the authority to enforce or is otherwise not enforcing, or HHS has made a determination that a State has failed to

substantially enforce the requirements. However, in the Departments' view, the federalism implications of these proposed rules are substantially mitigated because some States have their own process for determining the total amount payable under a plan or coverage for out-of-network emergency services and to out-of-network providers for patient visits to in-network facilities. Where a State has a specified State law, the State law, rather than the Federal IDR process, would apply. The Departments anticipate that some States, with their own process, may want to change their laws or adopt new laws in response to these proposed rules. The Departments anticipate that these States would incur a small incremental cost when making changes to their laws.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis.

While developing these rules, the Departments attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

Laurie Bodenheimer,

Associate Director

Healthcare and Insurance

Office of Personnel Management.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement,

Internal Revenue Service

Lisa M. Gomez

Assistant Secretary,

Employee Benefits Security Administration,

Department of Labor

Xavier Becerra,

Secretary,

Department of Health and Human Services.

List of Subjects

5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Reporting and recordkeeping requirements.

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 149

Balance billing, Health care, Health insurance, Reporting, and recordkeeping requirements, Surprise billing, State regulation of health insurance, and Transparency in coverage.

OFFICE OF PERSONNEL MANAGEMENT

For the reasons stated in the preamble, the Office of Personnel Management proposes to amend 5 CFR part 890 as set forth below:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.102 also issued under sections 11202(f), 11232(e), and 11246(b) of Pub. L. 105-33, 111 Stat. 251; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104-106, 110 Stat. 521 (36 U.S.C. 5522); Sec. 890.112 also issued under section 1 of Pub. L. 110-279, 122 Stat. 2604 (2 U.S.C. 2051); Sec. 890.113 also issued under section 1110 of Pub. L. 116-92, 133 Stat. 1198 (5 U.S.C. 8702 note); Sec. 890.301 also issued under section 311 of Pub. L. 111-3, 123 Stat. 64 (26 U.S.C. 9801); Sec. 890.302(b) also issued under section 1001 of Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029 (42 U.S.C. 300gg-14); Sec. 890.803 also issued under 50 U.S.C. 3516 (formerly 50 U.S.C. 403p) and 22 U.S.C. 4069c and 4069c-1; subpart L also issued under section 599C of Pub. L. 101-513, 104 Stat. 2064 (5 U.S.C. 5561 note), as amended; and subpart M also issued under section 721 of Pub. L. 105-261 (10 U.S.C. 1108), 112 Stat. 2061; 25 U.S.C. 1647b.

2. Section 890.114 is amended by revising paragraph (a) to read as follows:

§ 890.114 Surprise billing.

(a) A carrier must comply with requirements described in 26 CFR 54.9816-3, 54.9816-3T through 54.9816-6T, 54.9816-6A, 54.9816-6, 54.9816-8T, 54.9816-8, 54.9817-1T, 54.9817-2, 54.9817-2T, 54.9822-1T, and 54.9825-3T through 6T; 29 CFR 2590.716-3 through 2590.716-6, 2590.716-6A, 2590.716-8, 2590.717-1, 2590.717-2, 2590.722, 2590.725-1 through 2590.725-4; and 45 CFR 149.30, 149.100, 149.110 through 149.140, 149.310, 149.510 through 530, and 149.710 through 149.740 in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5

U.S.C. 8902(m)(1), and the provisions of the carrier's contract. For purposes of application of such sections, all carriers are deemed to offer health benefits in the large group market.

* * * * *

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 54 as follows:

PART 54 – PENSION EXCISE TAXES

3. The authority citation for part 54 is amended by adding entries for §§ 54.9816-3, 54.9816-6A and 54.9816-9 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 54.9816-3 also issued under 26 U.S.C. 9816.

Section 54.9816-6A also issued under 26 U.S.C. 9816.

Section 54.9816-9 also issued under 26 U.S.C. 9816.

* * * * *

4. Section 54.9816-3 is added to read as follows:

§ 54.9816-3 Definitions.

(a) The definitions in § 54.9801–2 apply to §§ 54.9816–4 through 54.9816-9, 54.9817–1, 54.9817-2, and 54.9822–1, unless otherwise specified. In addition, for purposes of §§ 54.9816–4 through 54.9816-9, 54.9817–1, 54.9817-2, and 54.9822–1, the following definition applies:

Bundled payment arrangement means an arrangement under which—

(1) A provider, facility, or provider of air ambulance services bills for multiple items and/or services furnished to a single patient under a single service code that represents multiple items or services (for example, a Diagnosis-Related Group (DRG) code); or

(2) A plan or issuer makes an initial payment or notice of denial of payment to a provider, facility, or provider of air ambulance services under a single service code that represents multiple items or services furnished to a single patient (for example, a DRG code).

(b) For further guidance, see § 54.9816-3T.

5. Section 54.9816-3T is amended by--

a. Revising the introductory text; and

b. Adding the definition of "Bundled payment arrangement" in alphabetical order.

The revisions and additions read as follows:

§ 54.9816-3T Definitions (temporary).

For further guidance, see § 54.9816-3 introductory text;

* * * * *

Bundled payment arrangement has the meaning given in § 54.9816-3(a).

* * * * *

6. Section 54.9816-6A is added to read as follows:

§ 54.9816-6A Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes.

(a) *In general.* When providing any paper or electronic remittance advice to an entity that does not have a contractual relationship directly or indirectly with a group health plan or a health insurance issuer offering group or individual health insurance coverage with respect to the furnishing of the item or service under the plan or coverage in response to a claim for payment for health care items and services furnished by that entity, the plan or issuer must use claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) (see 45 CFR 162.1602 and 162.1603) as specified in guidance issued by the Secretaries of the Treasury, Labor, and Health and Human Services, or as required under any applicable adopted standards and operating rules under 45 CFR part 162, to communicate information related to whether the claim is or is not subject to the provisions of this part and 45 CFR part 149, subpart E.

(b) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section

and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 54.9816-6A are intended to be severable from the provisions in §§ 54.9816-6, 54.9816-6T, 54.9816-8, 54.9816-8T, and 54.9816-9, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 54.9816-6, 54.9816-6T, 54.9816-8, 54.9816-8T, and 54.9816-9.

7. Section 54.9816-6 is amended by adding a heading to paragraph (a), revising paragraphs (b), (c), and (d) and adding paragraph (h) to read as follows:

§ 54.9816-6 Methodology for calculating qualifying payment amount.

(a) *Definitions.* * * *

(b) *Methodology for calculation of median contracted rate*. For further guidance, see § 54.9816-6T(b).

(c) *Methodology for calculation of the qualifying payment amount*. For further guidance, see § 54.9816-6T(c).

(d) *Information to be shared about the qualifying payment amount.* In cases in which the recognized amount, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility, is the qualifying payment amount or the amount billed by the provider or facility, or if the amount on which cost sharing is based with respect to air ambulance services furnished by a nonparticipating provider of air ambulance services is the qualifying payment amount or the amount billed by the provider of air ambulance services, the plan must provide to the provider, facility, or provider of air ambulance services, as applicable, in writing, in paper or electronic form –

(1) With an initial payment or notice of denial of payment under §54.9816-4, §54.9816-4T, §54.9816-5, §54.9816-5T, §54.9817 or §54.9817-T:

(i) For further guidance, see §54.9816-6T(d)(i);

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded.

(iii) For further guidance, see §54.9816-6T(d)(1)(iii);

(iv) A statement that –

(A) If the provider, facility, or provider of air ambulance services, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the out-of-network rate, the provider, facility, or provider of air ambulance services must:

(*1*) Contact the appropriate person or office to initiate open negotiation within 30 business days of receiving the initial payment or notice of denial of payment, and

(*2*) For disclosures required to be provided on or after [DATE 90 DAYS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**] and once the open negotiation notice can be submitted through the Federal IDR portal, notify the Secretary as described under § 54.9816-8(b)(1)(i); and

(B) If the 30-business-day open negotiation period does not result in an agreement on the amount of payment the provider, facility, or provider of air ambulance services may generally initiate the Federal IDR process within 4 business days after the end of the open negotiation period;

(v) For disclosures required to be provided on or after [DATE 90 DAYS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**], the legal

business name of the group health plan (if any), the legal business name of the plan sponsor (if applicable), and the registration number assigned under § 54.9816-9, if the plan is registered under § 54.9816-9.

(vi) For further guidance, see § 54.9816-6T(d)(1)(vi);

(2) In a timely manner upon request of the provider, facility, or provider of air ambulance services:

(i) For further guidance, see §54.9816-6T(d)(2)(i) through (iv)

(ii) [Reserved]

* * * * *

(h) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 54.9816-6 are intended to be severable from the provisions in §§ 54.9816-6A, 54.9816-6T, 54.9816-8, 54.9816-8T, and 54.9816-9, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 54.9816-6A, 54.9816-8, 54.9816-8T, and 54.9816-9.

8. Section 54.9816-6T is amended by:

a. Revising paragraphs (d) introductory text, (d)(1)(iv) and (v);

b. Adding paragraph (d)(1)(vi);

c. Revising paragraph (d)(2) introductory text; and

d. Adding paragraph (h).

The additions read as follows:

§ 54.9816-6T Methodology for calculating qualifying payment amount (temporary).

* * * * *

(d) For further guidance, see § 54.9816-6(d) introductory text;

(1) * * *

(iv) For further guidance, see § 54.9816-6(d)(1)(iv); and

(v) For further guidance, see § 54.9816-6(d)(1)(v);

(vi) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) For further information see § 54.9816-6(d)(2):

* * * * *

(h) *Severability*. For further guidance, see § 54.9816-6(h).

9. Section 54.9816-8 is amended by revising paragraphs (a), (b), (c), (d), (e), (g), and (h), and adding paragraph (i) to read as follows:

The revisions and additions read as follows:

§ 54.9816-8 Independent dispute resolution process.

(a) *Scope and definitions*--(1) *Scope*. For further guidance, see § 54.9816-8T(a)(1).

(2) *Definitions*. For further guidance, see § 54.9816-8T(a)(2). Additionally, for purposes of this section, the following definitions apply:

(i) *Batched qualified IDR 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 accordance with paragraph (c)(4) of this section.

(ii) For further guidance, see § 54.9816-8T(a)(2)(ii)-(xii).

(b) *Determination of payment amount through open negotiation and the initiation of the Federal IDR process*--(1) *Determination of payment amount through open negotiation*--(i) *In general.* With respect to an item or service that meets the requirements of § 54.9816-

8T(a)(2)(xi)(A), the provider, facility, or provider of air ambulance services, or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must submit a written open negotiation notice with the content specified in paragraph (b)(1)(ii) of this section to the other party and to the Secretary in the manner specified in paragraph (b)(3) of this section. The 30-business-day open negotiation period begins on the day on which the party first submits the open negotiation notice and the remittance advice documentation specified in paragraph (b)(1)(ii)(A)(*12*) of this section to the other party and the Secretary. The party in receipt of the open negotiation notice must provide to the other party and to the Secretary in the manner specified in paragraph (b)(3) of this section as soon as practicable, but no later than the 15th business day of the 30-business-day open negotiation period, a written notice and supporting documentation in response to the open negotiation notice, as specified in paragraph (b)(1)(iii)(A) of this section.

(ii) *Open negotiation notice*--(A) *Content.* The open negotiation notice must include, with respect to the item or service that is the subject of the open negotiation notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or air ambulance provider to the plan or issuer, and the National Provider Identifier (NPI);

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 54.9816-9, if the plan or issuer is registered under

§ 54.9816-9, or an attestation from the party submitting the open negotiation notice that the plan or issuer was not registered prior to the date it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation notice is a plan or issuer, the plan type (for example, self-insured or fully-insured);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation;

(*4*) Information sufficient to identify the item or service, including: the date(s) the item or service was furnished and, if the party submitting the open negotiation notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for the item or service from the plan or issuer; the type of item or service (specifically, whether the item or service is an emergency service as defined in § 54.9816-4T(c)(2)(i) or (ii), a non-emergency service as described in § 54.9816-5T(b), or an air ambulance service as defined in § 54.9816-3T); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location where the item or service was furnished (such as, place of service code or bill type code);

(*5*) The initial payment amount (including $0 if, for example, payment is denied);

(*6*) The qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the party submitting the open negotiation notice is a plan or issuer;

(*7*) An offer of an out-of-network rate for each item or service;

(*8*) If the party submitting the open negotiation notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*9*) If the party submitting the open negotiation notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or § 149.420(c) through (i);

(*10*) A statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished;

(*11*) General information listed in the standard open negotiation notice developed by the Secretary pursuant to paragraph (b)(3) of this section describing the open negotiation period and the Federal IDR process (including a description of the purpose of the open negotiation period and Federal IDR process and key deadlines in the open negotiation period and Federal IDR process); and

(*12*) A copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under §§ 54.9816-6T(d)(1) and 54.9816-6(d)(1), with respect to the item or service.

(B) [Reserved]

(iii) *Open negotiation response notice*--(A) *Content.* The response to the open negotiation notice must include, with respect to the item or service that is the subject of the open negotiation response notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or provider of air ambulance services to the plan or issuer, and the NPI;

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 54.9816-9 if the plan or issuer is registered under

§ 54.9816-9, or an attestation from the party submitting the open negotiation response notice that the plan or issuer was not registered prior to the date it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation response notice is a plan or issuer, the plan type (for example, self-insured or fully-insured);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation response notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation;

(*4*) Information sufficient to identify the item or service included in the open negotiation notice, including the date(s) the item or service was furnished, and if the party submitting the open negotiation response notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number;

(*5*) If the party submitting the open negotiation response notice is a plan or issuer, a statement as to whether it agrees that the initial payment amount (including $0 if, for example, payment is denied) and the qualifying payment amount reflected in the open negotiation notice accurately reflect the initial payment amount and qualifying payment amount disclosed with the initial payment for the item or service, and if not, or if the open negotiation notice indicates that the qualifying payment amount was not communicated by the plan or issuer with the initial payment or notice of denial of payment or other remittance advice, the initial payment amount (including $0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount);

(*6*) If the party submitting the open negotiation response notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*7*) A counteroffer for an out-of-network rate for each item or service or an acceptance of the other party's offer;

(*8*) If the party submitting the open negotiation response notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 45 CFR 149.420(c) through (i);

(*9*) With respect to each item or service, either a statement and supporting documentation that explains why the item or service is not subject to the Federal IDR process or a statement agreeing that the item or service is subject to the Federal IDR process;

(*10*) A statement as to whether any of the information provided in the open negotiation notice is inaccurate and the basis for the statement, as well as supporting documentation; and

(*11*) A statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the party submitting the open negotiation notice under paragraph (b)(1)(ii)(A)(*12*) of this section is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of payment or other remittance advice required to include the disclosures under § 54.9816-6(d)(1) and § 54.9816-6T(d)(1), with respect to the item or service.

(B) [Reserved]

(2) *Initiating the Federal IDR process*--(i) *In general.* Either party may initiate the Federal IDR process with respect to a qualified IDR item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period provided for under paragraph (b)(1) of this section. To initiate the Federal IDR process, a party (the initiating party) must submit a written notice of IDR initiation, consistent with paragraph (b)(2)(ii) of this section, to the other party to the dispute (the non-initiating party), and to the Secretary in the manner specified in paragraph (b)(3) of this section, during the 4-business-day period beginning on the first business day after the last day of the open negotiation period (unless it is otherwise

required to be submitted in the timeframe specified in paragraph (c)(5)(vii)(C) of this section). The date of IDR initiation is the date that the Secretary receives the notice of IDR initiation described in paragraph (b)(2)(ii) of this section.

(A) *Exception for items and services provided by certain nonparticipating providers and facilities*. A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(B) [Reserved]

(ii) *Notice of IDR initiation*--(A) *Content.* The notice of IDR initiation must include, with respect to the item or service that is the subject of the notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address), and the NPI; and if the initiating party is a provider, facility, or provider of air ambulance services, the Tax Identification Number (TIN);

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 54.9816-9 if the plan or issuer is registered under § 54.9816-9, or an attestation from the initiating party that the plan or issuer was not registered prior to the date that it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the initiating party is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the initiating party, and an

attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process;

(*4*) Information sufficient to identify whether the dispute being initiated includes batched or bundled qualified IDR items or services as described in paragraph (c)(4) of this section;

(*5*) Information sufficient to identify the qualified IDR item or service that is the subject of the notice of IDR initiation, including the date(s) the qualified IDR item or service was furnished; if the initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer; the date the open negotiation period under paragraph (b)(1) of this section began; the type of item or service (specifically, whether the qualified IDR item or service is an emergency service as defined in § 54.9816-4T(c)(2)(i) or (ii), a non-emergency service as described in § 54.9816-5T(b), or an air ambulance service as defined in § 54.9816-3T); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location the item or service was furnished (including place of service code or bill type code);

(*6*) The initial payment amount (including $0 if, for example, payment is denied);

(*7*) The qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the initiating party is a plan or issuer;

(*8*) If the initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 45 CFR 149.420(c) through (i);

(*9*) A statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished;

(*10*) Attestation that the item or service under dispute is a qualified IDR item or service, and the basis for the attestation;

(*11*) General information listed in the standard notice of IDR initiation developed by the Secretary pursuant to paragraph (b)(3) of this section describing the Federal IDR process (including a description of the purpose of the Federal IDR process and key deadlines in the Federal IDR process);

(*12*) A copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under § 54.9816-6(d)(1) and § 54.9816-6T(d)(1), with respect to the item or service;

(*13*) Preferred certified IDR entity; and

(*14*) A statement describing the key aspects of the claim, such as patient acuity or level of training of the provider, facility, or provider of air ambulance services that furnished the qualified IDR item or service, discussed by the parties during open negotiation that relate to the payment for the disputed claim, whether the reasons for initiating the Federal IDR process are different from the aspects of the claim discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process, including any of the permissible considerations described in paragraph (c)(5)(iii) of this section and § 54.9817-2(b)(2) that serve as the party's basis for initiating the Federal IDR process.

(B) [Reserved]

(iii) *Notice of IDR initiation response*. -The non-initiating party must provide to the initiating party and to the Secretary in the manner specified in paragraph (b)(3) of this section within 3 business days after the date of IDR initiation, a written notice and supporting documentation in response to the notice of IDR initiation, as specified in paragraph (b)(2)(iii)(A) of this section.

(A) *Content*. The notice of IDR initiation response must include, with respect to the item or service that is the subject of the notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address), and the NPI; and if the non-initiating party is a provider, facility, or provider of air ambulance services, the TIN;

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 54.9816-9 if the plan or issuer is registered under § 54.9816-9 or an attestation from the non-initiating party that the plan or issuer was not registered prior to the date that it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the non-initiating party is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the non-initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process;

(*4*) Information sufficient to identify each item or service included in the notice of IDR initiation, including the date(s) the item or service was furnished. If the non-initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number;

(*5*) If the non-initiating party is a plan or issuer, a statement as to whether the non-initiating party agrees that the initial payment (including $0 if, for example, payment is denied)

and the qualifying payment amount reflected in the notice of IDR initiation are accurate for the item or service that is the subject of the dispute, and if not, the initial payment amount (including $0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount);

(*6*) If the non-initiating party is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*7*) If the non-initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 45 CFR 149.420(c) through (i);

(*8*) With respect to each item or service that is the subject of the dispute, either an attestation that the item or service is a qualified IDR item or service, or, for each item or service that the non-initiating party asserts is not a qualified IDR item or service, an explanation and documentation to support the statement;

(*9*) A statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the initiating party under paragraph (b)(2)(ii)(A)(*12*) of this section is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of payment or other remittance advice required to include the disclosures under §§ 54.9816-6(d)(1) and 54.9816-6T(d)(1), with respect to the item or service;

(*10*) A statement as to whether any of the information provided in the notice of IDR initiation is inaccurate and the basis for the statement as well as any supporting documentation; and

(*11*) A statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity. If the non-initiating party objects to the initiating party's preferred certified IDR entity, the notice of IDR initiation response must include the name of an

alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the initiating party's preferred certified IDR entity .

(B) [Reserved].

(3) *Manner.* A party furnishing notices as required under paragraphs (b)(1)(ii) and (iii), and (b)(2)(ii) and (iii) of this section must furnish the notices using the standard forms developed by the Secretary and must furnish the notices and supporting documentation to the other party and the Secretary, through the Federal IDR portal.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*--(i) *Preliminary selection of the certified IDR entity.* Within 3 business days after the date of IDR initiation, the non-initiating party must agree or object to the preferred certified IDR entity identified in the notice of IDR initiation, as described in paragraph (b)(2)(iii)(A)(*11*) of this section.

(A) If the non-initiating party agrees, or fails to object, to the selection of the initiating party's preferred certified IDR entity in the manner described in paragraph (b)(2)(iii)(A)(*11*) of this section and within the timeframe specified in paragraph (c)(1)(i) of this section, the initiating party's preferred certified IDR entity will be considered jointly selected on the third business day after the date of IDR initiation.

(B) If the non-initiating party objects to the selection of the initiating party's preferred certified IDR entity by designating an alternative preferred certified IDR entity in the manner described in paragraph (b)(2)(iii)(A)(*11*) of this section and within 3 business days after the date of IDR initiation, the initiating party may then agree or object to the non-initiating party's alternative preferred certified IDR entity by submitting the notice of certified IDR entity selection in the manner specified in paragraph (c)(1)(i)(D) of this section. If the initiating party agrees to the non-initiating party's alternative preferred certified IDR entity within 3 business days after the date of IDR initiation, or if the non-initiating party submits the notice of IDR initiation response on or before the second business day after the date of IDR initiation and the

initiating party fails to respond within 3 business days after the date of IDR initiation, the alternative preferred certified IDR entity will be considered jointly selected by the parties. If the non-initiating party submits the notice of IDR initiation response on the third business day after the date of IDR initiation and the initiating party does not agree on the same day, selection will proceed under paragraph (c)(1)(i)(C) of this section.

(C) If a certified IDR entity is not jointly selected under paragraph (c)(1)(i)(A) or (B) of this section, either party may select an alternative preferred certified IDR entity by submitting the notice of certified IDR entity selection in the manner specified in paragraph (c)(1)(i)(D) of this section, until the earlier of the date that the parties agree on the alternative preferred certified IDR entity or the deadline for joint selection, which is 3 business days after the date of IDR initiation. Once a party submits a notice of certified IDR entity selection, it may not submit another notice of certified IDR entity selection until after it receives a responding notice of certified IDR entity selection from the other party.

(*1*) If a party submits a notice of certified IDR entity selection to the other party on the first or second day after the date of IDR initiation and the party in receipt of the notice agrees or fails to object to the alternative preferred certified IDR entity by the third business day after the date of IDR initiation, the alternative preferred certified IDR entity will be considered jointly selected by the parties.

(*2*) If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice agrees to the alternative preferred certified IDR entity on the same day, the alternative preferred certified IDR entity will be considered jointly selected by the parties.

(*3*) If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice does not agree to the alternative preferred certified IDR entity on the same day, the parties will have failed to jointly select a certified IDR entity.

(D) To notify the other party and the Secretary of an agreement or objection to an alternative preferred certified IDR entity under paragraph(c)(1)(i)(C) of this section, a party must submit the notice of certified IDR entity selection. The party must furnish the notice of certified IDR entity selection using the standard form developed by the Secretary and must furnish the notice to the other party and the Secretary through the Federal IDR portal within 3 business days after the date of IDR initiation. However, in the event the conditions under paragraph (c)(1)(ii) of this section apply, the party may notify the Secretary of an agreement or objection to an alternative preferred certified IDR entity in accordance with paragraph (c)(1)(ii) of this section. The notice of certified IDR entity selection must include a statement indicating the party's agreement with or objection to the other party's alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the alternative preferred certified IDR entity. If the party in receipt of a notice of certified IDR entity selection objects to the other party's alternative preferred certified IDR entity and the party submits a notice of certified IDR entity selection by the end of the third business day after the date of IDR initiation, that party's notice of certified IDR entity selection reflecting the objection must include the name of another alternative preferred certified IDR entity.

(ii) *Failure to jointly select a certified IDR entity.* If the parties fail to jointly select a certified IDR entity within 3 business days after the date of IDR initiation, the Secretary will select a certified IDR entity. The parties will have failed to jointly select a certified IDR entity if, by the end of the third business day after the date of IDR initiation, the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection has objected to the other party's alternative preferred certified IDR entity, or if the notice of IDR initiation response or the notice of certified IDR entity selection is submitted to the other party on the third business day after the date of IDR initiation and the party in receipt of the notice does not agree to the alternative preferred certified IDR entity within 3 business days after the date of IDR initiation.

(A) In selecting the certified IDR entity, the Secretary will first confirm whether a party submitted the notice of IDR initiation response or the notice of certified IDR entity selection with an alternative preferred certified IDR entity on the third business day after the date of IDR initiation without the other party's agreement to the selection. If either notice was provided on the third business day after the date of IDR initiation without the other party's agreement to the alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Secretary will provide the party last in receipt of the applicable notice 2 additional business days to agree or object to the other party's alternative preferred certified IDR entity selection.

(*1*) If the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection agrees with the other party's alternative preferred certified IDR entity and notifies the Secretary of the agreement or fails to notify the Secretary of its objection in the Federal IDR portal by the fifth business day after the date of IDR initiation, the Secretary will select the final alternative preferred certified IDR entity selected in the applicable notice. In disputes where the applicable notice was submitted on the third business day after the date of IDR initiation, the party last in receipt of the notice will not be allowed to select another alternative preferred certified IDR entity.

(*2*) If the party notifies the Secretary of its objection to the alternative preferred certified IDR entity by the fifth business day after the date of IDR initiation, the Secretary will proceed with the random selection of the certified IDR entity from among the certified IDR entities (other than the preferred certified IDR entity and any alternative preferred certified IDR entity previously selected in such dispute by a party, unless there is no other certified IDR entity available to select) that charge a fee within the allowed range of certified IDR entity fees on the sixth business day after the date of IDR initiation. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary will select a certified IDR entity that has received approval, as described in

§ 54.9816-8T(e)(2)(vii)(B), to charge a fee outside of the allowed range of certified IDR entity fees. In either case, the Secretary will notify the parties of the preliminary selection of the certified IDR entity not later than 6 business days after the date of IDR initiation.

(B) [Reserved].

(iii) *Date of preliminary selection of the certified IDR entity*. The date of preliminary selection of the certified IDR entity will be:

(A) Three business days after the date of IDR initiation if the parties jointly selected a certified IDR entity, as specified in paragraph (c)(1)(i) of this section; or

(B) Six business days after the date of IDR initiation, if the parties fail to jointly select a certified IDR entity as specified in paragraph (c)(1)(ii) of this section.

(iv) *Final selection of certified IDR entity*--(A) *Conflict-of-interest review*. The certified IDR entity preliminarily selected for a dispute must review the selection. The selection of the certified IDR entity will be finalized only if the certified IDR entity attests to the Secretary that it meets the following requirements:

(*1*) The certified IDR entity does not have a conflict of interest as defined in § 54.9816-8T(a)(2)(iv);

(*2*) The certified IDR entity will only assign personnel to a dispute and make decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute in a manner that is not based upon the likelihood that the assigned personnel will support a particular party to the dispute; and

(*3*) The certified IDR entity will not assign any personnel to a dispute who would have any conflicts of interest, as defined in § 54.9816-8T(a)(2)(iv), regarding any party to the dispute or whose relationship with a party within the 1 year immediately preceding the assignment to the dispute would violate the restrictions on aiding or advising a former employer or principal in a manner similar to the restrictions set forth in 18 U.S.C. 207(b).

(B) *Failure to meet conflict-of-interest requirements.* If the certified IDR entity notifies the Secretary within 3 business days of the date of preliminary selection of the certified IDR entity that it does not meet the requirements of paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section or if the certified IDR entity does not respond within 3 business days after the date of preliminary selection of the certified IDR entity, the Secretary will randomly select another certified IDR entity consistent with paragraph (c)(1)(ii) of this section. The Secretary will notify the parties of the new randomly preliminarily selected certified IDR entity no later than 1 business day after the previously selected certified IDR entity notifies the Secretary that it has a conflict of interest or, if the previously selected certified IDR entity fails to respond within 3 business days after the date of preliminary selection of the certified IDR entity, no later than 1 business day after the end of the 3-business-day period.

(C) *Date of final selection of the certified IDR entity*. If the certified IDR entity that has been preliminarily selected attests within 3 business days that it meets the requirements of paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section, the Secretary will notify the parties of the final selection of the certified IDR entity no later than 1 business day after the certified IDR entity attests that it meets the conflict-of-interest requirements. The date of final selection of the certified IDR entity is the date that the Secretary provides this notice to the parties.

(2) *Federal IDR process eligibility review*--(i) *Federal IDR process eligibility determination by certified IDR entity*. Unless the departmental eligibility review described in paragraph (c)(2)(ii) of this section applies, the selected certified IDR entity must review the information in the notice of IDR initiation, notice of IDR initiation response, and any additional information described in paragraph (c)(2)(iii) of this section, and make a final determination as to whether the item or service is a qualified IDR item or service, as defined in § 54.9816-8T(a)(2)(xi), that is eligible for the Federal IDR process. The certified IDR entity must make such a determination and notify the Secretary and both parties no later than 5 business days after the date of final selection of the certified IDR entity. If the certified IDR entity determines that

the item or service is not a qualified IDR item or service, the dispute will be closed, and the selected certified IDR entity will not take any action with regard to the dispute.

(ii) *Departmental eligibility review for Federal IDR process eligibility determinations*. When the conditions for the departmental eligibility review set forth in paragraph (c)(2)(ii)(A) of this section are met, the Secretary will conduct the eligibility review and make the eligibility determination instead of the certified IDR entity. If the Secretary determines that the item or service is not a qualified IDR item or service, the dispute will be closed, and the selected certified IDR entity will not take any action with regard to the dispute. If the dispute is found to be eligible, the Secretary will inform the preliminarily selected certified IDR entity of the dispute's eligibility so that it may conduct its conflict-of-interest assessment, and the dispute will otherwise continue through the Federal IDR process, including notification of the eligibility determination to the disputing parties by the preliminarily selected certified IDR entity.

(A) *Application of the departmental eligibility review.* The departmental eligibility review will apply when the Secretary determines that any of the extenuating circumstances described in paragraph (g)(1) of this section require application of the departmental eligibility review to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process.

(B) *Notification regarding applicability of the departmental eligibility review.* Before invoking the application of the departmental eligibility review, the Secretary will post advance public notification of the date on which the departmental eligibility review will take effect and the reasons for invoking the application of the departmental eligibility review. Before ending the application of the departmental eligibility review, the Secretary will post advance public notification of the date on which the departmental eligibility review will no longer be in effect and the reasons for ending the application of the departmental eligibility review.

(iii) *Request for additional information*. The Secretary or the selected certified IDR entity may request additional information from either party to a dispute at any time, including for the

purpose of assessing whether a conflict of interest exists, conducting an eligibility determination, or making a payment determination.

(A) Upon request, a party must submit the additional information within 5 business days to the Secretary or the selected certified IDR entity, as applicable, through the Federal IDR portal. Following a request for additional information, the time period for the applicable stage of the Federal IDR process will be tolled until the earlier of the date either all of the requested information is provided or the 5-business-day period expires, and each subsequent timeframe in the Federal IDR process will be determined based on the date of completion of the stage of the Federal IDR process that was tolled for provision of the requested information.

(B) If a party fails to submit the additional information as required, the related determination, including the eligibility determination, conflict-of-interest review, or payment determination will be made without the requested information unless a good-cause extension of the 5-business-day period, as specified in paragraph (g)(1)(i) of this section, has been provided, and the party subsequently submits the additional information requested within the extended period.

(3) *Authority to continue negotiations or withdraw*—(i) *Authority to continue to negotiate.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary required under paragraph (b)(2)(ii) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount and any cost sharing paid or required to be paid by the participant, beneficiary, or enrollee, or there was an initial denial of payment, payment must be made directly by the plan or issuer to the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional

payment from the participant, beneficiary, or enrollee, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the dispute number, a statement of the out-of-network rate for the qualified IDR item or service, and signatures from authorized signatories for both parties.

(ii) *Withdrawals*. A dispute may be withdrawn from the Federal IDR process by the initiating party, the Secretary, or a certified IDR entity before a payment determination is made if one of the following conditions is met:

(A) The initiating party provides notification through the Federal IDR portal to the Secretary and the certified IDR entity (if selected) that both parties to the dispute agree to withdraw the dispute from the Federal IDR process without agreement on an out-of-network rate. The notification must include the dispute number, a statement about both parties' agreement to withdraw, and signatures from authorized signatories for both parties.

(B) The initiating party provides a standard withdrawal request notice through the Federal IDR portal to the Secretary, the certified IDR entity (if selected), and the non-initiating party of its request to withdraw the dispute from the Federal IDR process and the non-initiating party notifies the Secretary, certified IDR entity (if selected), and the initiating party through the Federal IDR portal of its agreement to withdraw from the Federal IDR process within 5 business days of the initiating party's request. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party will be considered to have agreed to the withdrawal, and the dispute will be withdrawn.

(C) The certified IDR entity or Secretary cannot determine eligibility because both parties to the dispute are unresponsive to any requests for additional information to determine eligibility as described in paragraph (c)(2)(iii) of this section, or

(D) The certified IDR entity cannot make a payment determination because both parties to the dispute have failed to submit an offer as described in paragraph (c)(5)(i) of this section.

(4) *Treatment of batched qualified IDR items and services*–(i) *In general.* A certified IDR entity may consider up to 25 qualified IDR items and services jointly as part of one payment determination that is subject to the certified IDR entity fee for batched determinations only if the qualified IDR items and services meet the requirements of this paragraph (c)(4)(i).

(A) For further guidance, see § 54.9816-8T(c)(4)(i)(A);

(B) Payment for the qualified IDR items and services is required to be made by the same group health plan or health insurance issuer. For group or individual health insurance coverage, this requirement is satisfied if the same issuer is required to make payment for the qualified IDR items and services, even if the qualified IDR items and services relate to claims from different group health plans or individual market policies. For self-insured group health plans, this requirement is satisfied if the same self-insured group health plan is required to make payment for the qualified IDR items and services, including when the plan makes payments through a third party administrator; the requirement is not satisfied if multiple self-insured group health plans are required to make payments for the qualified IDR items and services, even if those group health plans make payments through the same third party administrator;

(C) The qualified IDR items and services meet any of the following criteria under which multiple qualified IDR items and services relate to the treatment of a similar condition and therefore are permitted to be considered jointly as a single payment determination for purposes of encouraging efficiencies (including minimizing costs) in the Federal IDR process:

(*1*) The qualified IDR items or services were furnished to a single patient during the same patient encounter. For purposes of this section, a single patient encounter is defined as a patient encounter on one or more consecutive days during which the qualified IDR items or services were furnished to the same patient and billed on the same claim form; or

(*2*) The qualified IDR items and services were furnished to one or more patients and were billed under the same service code or a comparable code under a different procedural coding system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) codes with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; or

(*3*) For anesthesiology, radiology, pathology, and laboratory qualified IDR items and services, the qualified IDR items and services were furnished to one or more patients and were billed under service codes belonging to the same Category I CPT code range, as specified in guidance published by the Secretary; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period following the date on which the first item or service included in the batched determination was furnished and were the subjects of a 30-business-day open negotiation period that ended within 4 business days of IDR initiation, except as provided in paragraph (c)(5)(vii) of this section.

(ii) *Treatment of bundled payment arrangements.* Qualified IDR items and services that meet the definition of a bundled payment arrangement under § 54.9816-3 may be submitted and considered as a single payment determination, and the certified IDR entity must make a single payment determination for the multiple qualified IDR items and services included in the bundled payment arrangement. Bundled payment arrangements as defined in § 54.9816-3 and submitted under this paragraph (c)(4)(ii) are subject to the certified IDR entity fee for single determinations.

(5) *Payment determination for a qualified IDR item or service*--(i) *Submission of offers*. Not later than 10 business days after the date of final selection of the certified IDR entity as described in paragraph (c)(1)(iv)(C) of this section (or not later than 10 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section, when the Secretary determines that any of the extenuating circumstances described in

paragraph (g)(1)(ii) of this section apply), the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) For further guidance, see § 54.9816-8T(c)(5)(i)(A).

(B) For further guidance, see § 54.9816-8T(c)(5)(i)(B);

(ii) *Payment determination and notification*. Not later than 30 business days after the date of final selection of the certified IDR entity as described in paragraph (c)(1)(iv)(C) of this section (or not later than 30 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section, when the Secretary determines that any of the extenuating circumstances described in paragraph (g) of this section apply), the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(5)(i) of this section, weighing only the considerations specified in paragraph (c)(5)(iii) of this section (as applied to the information provided by the parties pursuant to § 54.9816-8T(c)(5)(i)). The certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

(*1*) *Prevailing party*. In the case of single determinations, the party whose offer is selected by the certified IDR entity is considered the prevailing party. In the case of batched determinations, the party with the most determinations in its favor is considered the prevailing party; if each party prevails in an equal number of determinations, neither party will be considered the prevailing party, and the certified IDR entity fee will be split evenly between the parties.

(*2*) *Non-prevailing party*. In the case of single determinations, the party whose offer is not selected by the certified IDR entity is considered the non-prevailing party. In the case of batched determinations, the party with the fewest determinations in its favor is considered the non-prevailing party.

(B) *For further guidance, see § 54.9816-8T(c)(5)(ii)(B).*

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant or beneficiary receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under § 54.9816–8T(c)(4)(i)(A)(*2*) that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in § 54.9816–8T(c)(4)(v).

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in § 54.9816–8T(c)(4)(v).

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1* —(*1*) *Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not

a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2* —(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject

of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3* —(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and

management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4* —(*1*) *Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope

of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5* —(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal

to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 54.9816–6(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 54.9816–6(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

(v) *Prohibition on consideration of certain factors.* For further guidance, see § 54.9816-8T(c)(5)(v).

(vi) *Written Decision*. For further guidance, see § 54.9816-8T(c)(5)(vi).

(vii) *Effects of determination*—(A) *Binding.* For further guidance see § 54.9816-8T(c)(5)(vii)(A).

(B) *Suspension of certain subsequent IDR requests*.--In the case of a determination made by a certified IDR entity under paragraph (c)(5)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted*. If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(5)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements*. For further guidance see § 54.9816-8T(c)(5)(viii).

(ix) *Payment*. For further guidance see § 54.9816-8T(c)(5)(ix).

(d) *Costs of IDR process*—(1)*Certified IDR entity fee*—(i) *Timing of payment of certified IDR entity fee.* Each party to a dispute for which there is a final selection of the certified IDR entity and a determination that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section must pay to the certified IDR entity the predetermined certified IDR entity fee charged by the certified IDR entity. The certified IDR entity fee must be paid no later than the date a party submits its offer to the certified IDR entity, in accordance with paragraph (c)(5)(i) of this section.

(ii) *Failure to timely pay certified IDR entity fee*. If a party fails to pay the certified IDR entity fee as specified in paragraph (d)(1)(i) of this section, that party's offer will not be considered received. Such party will continue to be responsible for payment of the certified IDR entity fee.

(iii) *Method of allocation of the certified IDR entity fee after a payment determination.* After making a payment determination, the certified IDR entity shall retain the certified IDR entity fee described under paragraph (d)(1)(i) of this section paid by the non-prevailing party as defined in paragraph (c)(5)(ii)(A)(*2*) of this section. The certified IDR entity must return the fee paid by the prevailing party, as defined in paragraph (c)(5)(ii)(A)(*1*) of this section, within 30 business days following the date of the certified IDR entity's payment determination. In the event of a batched dispute in which each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. In that case, the certified IDR entity must return half the fee paid by each party within 30 business days following the date of the certified IDR entity's payment determination.

(iv) *Method of allocation of the certified IDR entity fee upon agreement or withdrawal after an eligibility determination.* For a dispute for which there is a final selection of the certified IDR entity and a determination that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, unless directed otherwise by both parties, the certified IDR entity is required to return half of each party's certified IDR entity fee within 30 business days of the date both parties notify the certified IDR entity that they have:

(A) Reached an agreement on an out-of-network rate for qualified IDR items or services before the certified IDR entity has made its payment determination, as described in paragraph (c)(3)(i) of this section; or

(B) Withdrawn the dispute before the certified IDR entity has made its payment determination, as described in paragraph (c)(3)(ii) of this section.

(v) *Method of allocation of the certified IDR entity fee upon agreement or withdrawal before an eligibility determination.* When the parties reach an agreement on an out-of-network rate or withdraw a dispute for which there is a final selection of the certified IDR entity, but for which no eligibility determination has yet been made, unless directed otherwise by both parties, the certified IDR entity is required to return each party's full certified IDR entity fee within 30 business days of the date both parties notify the certified IDR entity that they have agreed on an out-of-network rate or agreed to withdraw the dispute.

(2) *Administrative fee*—(i) *In general.* Each party to a dispute for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay a non-refundable administrative fee to the Secretary for participating in the Federal IDR process.

(A) *Timing of payment of administrative fee*. The initiating party must pay the administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity as described in paragraph (c)(1)(iii) of this section. The non-initiating party must pay the administrative fee within 2 business days of the date the non-initiating party receives notice that an eligibility determination for the Federal IDR process has been reached by either the certified IDR entity or the Departments in accordance with paragraph (c)(2) of this section.

(B) *Agreements and withdrawals.* In the case of an agreement, as described in paragraph (c)(3)(i) of this section, or a withdrawal, as described in paragraph (c)(3)(ii) of this section, the administrative fee will not be returned to the parties if preliminary selection of the certified IDR entity has occurred, as described in paragraph (c)(1)(i) of this section; if not yet collected, the administrative fee must still be paid, except as provided in paragraph (d)(2)(i)(C) of this section for a dispute closed for nonpayment by an initiating party.

(C) *Failure to pay administrative fee*. If the initiating party fails to pay the administrative fee in accordance with paragraph (d)(2)(i)(A) of this section, the dispute will be closed due to nonpayment and neither party will be responsible for the administrative fee. If the non-initiating party fails to pay the administrative fee in accordance with paragraph (d)(2)(i)(A) of this section,

that party's offer will not be considered received and the non-initiating party will continue to be responsible for payment of the administrative fee.

(D) *Collection of unpaid fees.* Any party that fails to pay the administrative fee owed in accordance with paragraph (d)(2)(i)(A) of this section is obligated to pay the administrative fee otherwise due and owing, except as provided in paragraph (d)(2)(i)(C) of this section for a dispute closed for nonpayment by an initiating party. The Secretary will pursue collection from a party to a dispute of any administrative fee that is not timely paid pursuant to applicable debt collection authorities.

(ii) *Administrative fee amount*. The administrative fee amount and method of payment will be established through notice and comment rulemaking in a manner such that the total administrative fees paid for a year, including administrative fees reduced under paragraph (d)(2)(iii) of this section, are estimated to be equal to the projected amount of expenditures made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(A) For disputes initiated on or after the later of the effective date of Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges final rules or January 1, 2024, the administrative fee amount is $150 per party per dispute, which will remain in effect until changed by subsequent rulemaking.

(B) [Reserved]

(iii) *Reducing the administrative fee amount*. For disputes initiated on or after January 1, 2025—

(A) The Secretary may reduce the administrative fee for both parties in accordance with paragraph (d)(2)(iii)(C) of this section when the highest offer made by either party during open negotiation for the dispute is less than the threshold established through notice and comment rulemaking, pursuant to paragraph (d)(2)(ii) of this section. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph and for which a

determination has been made that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, the administrative fee amount may be reduced to 50 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section for each party to the dispute. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph and for which a determination has been made that the dispute is ineligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, the administrative fee amount may be reduced to 50 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section for the initiating party and to 20 percent of the administrative fee amount for the non-initiating party.

(B) The Secretary may reduce the administrative fee for a non-initiating party in accordance with paragraph (d)(2)(iii)(C) of this section when the dispute is determined to be ineligible for the Federal IDR process in accordance with paragraph (c)(2) of this section. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph, the administrative fee amount for the non-initiating party may be reduced to 20 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section.

(C) The reduced administrative fee amounts provided for in paragraphs (d)(2)(iii)(A) and (B) of this section shall be established in notice and comment rulemaking and will remain in effect until changed by subsequent rulemaking, pursuant to paragraph (d)(2)(ii) of this section.

(e) Certification of IDR entity—(1) In general. For further guidance, see § 54.9816-8T(e)(1);

(2) *Requirements.* For further guidance, see § 54.9816-8T(e)(2) introductory text;

(i) For further guidance, see § 54.9816-8T(e)(2)(i);

(ii) For further guidance, see § 54.9816-8T(e)(2)(ii);

(iii) For further guidance, see § 54.9816-8T(e)(2)(iii);

(iv) For further guidance, see § 54.9816-8T(e)(2)(iv);

(v) For further guidance, see § 54.9816-8T(e)(2)(v);

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees (if applicable) received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the certified IDR entity;

(vii) For further guidance, see § 54.9816-8T(e)(2)(vii);

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party or a portion of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(3)(i) of this section, a withdrawal described in paragraph (c)(3)(ii) of this section, or a circumstance described under paragraph (d)(1)(iii) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees (if applicable) described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) For further guidance, see § 54.9816-8T(e)(2)(x); and

(xi) For further guidance, see § 54.9816-8T(e)(2)(xi);

(3) *Conflict-of-interest standards*. For further guidance, see § 54.9816-8T(e)(3).

(4) *Period of Certification*. For further guidance, see § 54.9816-8T(e)(4).

(5) *Petition for denial or revocation*. For further guidance, see § 54.9816-8T(e)(5).

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*. For further guidance, see § 54.9816-8T(e)(6).

* * * * *

(g) *Extension of time periods for extenuating circumstances*--(1) *In general.* The time periods specified in this section (other than the time for payment, if applicable, under § 54.9816-8T(c)(5)(ix)) may be extended in extenuating circumstances at the Secretary's discretion. Extenuating circumstances include, but are not limited to when:

(i) With respect to a specific dispute, the Secretary determines that the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of one or both parties or the certified IDR entity, or for other good cause. The certified IDR entity or either party may also submit a request for an extension due to extenuating circumstances to the Secretary through the Federal IDR portal. The requesting certified IDR entity or party must attest that it will take prompt action to ensure that the certified IDR entity's payment determination under this section may be made as soon as administratively practicable under the circumstances; or

(ii) The Secretary determines that the parties or certified IDR entity cannot meet applicable timeframes due to systematic delays in processing disputes under the Federal IDR process, such as an unforeseen volume of disputes or Federal IDR portal system failures. Extensions provided due to extenuating circumstances caused by an unforeseen volume of disputes will be applied to the timeframe for eligibility determinations under paragraph (c)(2) of this section. Extensions provided due to extenuating circumstances caused by systems failures within the Federal IDR portal will be applied to the Federal IDR process timeframe(s) determined relevant by the Secretary. The Secretary will post a public notice regarding any extensions of time periods pursuant to this paragraph (g)(1)(ii).

(A) *Timeframe following an extension to eligibility determination.* When an extension to the eligibility determination timeframe pursuant to paragraph (g)(1)(ii) of this section is in effect, the start date of the subsequent timeframes in the Federal IDR process will be determined based on the date of completion of the eligibility determination by the certified IDR entity or the Secretary.

(*1*) *Submission of offers.* The parties must submit their offers and certified IDR entity fees to the certified IDR entity not later than 10 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section.

(*2*) *Payment Determination.* The certified IDR entity must make the payment determination and notification of the payment determination to the parties not later than 30 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section.

(B) *Timeframe following an extension to other timeframes in the Federal IDR process.* When an extension to any timeframe within the Federal IDR process, other than the eligibility timeframe, is in effect pursuant to paragraph (g)(1)(ii) of this section, the start date of each subsequent timeframe in the Federal IDR process will be determined based on the date of completion of the process for which the extension was granted.

(2) [Reserved]

(h) *Applicability date***.** (1) Paragraph (a) of § 54.9816-8T is applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at § 54.9816-8T(a) and (e) are applicable beginning on October 7, 2021, and the revised definition for batched qualified IDR items and services at paragraph (a)(2)(i) of this section is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(2) Paragraph (b) of this section is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(3) Paragraph (c)(1) of this section, regarding the selection of a certified IDR entity, is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule, except that paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section, regarding the conflict-of-interest standards, are applicable with respect to plan years beginning on or after January 1, 2022.

(4) Paragraph (c)(2) of this section, regarding the Federal IDR process eligibility review and paragraph (c)(3) of this section regarding the authority to continue negotiations or withdraw, are applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule, and paragraph (c)(4) of this section regarding the treatment of batched and bundled qualified IDR items and services is applicable 90 days after the effective date of the rule.

(5) Paragraphs (c)(5)(i) and (ii), and (c)(5)(vii)(B) and(C) of this section regarding the deadlines for the submission of offers, payment determination and notification, suspension of certain subsequent IDR requests, and subsequent submission of requests submitted are applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule. Paragraphs (c)(5)(iii) and (vi) of this section regarding considerations in payment determinations and the related examples and paragraph (c)(5)(vi)(B) of this section regarding written decisions are applicable with respect to items or services furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022. Section 54.9816-8T(c)(5)(v) through (c)(5)(vi)(A), § 54.9816-8T(c)(5)(vii)(A), and § 54.9816-8T(c)(5)(viii) and (ix) are applicable with respect to plan years beginning on or after January 1, 2022.

(6) Paragraph (d) of this section regarding the costs of the IDR process is applicable to disputes initiated on or after January 1, 2025.

(7) Section 54.9816-8T(e) is applicable with respect to plan years beginning on or after January 1, 2022. The provisions regarding IDR entity certification at paragraphs (1), (e)(2)(i) through (vi), (e)(2)(x) and (xi), and (e)(3) through (6) of this section are applicable beginning on October 7, 2021. Paragraphs (e)(2)(vi), (viii), and (ix) of this section regarding the certified IDR entity's controls to prevent and detect improper financial activities, and procedures to retain the certified IDR entity fee and administrative fee are applicable upon the effective date of the rule.

(8) Section 54.9816-8T(f) is applicable with respect to plan years beginning on or after January 1, 2022. Section 54.9816-8(f)(1)(v)(F) regarding reporting of information relating to the Federal IDR process is applicable with respect to items or services furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

(9) Paragraph (g) of this section regarding the extension of time periods for extenuating circumstances is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(10) Until the relevant applicability date for the requirements of this section, plans, issuers, providers, facilities, providers of air ambulance services and certified IDR entities are required to continue to comply with the corresponding section of §§ 54.9816-8 and 54.9816-8T in effect on October 25, 2022.

(i) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions of paragraphs (b)(1), (c)(2)(ii), (c)(4), (d)(2), and (g)(1) of this section are intended to be severable from one another, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in those paragraphs. The provisions in §§ 54.9816-8 and 54.9816-8T are intended to be severable from the provisions in §§ 54.9816-6A, 54.9816-6, 54.9816-6T, and 54.9816-9, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 54.9816-6A, 54.9816-6, 54.9816-6T, and 54.9816-9.

10. Section 54.9816-8T is amended by:

a. Revising paragraphs (a)(2)(i), (b)(1) through (3), (c)(1)(i) and (c)(2);

b. Redesignating paragraphs (c)(3) through (c)(4) as (c)(4) through (c)(5);

c. Adding new paragraph (c)(3);

d. Revising newly redesignated paragraphs (c)(4)(i) introductory text, (c)(4)(i)(B) through (D), (c)(4)(ii), (c)(5(i) introductory text, (c)(5)(ii), (iii) and (iv), (c)(5)(vi)(B), (c)(5)(vii)(A) introductory text, and (c)(5)(vii)(B) and (C);

e. Revising paragraphs (d) introductory text, (e)(2)(vi), (viii) and (ix), and (g); and

f. Adding paragraphs (h) and (i).

The revisions and additions read as follows:

§ 54.9816-8T Independent dispute resolution process. (temporary)

(a) * * *

(2) * * *

(i) *Batched items and services*—For further guidance, see § 54.9816-8(a)(2)(i);

* * * * *

(b) * * *

(1) *Determination of payment amount through open negotiation*. For further guidance, see § 54.9816-8(b)(1);

(2) *Initiating the Federal IDR process*. For further guidance, see § 54.9816-8(b)(2);

(3) *Manner.* For further guidance, see § 54.9816-8(b)(3).

(c) * * *

(1) * * *

(i) *Preliminary selection of the certified IDR entity*. For further guidance, see § 54.9816-8(c)(1).

*****

(2) *Federal IDR process eligibility review.* For further guidance, see § 54.9816-8(c)(2).

(3) *Authority to continue negotiations or withdraw.* For further guidance, see § 54.9816-8(c)(3).

(4) * * *

(i) *In general*. For further guidance, see § 54.9816-8(c)(4)(i).

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) For further guidance, see § 54.9816-8(c)(4)(i)(B).

(C) For further guidance, see § 54.9816-8(c)(4)(i)(C).

(D) For further guidance, see § 54.9816-8(c)(4)(i)(D).

(ii) *Treatment of bundled payment arrangements*. For further guidance, see § 54.9816-8(c)(4)(ii)

(5) * * *

(i) *Submission of offers*. For further guidance, see § 54.9816-8(c)(5)(i).

* * * * *

(ii) *Payment determination and notification*. For further guidance, see § 54.9816-8(c)(5)(ii).

(A) For further guidance, see § 54.9816-8(c)(5)(ii)(A)

(B) Notify the plan and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(5)(ii)(A) of this section, and provide the written decision required under (c)(5)(vi) of this section.

(iii) *Considerations in determination.* For further guidance, see § 54.9816-8(c)(5)(iii).

(iv) *Examples*. For further guidance, see § 54.9816-8(c)(5)(iv).

* * * *

(vi) * * *

(B) For further guidance, see § 54.9816-8(c)(5)(vi)(B).

(vii) * * *

(A) *Binding* determination made by a certified IDR entity under paragraph (c)(5)(ii) of this section:

* * *

(B) *Suspension of certain subsequent IDR requests*. For further guidance, see § 54.9816-8(c)(5)(vii)(B).

(C) *Subsequent submission of requests permitted*. For further guidance, see § 54.9816-8(c)(5)(vii)(C).

* * * * * *

(d) Costs of IDR process. For further guidance, see § 54.9816-8(d);

* * * * *

(e) * * *

(2) * * *

(vi) For further guidance, see § 54.9816-8(e)(2)(vi);

* * *

(viii) For further guidance, see § 54.9816-8(e)(2)(viii);

(ix) For further guidance, see § 54.9816-8(e)(2)(ix);

* * * * *

(g) *Extension of time periods for extenuating circumstances*. For further guidance, see § 54.9816-8(g).

(h) *Applicability date*. For further guidance, see § 54.9816-8(h);

(i) *Severability*. For further guidance, see § 54.9816-8(i).

11. Section 54.9816-9 is added to read as follows:

§ 54.9816-9 Federal Independent Dispute Resolution Registry of Group Health Plans, Health Insurance Issuers, and Federal Employees Health Benefits Carriers.

(a) *Establishment of Federal independent dispute resolution registry.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will establish a Federal IDR registry consisting of the information described in paragraph (b)(2) of this section and will assign a registration number for each group health plan, health insurance issuer offering group or individual health insurance coverage, and Federal Employees Health Benefits (FEHB) Program carrier. The information contained in the registry will be made available to parties seeking to initiate an open negotiation or a dispute through the Federal IDR portal, and will be searchable, including by registration number.

(b) *Federal IDR registration*--(1) *Registration requirement.* Each group health plan subject to the Federal IDR process must register with the Federal IDR registry as specified by the Secretary in guidance. Initial registration must be completed by the later of the date that is 30 business days after the effective date of the final rule, the date that is 30 business days after the registry becomes available, or the date the group health plan begins offering a group health plan coverage subject to the Federal IDR process.

(2) *Required data elements.* Group health plans subject to the registration requirement must include the following information with their registration:

(i) The legal business name (if any) of the group health plan, and, if applicable, the legal business name of the group health plan sponsor;

(ii) Whether the plan is a self- or fully-insured group health plan subject to ERISA or a self- or fully-insured church plan;

(iii) The State(s) in which the plan is subject to a specified State law, as defined in § 54.9816-3T for any items or services for which the protections of §§ 54.9816-1T, 54.9816-4T, and 54.9816-5T apply;

(iv) The State(s) in which the plan is subject to an All-Payer Model Agreement under section 1115A of the Social Security Act for any items or services to which the protections in §§ 54.9816-1T, 54.9816-4T, and 54.9816-5T, apply;

(v) For self-insured group health plans not otherwise subject to State law, any State(s) in which the group health plan has properly effectuated an election to opt in to a specified State law as defined in § 54.9816-3T, if that State allows a plan not otherwise subject to the State law to opt-in;

(vi) Contact information, including a telephone number and email address, for the appropriate person or office with whom to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service;

(vii) The 14-digit Health Insurance Oversight System (HIOS) identifier; or if the 14-digit HIOS identifier has not been assigned, the 5-digit HIOS identifier; or if no HIOS identifier is available, the plan's or the plan sponsor's Employer Identification Number (EIN) and the plan's plan number (PN), if a PN is available;

(viii) Additional information needed to identify the plan and the applicable Federal and State requirements for determining appropriate out-of-network payment rates for items or services to which the protections against balance billing in this part apply, as specified by the Secretary in guidance; and

(ix) Additional information needed for purposes of administrative fee collection, as specified by the Secretary in guidance.

(3) *Updating disclosures.* A plan must timely report to the Secretary changes to the information required under this section within 30 calendar days after the information changes. A plan must confirm the accuracy of its registration annually in the fourth quarter of each calendar year.

(4) *Third party authority.* The requirements of paragraphs (b)(1) through (3) of this section may be performed by a third party administrator or service provider with authority to act

on behalf of the group health plan subject to the Federal IDR process. If the registration requirements are performed by such third party administrator or service provider the group health plan or health insurance issuer offering group or individual health insurance coverage must require that such third party administrator or service provider clearly delineate each group health plan or health insurance issuer offering group health insurance coverage for which it has authority to act. If such third party administrator or service provider fails to provide the information in compliance with the requirements of paragraphs (b)(1) through (3) of this section the plan or issuer will be in violation of the requirements of this section.

(c) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 54.9816-9 are intended to be severable from the provisions in §§ 54.9816-6, 54.9816-6T, 54.9816-8, and 54.9816-8T, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 54.9816-6, 54.9816-6T, 54.9816-8, and 54.9816-8T.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

12. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Division M, Pub. L. 113-235, 128 Stat. 2130; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

Subpart D—Surprise Billing and Transparency Requirements

13. Section 2590.716-3 is amended by adding the definition of "Bundled payment arrangement" in alphabetical order to read as follows:

§ 2590.716-3 Definitions.

* * * * *

Bundled payment arrangement means an arrangement under which—

(1) A provider, facility, or provider of air ambulance services bills for multiple items or services furnished to a single patient under a single service code that represents multiple items or services (for example, a Diagnosis-Related Group (DRG) code); or

(2) A plan or issuer makes an initial payment or notice of denial of payment to a provider, facility, or provider of air ambulance services under a single service code that represents multiple items or services furnished to a single patient (for example, a DRG code).

* * * * *

14. Section 2590.716-6 is amended by:

a. Revising paragraphs (d) introductory text and (d)(1)(iv);

b. Redesignating paragraph (d)(1)(v) as paragraph (d)(1)(vi);

c. Adding a new paragraph (d)(1)(v);

d. Revising paragraph (d)(2) introductory text; and

e. Adding paragraph (g).

The revisions and additions read as follows:

§ 2590.716-6 Methodology for calculating qualifying payment amount.

* * * * *

(d) *Information to be shared about the qualifying payment amount.* In cases in which the recognized amount, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility, is the qualifying payment amount or the amount billed by the provider or facility, or if the amount on which cost sharing is based with respect to air ambulance services furnished by a nonparticipating provider of air ambulance services is the qualifying payment amount or the amount billed by the provider of air ambulance services, the plan or issuer must provide to the provider, facility, or provider of air ambulance services, as applicable, in writing, in paper or electronic form –

(1) * * *

(iv) A statement that –

(A) If the provider, facility, or provider of air ambulance services, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the out-of-network rate, the provider, facility, or provider of air ambulance services must:

(*1*) Contact the appropriate person or office to initiate open negotiation within 30 business days of receiving the initial payment or notice of denial of payment, and

(*2*) For disclosures required to be provided on or after [DATE 90 DAYS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**] and once the

open negotiation notice can be submitted through the Federal IDR portal, notify the Secretary as described under § 2590.716-8(b)(1)(i); and

(B) If the 30-business-day open negotiation period does not result in an agreement on the amount of payment the provider, facility, or provider of air ambulance services may generally initiate the Federal IDR process within 4 business days after the end of the open negotiation period;

(v) For disclosures required to be provided on or after [date 90 days after publication of final regulations in the **Federal Register**], the legal business name of the group health plan (if any) or issuer, the legal business name of the plan sponsor (if applicable), and the registration number assigned under § 2590.716-9, if the plan or issuer is registered under § 2590.716-9.

(2) In a timely manner upon the request of the provider, facility, or provider of air ambulance services:

* * * * *

(g) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 2590.716-6 are intended to be severable from the provisions in §§ 2590.716-6A, 2590.716-8, and 2590.716-9, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 2590.716-6A, 2590.716-8, and 2590.716-9.

15. Section 2590.716-6A is added to subpart D to read as follows:

§ 2590.716-6A Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes.

(a) *In general.* When providing any paper or electronic remittance advice to an entity that does not have a contractual relationship directly or indirectly with a group health plan or a health insurance issuer offering group or individual health insurance coverage with respect to the furnishing of the item or service under the plan or coverage in response to a claim for payment for health care items and services furnished by that entity, the plan or issuer must use claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) (see 45 CFR 162.1602 and 162.1603) as specified in guidance issued by the Secretaries of the Treasury, Labor, and Health and Human Services, or as required under any applicable adopted standards and operating rules under 45 CFR part 162, to communicate information related to whether the claim is or is not subject to the provisions of this subpart and 45 CFR part 149, subpart E.

(b) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 2590.716-6A are intended to be severable from the provisions in §§ 2590.716-6, 2590.716-8, and 2590.716-9, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 2590.716-6, 2590.716-8, and 2590.716-9.

16. Section 2590.716-8 is amended by:

a. Revising paragraphs (a)(2)(i), (b)(1)(i), and (b)(1)(ii)(A);

b. Removing and reserving paragraph (b)(1)(ii)(B);

c. Adding paragraph (b)(1)(iii);

d. Revising paragraph (b)(2)(i);

e. Redesignating paragraph (b)(2)(ii) as (b)(2)(i)(A);

f. Adding and reserving paragraph (b)(2)(i)(B);

g. Redesignating paragraph (b)(2)(iii) as (b)(2)(ii);

h. Revising newly redesignated paragraph (b)(2)(ii)(A);

i. Reserving newly redesignated paragraph (b)(2)(ii)(B);

j. Removing newly redesignated paragraph (b)(2)(ii)(C);

k. Adding paragraphs (b)(2)(iii) and (b)(3);

l. Revising paragraph (c)(1);

m. Redesignating paragraphs (c)(2) through (4) as paragraphs (c)(3) through (5), respectively;

n. Adding a new paragraph (c)(2);

o. Revising newly redesignated paragraphs (c)(3), (c)(4)(i) introductory text, (c)(4)(i)(B) through (D), (c)(4)(ii), (c)(5)(i) introductory text, (c)(5)(ii) introductory text,

p. Adding paragraphs (c)(5)(ii)(A)(*1*) and (*2*) and removing the reference to "(c)(4)" and adding in its place "(c)(5)" in newly redesignated paragraphs (c)(5)(ii)(A) introductory text and (B);;

q. Revising paragraphs (c)(5)(vii)(B) and (C);;

r. Revising paragraphs (d), (e)(2)(vi), (viii), and (ix), (g) and (h);

s. Adding paragraph (i).

The revisions and additions read as follows:

§ 2590.716-8 Independent dispute resolution process.

(a) * * *

(2) * * *

(i) *Batched qualified IDR 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 accordance with paragraph (c)(4) of this section.

* * * * *

(b) * * *

(1) * * *

(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xi)(A) of this section, the provider, facility, or provider of air ambulance services, or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must submit a written open negotiation notice with the content specified in paragraph (b)(1)(ii) of this section to the other party and to the Secretary in the manner specified in paragraph (b)(3) of this section. The 30-business-day open negotiation period begins on the day on which the party first submits the open negotiation notice and the remittance advice documentation specified in paragraph (b)(1)(ii)(A)(*12*) of this section to the other party and the Secretary. The party in receipt of the open negotiation notice must provide to the other party and to the Secretary in the manner specified in paragraph (b)(3) of this section as soon as practicable, but no later than the 15th business day of the 30-business-day open negotiation period, a written notice and supporting documentation in response to the open negotiation notice, as specified in paragraph (b)(1)(iii)(A) of this section.

(ii) * * *

(A) *Content.* The open negotiation notice must include, with respect to the item or service that is the subject of the open negotiation notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name,

email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or air ambulance provider to the plan or issuer, and the National Provider Identifier (NPI);

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 2590.716-9, if the plan or issuer is registered under § 2590.716-9, or an attestation from the party submitting the open negotiation notice that the plan or issuer was not registered prior to the date it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation notice is a plan or issuer, the plan type (for example, self-insured or fully-insured);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation;

(*4*) Information sufficient to identify the item or service, including: the date(s) the item or service was furnished and, if the party submitting the open negotiation notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for the item or service from the plan or issuer; the type of item or service (specifically, whether the item or service is an emergency service as defined in § 2590.716-4(c)(2)(i) or (ii), a non-emergency service as described in § 2590.716-5(b), or an air ambulance service as defined in § 2590.716-3); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location where the item or service was furnished (such as, place of service code or bill type code);

(*5*) The initial payment amount (including $0 if, for example, payment is denied);

(*6*) The qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the party submitting the open negotiation notice is a plan or issuer;

(*7*) An offer of an out-of-network rate for each item or service;

(*8*) If the party submitting the open negotiation notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*9*) If the party submitting the open negotiation notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i);

(*10*) A statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished;

(*11*) General information listed in the standard open negotiation notice developed by the Secretary pursuant to paragraph (b)(3) of this section describing the open negotiation period and the Federal IDR process (including a description of the purpose of the open negotiation period and Federal IDR process and key deadlines in the open negotiation period and Federal IDR process); and

(*12*) A copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under § 2590.716-6(d)(1), with respect to the item or service.

(B) [Reserved]

(iii) *Open negotiation response notice.* (A) *Content.* The response to the open negotiation notice must include, with respect to the item or service that is the subject of the open negotiation response notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name,

email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or provider of air ambulance services to the plan or issuer, and the NPI;

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 2590.716-9 if the plan or issuer is registered under § 2590.716-9, or an attestation from the party submitting the open negotiation response notice that the plan or issuer was not registered prior to the date it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation response notice is a plan or issuer, the plan type (for example, self-insured or fully-insured);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation response notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation;

(*4*) Information sufficient to identify the item or service included in the open negotiation notice, including the date(s) the item or service was furnished, and if the party submitting the open negotiation response notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number;

(*5*) If the party submitting the open negotiation response notice is a plan or issuer, a statement as to whether it agrees that the initial payment amount (including $0 if, for example, payment is denied) and the qualifying payment amount reflected in the open negotiation notice accurately reflects the initial payment amount and qualifying payment amount disclosed with the initial payment for the item or service, and if not, or if the open negotiation notice indicates that qualifying payment amount was not communicated by the plan or issuer with the initial payment

or notice of denial of payment or other remittance advice, the initial payment amount (including $0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount);

(*6*) If the party submitting the open negotiation response notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*7*) A counteroffer for an out-of-network rate for each item or service or an acceptance of the other party's offer;

(*8*) If the party submitting the open negotiation response notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i);

(*9*) With respect to each item or service, either a statement and supporting documentation that explains why the item or service is not subject to the Federal IDR process or a statement agreeing that the item or service is subject to the Federal IDR process;

(*10*) A statement as to whether any of the information provided in the open negotiation notice is inaccurate and the basis for the statement, as well as supporting documentation; and

(*11*) A statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the party submitting the open negotiation notice under paragraph (b)(1)(ii)(A)(*12*) of this section is accurate, and if inaccurate, a copy of the accurate initial payment, or notice of denial of payment, or other remittance advice required to include the disclosures under § 2590.716-6(d)(1), with respect to the item or service.

(B) [Reserved]

(2) * * *

(i) *In general.* Either party may initiate the Federal IDR process with respect to a qualified IDR item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period provided for under paragraph (b)(1) of this section. To

initiate the Federal IDR process, a party (the initiating party) must submit a written notice of IDR initiation, consistent with paragraph (b)(2)(ii) of this section, to the other party to the dispute (the non-initiating party), and to the Secretary in the manner specified in paragraph (b)(3) of this section, during the 4-business-day period beginning on the first business day after the last day of the open negotiation period (unless it is otherwise required to be submitted in the timeframe specified in paragraph (c)(5)(vii)(C) of this section). The date of IDR initiation is the date that the Secretary receives the notice of IDR initiation described in paragraph (b)(2)(ii) of this section.

* * * * *

(B) [*Reserved*]

(ii) * * *

(A) *Content.* The notice of IDR initiation must include, with respect to the item or service that is the subject of the notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address), and the NPI; and if the initiating party is a provider, facility, or provider of air ambulance services, the Tax Identification Number (TIN);

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 2590.716-9 if the plan or issuer is registered under § 2590.716-9, or an attestation from the initiating party that the plan or issuer was not registered prior to the date that it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the initiating party is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process;

(*4*) Information sufficient to identify whether the dispute being initiated includes batched or bundled qualified IDR items or services as described in paragraph (c)(4) of this section;

(*5*) Information sufficient to identify the qualified IDR item or service that is the subject of the notice of IDR initiation, including the date(s) the qualified IDR item or service was furnished; if the initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer; the date the open negotiation period under paragraph (b)(1) of this section began; the type of item or service (specifically, whether the qualified IDR item or service is an emergency service as defined in § 2590.716-4(c)(2)(i) or (ii), a non-emergency service as described in § 2590.716-5(b), or an air ambulance service as defined in § 2590.716-3); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location the item or service was furnished (including place of service code or bill type code);

(*6*) The initial payment amount (including $0 if, for example, payment is denied);

(*7*) The qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the initiating party is a plan or issuer;

(*8*) If the initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i);

(*9*) A statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished;

(*10*) Attestation that the item or service under dispute is a qualified IDR item or service, and the basis for the attestation;

(*11*) General information listed in the standard notice of IDR initiation developed by the Secretary pursuant to paragraph (b)(3) of this section describing the Federal IDR process (including a description of the purpose of the Federal IDR process and key deadlines in the Federal IDR process);

(*12*) A copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under § 2590.716-6(d)(1), with respect to the item or service;

(*13*) Preferred certified IDR entity; and

(*14*) A statement describing the key aspects of the claim, such as patient acuity or level of training of the provider, facility, or provider of air ambulance services that furnished the qualified IDR item or service, discussed by the parties during open negotiation that relate to the payment for the disputed claim, whether the reasons for initiating the Federal IDR process are different from the aspects of the claim discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process, including any of the permissible considerations described in §§ 2590.716-8(c)(5)(iii) and 2590.717-2(b)(2) that serve as the party's basis for initiating the Federal IDR process.

(B) [Reserved]

(iii) *Notice of IDR initiation response*. The non-initiating party must provide to the initiating party and to the Secretary in the manner specified in paragraph (b)(3) of this section within 3 business days after the date of IDR initiation, a written notice and supporting

documentation in response to the notice of IDR initiation, as specified in paragraph (b)(2)(iii)(A) of this section.

(A) *Content*. The notice of IDR initiation response must include, with respect to the item or service that is the subject of the notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address), and the NPI; and if the non-initiating party is a provider, facility, or provider of air ambulance services, the TIN;

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 2590.716-9 if the plan or issuer is registered under § 2590.716-9 or an attestation from the non-initiating party that the plan or issuer was not registered prior to the date that it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the non-initiating party is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the non-initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process;

(*4*) Information sufficient to identify each item or service included in the notice of IDR initiation, including the date(s) the item or service was furnished. If the non-initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or

provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number;

(*5*) If the non-initiating party is a plan or issuer, a statement as to whether the non-initiating party agrees that the initial payment (including $0 if, for example, payment is denied) and the qualifying payment amount reflected in the notice of IDR initiation is accurate for the item or service that is the subject of the dispute, and if not, the initial payment amount (including $0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount);

(*6*) If the non-initiating party is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*7*) If the non-initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i);

(*8*) With respect to each item or service that is the subject of the dispute, either an attestation that the item or service is a qualified IDR item or service, or for each item or service that the non-initiating party asserts is not a qualified IDR item or service, an explanation and documentation to support the statement;

(*9*) A statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the initiating party under paragraph (b)(2)(ii)(A)(*12*) of this section is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of payment or other remittance advice required to include the disclosures under § 2590.716-6(d)(1), with respect to the item or service;

(*10*) A statement as to whether any of the information provided in the notice of IDR initiation is inaccurate and the basis for the statement as well as any supporting documentation; and

(*11*) A statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity. If the non-initiating party objects to the initiating party's preferred certified IDR entity, the notice of IDR initiation response must include the name of an alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the initiating party's preferred certified IDR entity.

(B) [Reserved].

(3) *Manner.* A party furnishing notices as required under paragraphs (b)(1)(ii) and(iii), and (b)(2)(ii) and (iii) of this section must furnish the notices using the standard forms developed by the Secretary and must furnish the notices and supporting documentation to the other party and the Secretary, through the Federal IDR portal.

(c) * * *

(1) *Selection of certified IDR entity*--(i) *Preliminary selection of the certified IDR entity.* Within 3 business days after the date of IDR initiation, the non-initiating party must agree or object to the preferred certified IDR entity identified in the notice of IDR initiation, as described in paragraph (b)(2)(iii)(A)(*11*) of this section.

(A) If the non-initiating party agrees, or fails to object, to the selection of the initiating party's preferred certified IDR entity in the manner described in paragraph (b)(2)(iii)(A)(*11*) of this section and within the timeframe specified in paragraph (c)(1)(i) of this section, the initiating party's preferred certified IDR entity will be considered jointly selected on the third business day after the date of IDR initiation.

(B) If the non-initiating party objects to the selection of the initiating party's preferred certified IDR entity by designating an alternative preferred certified IDR entity in the manner described in paragraph (b)(2)(iii)(A)(*11*) of this section and within the timeframe specified in paragraph (c)(1)(i) of this section, the initiating party may then agree or object to the non-initiating party's alternative preferred certified IDR entity by submitting the notice of certified IDR entity selection in the manner specified in paragraph (c)(1)(i)(D) of this section. If the

initiating party agrees to the non-initiating party's alternative preferred certified IDR entity within 3 business days after the date of IDR initiation, or if the non-initiating party submits the notice of IDR initiation response on or before the second business day after the date of IDR initiation and the initiating party fails to respond within 3 business days after the date of IDR initiation, the alternative preferred certified IDR entity will be considered jointly selected by the parties. If the non-initiating party submits the notice of IDR initiation response on the third business day after the date of IDR initiation and the initiating party does not agree on the same day, selection will proceed under paragraph (c)(1)(i)(C) of this section.

(C) If a certified IDR entity is not jointly selected under paragraph (c)(1)(i)(A) or (B) of this section, either party may select an alternative preferred certified IDR entity by submitting the notice of certified IDR entity selection in the manner specified in paragraph (c)(1)(i)(D) of this section, until the earlier of the date that the parties agree on the alternative preferred certified IDR entity or the deadline for joint selection, which is 3 business days after the date of IDR initiation. Once a party submits a notice of certified IDR entity selection, it may not submit another notice of certified IDR entity selection until after it receives a responding notice of certified IDR entity selection from the other party.

(*1*) If a party submits a notice of certified IDR entity selection to the other party on the first or second day after the date of IDR initiation and the party in receipt of the notice agrees or fails to object to the alternative preferred certified IDR entity by the third business day after the date of IDR initiation, the alternative preferred certified IDR entity will be considered jointly selected by the parties.

(*2*) If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice agrees to the alternative preferred certified IDR entity on the same day, the alternative preferred certified IDR entity will be considered jointly selected by the parties.

(*3*) If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice does not agree to the alternative preferred certified IDR entity on the same day, the parties will have failed to jointly select a certified IDR entity.

(D) To notify the other party and the Secretary of an agreement or objection to an alternative preferred certified IDR entity under paragraph (c)(1)(i)(C) of this section, a party must submit the notice of certified IDR entity selection. The party must furnish the notice of certified IDR entity selection using the standard form developed by the Secretary and must furnish the notice to the other party and the Secretary through the Federal IDR portal within 3 business days after the date of IDR initiation. However, in the event the conditions under paragraph (c)(1)(ii) of this section apply, the party may notify the Secretary of an agreement or objection to an alternative preferred certified IDR entity in accordance with paragraph (c)(1)(ii) of this section. The notice of certified IDR entity selection must include a statement indicating the party's agreement with or objection to the other party's alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the alternative preferred certified IDR entity. If the party in receipt of a notice of certified IDR entity selection objects to the other party's alternative preferred certified IDR entity and the party submits a notice of certified IDR entity selection by the end of the third business day after the date of IDR initiation, that party's notice of certified IDR entity selection reflecting the objection must include the name of another alternative preferred certified IDR entity.

(ii) *Failure to jointly select a certified IDR entity.* If the parties fail to jointly select a certified IDR entity within 3 business days after the date of IDR initiation, the Secretary will select a certified IDR entity. The parties will have failed to jointly select a certified IDR entity if, by the end of the third business day after the date of IDR initiation, the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection has objected to the other party's alternative preferred certified IDR entity, or if the notice of IDR initiation

response or the notice of certified IDR entity selection is submitted to the other party on the third business day after the date of IDR initiation and the party in receipt of the notice does not agree to the alternative preferred certified IDR entity within 3 business days after the date of IDR initiation.

(A) In selecting the certified IDR entity, the Secretary will first confirm whether a party submitted the notice of IDR initiation response or the notice of certified IDR entity selection with an alternative preferred certified IDR entity on the third business day after the date of IDR initiation without the other party's agreement to the selection. If either notice was provided on the third business day after the date of IDR initiation without the other party's agreement to the alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Secretary will provide the party last in receipt of the applicable notice 2 additional business days to agree or object to the other party's alternative preferred certified IDR entity selection.

(*1*) If the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection agrees with the other party's alternative preferred certified IDR entity and notifies the Secretary of the agreement or fails to notify the Secretary of its objection in the Federal IDR portal by the fifth business day after the date of IDR initiation, the Secretary will select the final alternative preferred certified IDR entity selected in the applicable notice. In disputes where the applicable notice was submitted on the third business day after the date of IDR initiation, the party last in receipt of the notice will not be allowed to select another alternative preferred certified IDR entity.

(*2*) If the party notifies the Secretary of its objection to the alternative preferred certified IDR entity by the fifth business day after the date of IDR initiation, the Secretary will proceed with the random selection of the certified IDR entity from among the certified IDR entities (other than the preferred certified IDR entity and any alternative preferred certified IDR entity previously selected in such dispute by a party, unless there is no other certified IDR entity

available to select) that charge a fee within the allowed range of certified IDR entity fees on the sixth business day after the date of IDR initiation. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vii)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees. In either case, the Secretary will notify the parties of the preliminary selection of the certified IDR entity not later than 6 business days after the date of IDR initiation.

(B) [Reserved].

(iii) *Date of preliminary selection of the certified IDR entity*. The date of preliminary selection of the certified IDR entity will be:

(A) Three business days after the date of IDR initiation if the parties jointly selected a certified IDR entity, as specified in paragraph (c)(1)(i) of this section; or

(B) Six business days after the date of IDR initiation, if the parties fail to jointly select a certified IDR entity as specified in paragraph (c)(1)(ii) of this section.

(iv) *Final selection of the certified IDR entity*--(A) *Conflict-of-interest review*. The certified IDR entity preliminarily selected for a dispute must review the selection. The selection of the certified IDR entity will be finalized only if the certified IDR entity attests to the Secretary that it meets the following requirements:

(*1*) The certified IDR entity does not have a conflict of interest as defined in paragraph (a)(2)(iv) of this section;

(*2*) The certified IDR entity will only assign personnel to a dispute and make decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute in a manner that is not based upon the likelihood that the assigned personnel will support a particular party to the dispute; and

(*3*) The certified IDR entity will not assign any personnel to a dispute who would have any conflicts of interest, as defined in paragraph (a)(2)(iv) of this section, regarding any party to

the dispute or whose relationship with a party within the 1 year immediately preceding the assignment to the dispute would violate the restrictions on aiding or advising a former employer or principal in a manner similar to the restrictions set forth in 18 U.S.C. 207(b).

(B) *Failure to meet conflict-of-interest requirements.* If the certified IDR entity notifies the Secretary within 3 business days of the date of preliminary selection of the certified IDR entity that it does not meet the requirements of paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section or if the certified IDR entity does not respond within 3 business days after the date of preliminary selection of the certified IDR entity, the Secretary will randomly select another certified IDR entity consistent with paragraph (c)(1)(ii) of this section. The Secretary will notify the parties of the new randomly preliminarily selected certified IDR entity no later than 1 business day after the previously selected certified IDR entity notifies the Secretary that it has a conflict of interest or, if the previously selected certified IDR entity fails to respond within 3 business days after the date of preliminary selection of the certified IDR entity, no later than 1 business day after the end of the 3-business-day period.

(C) *Date of final selection of the certified IDR entity*. If the certified IDR entity that has been preliminarily selected attests within 3 business days that it meets the requirements of paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section, the Secretary will notify the parties of final selection of the certified IDR entity no later than 1 business day after the certified IDR entity attests that it meets the conflict-of-interest requirements. The date of final selection of the certified IDR entity is the date that the Secretary provides this notice to the parties.

(2) *Federal IDR process eligibility review*--(i) *Federal IDR process eligibility determination by certified IDR entity*. Unless the departmental eligibility review described in paragraph (c)(2)(ii) of this section applies, the selected certified IDR entity must review the information in the notice of IDR initiation, notice of IDR initiation response, and any additional information described in paragraph (c)(2)(iii) of this section, and make a final determination as to whether the item or service is a qualified IDR item or service, as defined in paragraph

(a)(2)(xi) of this section, that is eligible for the Federal IDR process. The certified IDR entity must make such a determination and notify the Secretary and both parties no later than 5 business days after the date of final selection of the certified IDR entity. If the certified IDR entity determines that the item or service is not a qualified IDR item or service, the dispute will be closed, and the selected certified IDR entity will not take any action with regard to the dispute.

(ii) *Departmental eligibility review for Federal IDR process eligibility determinations*. When the conditions for the departmental eligibility review set forth in paragraph (c)(2)(ii)(A) of this section are met, the Secretary will conduct the eligibility review and make the eligibility determination instead of the certified IDR entity. If the Secretary determines that the item or service is not a qualified IDR item or service, the dispute will be closed, and the selected certified IDR entity will not take any action with regard to the dispute. If the dispute is found to be eligible, the Secretary will inform the preliminarily selected certified IDR entity of the dispute's eligibility so that it may conduct its conflict-of-interest assessment, and the dispute will otherwise continue through the Federal IDR process, including notification of the eligibility determination to the disputing parties by the preliminarily selected certified IDR entity.

(A) *Application of the departmental eligibility review.* The departmental eligibility review will apply when the Secretary determines that any of the extenuating circumstances described in paragraph (g)(1) of this section require application of the departmental eligibility review to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process.

(B) *Notification regarding applicability of the departmental eligibility review.* Before invoking the application of the departmental eligibility review, the Secretary will post advance public notification of the date on which the departmental eligibility review will take effect and the reasons for invoking the application of the departmental eligibility review. Before ending the application of the departmental eligibility review, the Secretary will post advance public

notification of the date on which the departmental eligibility review will no longer be in effect and the reasons for ending the application of the departmental eligibility review.

(iii) *Request for additional information*. The Secretary or the selected certified IDR entity may request additional information from either party to a dispute at any time, including for the purpose of assessing whether a conflict of interest exists, conducting an eligibility determination, or making a payment determination.

(A) Upon request, a party must submit the additional information within 5 business days to the Secretary or the selected certified IDR entity, as applicable, through the Federal IDR portal. Following a request for additional information, the time period for the applicable stage of the Federal IDR process will be tolled until the earlier of the date either all of the requested information is provided or the 5-business-day period expires, and each subsequent timeframe in the Federal IDR process will be determined based on the date of completion of the stage of the Federal IDR process that was tolled for provision of the requested information.

(B) If a party fails to submit the additional information as required, the related determination, including the eligibility determination, conflict-of-interest review, or payment determination will be made without the requested information unless a good-cause extension of the 5-business-day period, as specified in paragraph (g)(1)(i) of this section, has been provided, and the party subsequently submits the additional information requested within the extended period.

(3) *Authority to continue negotiations or withdraw*--(i) *Authority to continue to negotiate.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary required under paragraph (b)(2)(ii) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount and any cost sharing paid or required to be paid by the participant or

beneficiary, or there was an initial denial of payment, payment must be made directly by the plan or issuer to the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the dispute number, a statement of the out-of-network rate for the qualified IDR item or service, and signatures from authorized signatories for both parties.

(ii) *Withdrawals*. A dispute may be withdrawn from the Federal IDR process by the initiating party, the Secretary, or a certified IDR entity before a payment determination is made if one of the following conditions is met:

(A) The initiating party provides notification through the Federal IDR portal to the Secretary and the certified IDR entity (if selected) that both parties to the dispute agree to withdraw the dispute from the Federal IDR process without agreement on an out-of-network rate. The notification must include the dispute number, a statement about both parties' agreement to withdraw and signatures from authorized signatories for both parties.

(B) The initiating party provides a standard withdrawal request notice through the Federal IDR portal to the Secretary, the certified IDR entity (if selected), and the non-initiating party of its request to withdraw the dispute from the Federal IDR process and the non-initiating party notifies the Secretary, certified IDR entity (if selected), and the initiating party through the Federal IDR portal of its agreement to withdraw from the Federal IDR process within 5 business days of the initiating party's request. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party will be considered to have agreed to the withdrawal, and the dispute will be withdrawn.

(C) The certified IDR entity or Secretary cannot determine eligibility because both parties to the dispute are unresponsive to any requests for additional information to determine eligibility as described in paragraph (c)(2)(iii) of this section, or

(D) The certified IDR entity cannot make a payment determination because both parties to the dispute have failed to submit an offer as described in paragraph (c)(5)(i) of this section.

(4) *Treatment of batched qualified IDR items and services*–(i) *In general.* A certified IDR entity may consider up to 25 qualified IDR items and services jointly as part of one payment determination that is subject to the certified IDR entity fee for batched determinations only if the qualified IDR items and services meet the requirements of this paragraph (c)(4)(i):

* * * * *

(B) Payment for the qualified IDR items and services is required to be made by the same group health plan or health insurance issuer. For group or individual health insurance coverage, this requirement is satisfied if the same issuer is required to make payment for the qualified IDR items and services, even if the qualified IDR items and services relate to claims from different group health plans or individual market policies. For self-insured group health plans, this requirement is satisfied if the same self-insured group health plan is required to make payment for the qualified IDR items and services, including when the plan makes payments through a third party administrator; the requirement is not satisfied if multiple self-insured group health plans are required to make payments for the qualified IDR items and services, even if those group health plans make payments through the same third party administrator;

(C) The qualified IDR items and services meet any of the following criteria under which multiple qualified IDR items and services relate to the treatment of a similar condition and therefore are permitted to be considered jointly as a single payment determination for purposes of encouraging efficiencies (including minimizing costs) in the Federal IDR process:

(*1*) The qualified IDR items or services were furnished to a single patient during the same patient encounter. For purposes of this section, a single patient encounter is defined as a patient

encounter on one or more consecutive days during which the qualified IDR items or services were furnished to the same patient and billed on the same claim form; or

(*2*) The qualified IDR items and services were furnished to one or more patients and were billed under the same service code or a comparable code under a different procedural coding system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) codes with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; or

(*3*) For anesthesiology, radiology, pathology, and laboratory qualified IDR items and services, the qualified IDR items and services were furnished to one or more patients and were billed under service codes belonging to the same Category I CPT code range, as specified in guidance published by the Secretary; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period following the date on which the first item or service included in the batched determination was furnished and were the subjects of a 30-business-day open negotiation period that ended within 4 business days of IDR initiation, except as provided in paragraph (c)(5)(vii) of this section.

(ii) *Treatment of bundled payment arrangements.* Qualified IDR items and services that meet the definition of a bundled payment arrangement under § 2590.716-3 may be submitted and considered as a single payment determination, and the certified IDR entity must make a single payment determination for the multiple qualified IDR items and services included in the bundled payment arrangement. Bundled payment arrangements as defined in § 2590.716-3 and submitted under this paragraph (c)(4)(ii) are subject to the certified IDR entity fee for single determinations.

(5) * * *

(i) *Submission of offers*. Not later than 10 business days after the date of final selection of the certified IDR entity as described in paragraph (c)(1)(iv)(C) of this section (or not later than

10 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section, when the Secretary determines that any of the extenuating circumstances described in paragraph (g)(1)(ii) of this section apply), the plan or issuer and the provider, facility, or provider of air ambulance services:

* * * * *

(ii) *Payment determination and notification*. Not later than 30 business days after the date of final selection of the certified IDR entity as described in paragraph (c)(1)(iv)(C) of this section (or not later than 30 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section, when the Secretary determines that any of the extenuating circumstances described in paragraph (g) of this section apply), the certified IDR entity must:

(A) * * *

(*1*) *Prevailing party*. In the case of single determinations, the party whose offer is selected by the certified IDR entity is considered the prevailing party. In the case of batched determinations, the party with the most determinations in its favor is considered the prevailing party; if each party prevails in an equal number of determinations, neither party will be considered the prevailing party, and the certified IDR entity fee will be split evenly between the parties.

(*2*) *Non-prevailing party*. In the case of single determinations, the party whose offer is not selected by the certified IDR entity is considered the non-prevailing party. In the case of batched determinations, the party with the fewest determinations in its favor is considered the non-prevailing party.

* * * * *

(vii) *Effects of determination*.

(A) * * *

(B) *Suspension of certain subsequent IDR requests*. In the case of a determination made by a certified IDR entity under paragraph (c)(5)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted*. If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(5)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

* * * * *

(d) *Costs of IDR process*—(1) *Certified IDR entity fee*—(i) *Timing of payment of certified IDR entity fee.* Each party to a dispute for which there is a final selection of the certified IDR entity and a determination that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section must pay to the certified IDR entity the predetermined certified IDR entity fee charged by the certified IDR entity. The certified IDR entity fee must be paid no later than the date a party submits its offer to the certified IDR entity, in accordance with paragraph (c)(5)(i) of this section.

(ii) *Failure to timely pay certified IDR entity fee*. If a party fails to pay the certified IDR entity fee as specified in paragraph (d)(1)(i) of this section, that party's offer will not be considered received. Such party will continue to be responsible for payment of the certified IDR entity fee.

(iii) *Method of allocation of the certified IDR entity fee after a payment determination.* After making a payment determination, the certified IDR entity shall retain the certified IDR entity fee described under paragraph (d)(1)(i) of this section paid by the non-prevailing party as defined in paragraph (c)(5)(ii)(A)(*2*) of this section. The certified IDR entity must return the fee paid by the prevailing party, as defined in paragraph (c)(5)(ii)(A)(*1*) of this section, within 30 business days following the date of the certified IDR entity's payment determination. In the event of a batched dispute in which each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. In that case, the certified IDR entity must return half the fee paid by each party within 30 business days following the date of the certified IDR entity's payment determination.

(iv) *Method of allocation of the certified IDR entity fee upon agreement or withdrawal after an eligibility determination.* For a dispute for which there is a final selection of the certified IDR entity and a determination that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, unless directed otherwise by both parties, the certified IDR entity is required to return half of each party's certified IDR entity fee within 30 business days of the date both parties notify the certified IDR entity that they have:

(A) Reached an agreement on an out-of-network rate for qualified IDR items or services before the certified IDR entity has made its payment determination, as described in paragraph (c)(3)(i) of this section; or

(B) Withdrawn the dispute before the certified IDR entity has made its payment determination, as described in paragraph (c)(3)(ii) of this section.

(v) *Method of allocation of the certified IDR entity fee upon agreement or withdrawal before an eligibility determination.* When the parties reach an agreement on an out-of-network rate or withdraw a dispute for which there is a final selection of the certified IDR entity, but for which no eligibility determination has yet been made, unless directed otherwise by both parties, the certified IDR entity is required to return each party's full certified IDR entity fee within 30

business days of the date both parties notify the certified IDR entity that they have agreed on an out-of-network rate or agreed to withdraw the dispute.

(2) *Administrative fee*—(i) *In general.* Each party to a dispute for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay a non-refundable administrative fee to the Secretary for participating in the Federal IDR process.

(A) *Timing of payment of administrative fee*. The initiating party must pay the administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity as described in paragraph (c)(1)(iii) of this section. The non-initiating party must pay the administrative fee within 2 business days of the date the non-initiating party receives notice that an eligibility determination for the Federal IDR process has been reached by either the certified IDR entity or the Departments in accordance with paragraph (c)(2) of this section.

(B) *Agreements and withdrawals.* In the case of an agreement, as described in paragraph (c)(3)(i) of this section, or a withdrawal, as described in paragraph (c)(3)(ii) of this section, the administrative fee will not be returned to the parties if preliminary selection of the certified IDR entity has occurred, as described in paragraph (c)(1)(i) of this section; if not yet collected, the administrative fee must still be paid, except as provided in paragraph (d)(2)(i)(C) of this section for a dispute closed for nonpayment by an initiating party.

(C) *Failure to pay administrative fee*. If the initiating party fails to pay the administrative fee in accordance with paragraph (d)(2)(i)(A) of this section, the dispute will be closed due to nonpayment and neither party will be responsible for the administrative fee. If the non-initiating party fails to pay the administrative fee in accordance with paragraph (d)(2)(i)(A) of this section, that party's offer will not be considered received and the non-initiating party will continue to be responsible for payment of the administrative fee.

(D) *Collection of unpaid fees.* Any party that fails to pay the administrative fee owed in accordance with paragraph (d)(2)(i)(A) of this section is obligated to pay the administrative fee otherwise due and owing, except as provided in paragraph (d)(2)(i)(C) of this section for a

dispute closed for nonpayment by an initiating party. The Secretary will pursue collection from a party to a dispute of any administrative fee that is not timely paid pursuant to applicable debt collection authorities.

(ii) *Administrative fee amount*. The administrative fee amount and method of payment will be established through notice and comment rulemaking in a manner such that the total administrative fees paid for a year, including administrative fees reduced under paragraph (d)(2)(iii) of this section, are estimated to be equal to the projected amount of expenditures made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(A) For disputes initiated on or after the later of the effective date of Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges final rules or January 1, 2024, the administrative fee amount is $150 per party per dispute, which will remain in effect until changed by subsequent rulemaking.

(B) [Reserved]

(iii) *Reducing the administrative fee amount*. For disputes initiated on or after January 1, 2025—

(A) The Secretary may reduce the administrative fee for both parties in accordance with paragraph (d)(2)(iii)(C) of this section when the highest offer made by either party during open negotiation for the dispute is less than the threshold established in notice and comment rulemaking pursuant to paragraph (d)(2)(ii) of this section. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph and for which a determination has been made that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, the administrative fee amount may be reduced to 50 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section for each party to the dispute. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph and for which a determination has been

made that the dispute is ineligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, the administrative fee amount may be reduced to 50 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section for the initiating party and to 20 percent of the administrative fee amount for the non-initiating party.

(B) The Secretary may reduce the administrative fee for a non-initiating party in accordance with paragraph (d)(2)(iii)(C) of this section when the dispute is determined to be ineligible for the Federal IDR process in accordance with paragraph (c)(2) of this section. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph, the administrative fee amount for the non-initiating party may be reduced to 20 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section.

(C) The reduced administrative fee amounts provided for in paragraphs (d)(2)(iii)(A) and (d)(2)(iii)(B) of this section shall be established in notice and comment rulemaking and will remain in effect until changed by subsequent rulemaking, pursuant to paragraph (d)(2)(ii) of this section.

(e) * * *

(2) * * *

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees (if applicable) received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the certified IDR entity;

* * * * *

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party or a portion of each party's certified IDR

entity fee in the case of an agreement described in paragraph (c)(3)(i) of this section, a withdrawal described in paragraph (c)(3)(ii) of this section, or a circumstance described under paragraph (d)(1)(iii) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees (if applicable) described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

* * * * *

(g) *Extension of time periods for extenuating circumstance*—(1) *In general.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(5)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion. Extenuating circumstances include, but are not limited to when:

(i) With respect to a specific dispute, the Secretary determines that the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of one or both parties or the certified IDR entity, or for other good cause. The certified IDR entity or either party may also submit a request for an extension due to extenuating circumstances to the Secretary through the Federal IDR portal. The requesting certified IDR entity or party must attest that it will take prompt action to ensure that the certified IDR entity's payment determination under this section may be made as soon as administratively practicable under the circumstances; or

(ii) The Secretary determines that the parties or certified IDR entity cannot meet applicable timeframes due to systematic delays in processing disputes under the Federal IDR process, such as an unforeseen volume of disputes or Federal IDR portal system failures. Extensions provided due to extenuating circumstances caused by an unforeseen volume of disputes will be applied to the timeframe for eligibility determinations under paragraph (c)(2) of this section. Extensions provided due to extenuating circumstances caused by systems failures

within the Federal IDR portal will be applied to the Federal IDR process timeframe(s) determined relevant by the Secretary. The Secretary will post a public notice regarding any extensions of time periods pursuant to this paragraph (g)(1)(ii).

(A) *Timeframe following an extension to eligibility determination.* When an extension to the eligibility determination timeframe pursuant to paragraph (g)(1)(ii) of this section is in effect, the start date of the subsequent timeframes in the Federal IDR process will be determined based on the date of completion of the eligibility determination by the certified IDR entity or the Secretary.

(*1*) *Submission of offers.* The parties must submit their offers and certified IDR entity fees to the certified IDR entity not later than 10 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section.

(*2*) *Payment Determination.* The certified IDR entity must make the payment determination and notification of the payment determination to the parties not later than 30 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section.

(B) *Timeframe following an extension to other timeframes in the Federal IDR process.* When an extension to any timeframe within the Federal IDR process, other than the eligibility timeframe, is in effect pursuant to paragraph (g)(1)(ii) of this section, the start date of each subsequent timeframe in the Federal IDR process will be determined based on the date of completion of the process for which the extension was granted.

(2) [Reserved]

(h) *Applicability date***.** (1) Paragraph (a) of this section is applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021, and the revised definition for batched qualified IDR items and services at paragraph

(a)(2)(i) of this section is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(2) Paragraph (b) of this section is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(3) Paragraph (c)(1) of this section, regarding the selection of a certified IDR entity, is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule, except that paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section, regarding the conflict-of-interest standards, are applicable with respect to plan years beginning on or after January 1, 2022.

(4) Paragraph (c)(2) of this section, regarding the Federal IDR process eligibility review and paragraph (c)(3) of this section regarding the authority to continue negotiations or withdraw are applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule, and paragraph (c)(4) of this section regarding the treatment of batched and bundled qualified IDR items and services is applicable 90 days after the effective date of the rule.

(5) Paragraphs (c)(5)(i) and (ii), and (c)(5)(vii)(B) and (C) of this section regarding the deadlines for the submission of offers, payment determination and notification, suspension of certain subsequent IDR requests, and subsequent submission of requests submitted are applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule. Paragraphs (c)(5)(iii) and (iv) of this section regarding considerations in payment determinations and the related examples and paragraph (c)(5)(vi)(B) of this section regarding written decisions are applicable with respect to items or services furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022. Paragraphs (c)(5)(v) through (c)(5)(vi)(A), (c)(5)(vii)(A), and (c)(5)(viii) and (ix) are applicable with respect to plan years beginning on or after January 1, 2022.

(6) Paragraph (d) of this section regarding the costs of the IDR process is applicable to disputes initiated on or after January 1, 2025.

(7) Paragraph (e) of this section is applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (e)(1), (e)(2)(i) through (vi), (e)(2)(x) and (xi), and (e)(3) through (6) of this section are applicable beginning on October 7, 2021. Paragraphs (e)(2)(vi), (viii), and (ix) of this section regarding the certified IDR entity's controls to prevent and detect improper financial activities, and procedures to retain the certified IDR entity fee and administrative fee are applicable upon the effective date of the rule.

(8) Paragraph (f) of this section is applicable with respect to plan years beginning on or after January 1, 2022, except that paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process is applicable with respect to items or services furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

(9) Paragraph (g) of this section regarding the extension of time periods for extenuating circumstances is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(10) Until the relevant applicability date for the requirements of this section, plans, issuers, providers, facilities, providers of air ambulance services and certified IDR entities are required to continue to comply with the corresponding section of § 2590.716-8 in effect on October 25, 2022.

(i) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions of paragraphs (b)(1), (c)(2)(ii), (c)(4), (d)(2), and (g)(1) of this section are intended to be severable from one another, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in those paragraphs. The provisions in § 2590.716-8 are intended to be severable from the provisions in §§ 2590.716-6A, 2590.716-6, and 2590.716-9, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 2590.716-6A, 2590.716-6, and 2590.716-9.

17. Section 2590.716-9 is added to subpart F to read as follows:

§ 2590.716-9 Federal Independent Dispute Resolution Registry of Group Health Plans, Health Insurance Issuers, and Federal Employees Health Benefits Carriers.

(a) *Establishment of Federal independent dispute resolution registry.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will establish a Federal IDR registry consisting of the information described in paragraph (b)(2) of this section and will assign a registration number for each group health plan, health insurance issuer offering group or individual health insurance coverage, and Federal Employees Health Benefits (FEHB) Program carrier. The information contained in the registry will be made available to parties seeking to initiate an open negotiation or a dispute through the Federal IDR portal, and will be searchable, including by registration number.

(b) *Federal IDR registration*--(1) *Registration requirement.* Each group health plan and health insurance issuer offering group health insurance coverage subject to the Federal IDR process must register with the Federal IDR registry as specified by the Secretary in guidance. Initial registration must be completed by the later of the date that is 30 business days after the effective date of the final rule, the date that is 30 business days after the registry becomes available, or the date the group health plan or health insurance issuer begins offering a group health plan or health insurance coverage subject to the Federal IDR process.

(2) *Required data elements.* Group health plans and health insurance issuers offering group health insurance coverage subject to the registration requirement must include the following information with their registration:

(i) The legal business name (if any) of the group health plan, or issuer, and, if applicable, the legal business name of the group health plan sponsor;

(ii) Whether the plan or coverage is a self- or fully-insured group health plan subject to ERISA;

(iii) The State(s) in which the plan or coverage is subject to a specified State law, as defined in § 2590.716-3 for any items or services for which the protections of §§ 2590.716-4, 2590.716-5, and 2590.717-1 apply;

(iv) The State(s) in which the plan or coverage is subject to an All-Payer Model Agreement under section 1115A of the Social Security Act for any items or services to which the protections in §§ 2590.716-4, 2590.716-5, and 2590.717-1 apply;

(v) For self-insured group health plans not otherwise subject to State law, any State(s) in which the group health plan has properly effectuated an election to opt in to a specified State law as defined in § 2590.716-3, if that State allows a plan not otherwise subject to the State law to opt-in;

(vi) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service;

(vii) The 14-digit Health Insurance Oversight System (HIOS) identifier; or if the 14-digit HIOS identifier has not been assigned, the 5-digit HIOS identifier; or if no HIOS identifier is available, the plan's or the plan sponsor's Employer Identification Number (EIN) and the plan's plan number (PN), if a PN is available;

(viii) Additional information needed to identify the plan or issuer and the applicable Federal and State requirements for determining appropriate out-of-network payment rates for

items or services to which the protections against balance billing in this part apply, as specified by the Secretary in guidance; and

(ix) Additional information needed for purposes of administrative fee collection, as specified by the Secretary in guidance.

(3) *Updating disclosures.* A plan or issuer must timely report to the Secretary changes to the information required under this section within 30 calendar days after the information changes. A plan or issuer must confirm the accuracy of its registration annually in the fourth quarter of each calendar year.

(*4*) *Third party authority.* The requirements of paragraphs (b)(1) through (3) of this section may be performed by a third party administrator or service provider with authority to act on behalf of the group health plan or health insurance issuer offering group health insurance coverage subject to the Federal IDR process. If the registration requirements are performed by such third party administrator or service provider the group health plan or health insurance issuer offering group or individual health insurance coverage must require that such third party administrator or service provider clearly delineate each group health plan or health insurance issuer offering group health insurance coverage for which it has authority to act. If such third party administrator or service provider fails to provide the information in compliance with the requirements of paragraphs (b)(1) through (3) of this section the plan or issuer will be in violation of the requirements of this section.

(c) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 2590.716-9 are intended to be severable from the provisions in §§ 2590.716-6A, 2590.716-6, and 2590.716-8, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 2590.716-6A, 2590.716-6, and 2590.716-8.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 149 as set forth below:

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

18. The authority citation for part 149 continues to read as follows:

Authority: 42 U.S.C. 300gg-92 and 300gg-111 through 300gg-139, as amended.

Subpart A—General Provisions

19. Section 149.30 is amended by adding the definition of "Bundled payment arrangement" in alphabetical order to read as follows:

§ 149.30 Definitions.

* * * * *

Bundled payment arrangement means an arrangement under which—

(1) A provider, facility, or provider of air ambulance services bills for multiple items or services furnished to a single patient under a single service code that represents multiple items or services (for example, a Diagnosis-Related Group (DRG) code); or

(2) A plan or issuer makes an initial payment or notice of denial of payment to a provider, facility, or provider of air ambulance services under a single service code that represents multiple items or services furnished to a single patient (for example, a DRG code).

* * * * *

Subpart B— Requirements Relating to Health Care Access

20. Section 149.100 is added to subpart B to read as follows:

§ 149.100 Use of claim adjustment reason codes and remittance advice remark codes.

(a) *In general.* When providing any paper or electronic remittance advice to an entity that does not have a contractual relationship directly or indirectly with a group health plan or a health insurance issuer offering group or individual health insurance coverage with respect to the furnishing of the item or service under the plan or coverage in response to a claim for payment

for health care items and services furnished by that entity, the plan or issuer must use claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs) (see 45 CFR 162.1602 and 162.1603) as specified in guidance issued by the Secretaries of the Treasury, Labor, and Health and Human Services, or as required under any applicable adopted standards and operating rules under 45 CFR part 162, to communicate information related to whether the claim is or is not subject to the provisions of this subpart and subparts E and F of this part.

(b) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 149.100 are intended to be severable from the provisions in §§ 149.140, 149.510, and 149.530, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 149.140, 149.510, and 149.530.

21. Section 149.140 is amended by:

a. Revising paragraphs (d) introductory text and (d)(1)(iv);

b. Redesignating paragraph (d)(1)(v) as paragraph (d)(1)(vi);

c. Adding a new paragraph (d)(1)(v);

d. Revising paragraph (d)(2) introductory text; and

e. Adding paragraph (h).

The revisions and additions read as follows:

§ 149.140 Methodology for calculating qualifying payment amount.

* * * * *

(d) *Information to be shared about the qualifying payment amount.* In cases in which the recognized amount, with respect to an item or service furnished by a nonparticipating provider or

nonparticipating emergency facility, is the qualifying payment amount or the amount billed by the provider or facility, or if the amount on which cost sharing is based with respect to air ambulance services furnished by a nonparticipating provider of air ambulance services is the qualifying payment amount or the amount billed by the provider of air ambulance services, the plan or issuer must provide to the provider, facility, or provider of air ambulance services, as applicable, in writing, in paper or electronic form –

(1) * * *

(iv) A statement that –

(A) If the provider, facility, or provider of air ambulance services, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the out-of-network rate, the provider, facility, or provider of air ambulance services must:

(*1*) Contact the appropriate person or office to initiate open negotiation within 30 business days of receiving the initial payment or notice of denial of payment, and

(*2*) For disclosures required to be provided on or after [DATE 90 DAYS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**] and once the open negotiation notice can be submitted through the Federal IDR portal, notify the Secretary as described under § 149.510(b)(1)(i); and

(B) If the 30-business-day open negotiation period does not result in an agreement on the amount of payment the provider, facility, or provider of air ambulance services may generally initiate the Federal IDR process within 4 business days after the end of the open negotiation period;

(v) For disclosures required to be provided on or after [DATE 90 DAYS AFTER PUBLICATION OF FINAL REGULATIONS IN THE **FEDERAL REGISTER**], the legal business name of the group health plan (if any) or issuer, the legal business name of the plan sponsor (if applicable), and the registration number assigned under § 149.530, if the plan or issuer is registered under § 149.530.

* * * * *

(2) In a timely manner upon the request of the provider, facility, or provider of air ambulance services:

* * * * *

(h) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 149.140 are intended to be severable from the provisions in §§ 149.100, 149.510, and 149.530, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 149.100, 149.510, and 149.530.

22. Section 149.510 is amended by:

a. Revising paragraphs (a)(2)(i), (b), and (c)(1);

b. Redesignating paragraphs (c)(2) through (4) as paragraphs (c)(3) through (5), respectively;

c. Adding a new paragraph (c)(2);

d. Revising newly redesignated paragraphs (c)(3), (c)(4)(i) introductory text, (c)(4)(i)(B) through (D), (c)(4)(ii), (c)(5)(i) introductory text, (c)(5)(ii) introductory text;

e. In newly redesignated paragraphs (c)(5)(ii)(A) and (B), removing the reference to "(c)(4)" and adding in its place "(c)(5)";

f. Adding paragraphs (c)(5)(ii)(A)(*1*) and (*2*);

g. Adding paragraphs (c)(5)(vii)(B) and (C);

h. Revising paragraphs (d), (e)(2)(vi), (viii), and (ix), (g), and (h); and

i. Adding paragraph (i).

The revisions and additions read as follows:

§ 149.510 Independent dispute resolution process.

(a) * * *

(2) * * *

(i) *Batched qualified IDR 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 accordance with paragraph (c)(4) of this section.

* * * * *

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xi)(A) of this section, the provider, facility, or provider of air ambulance services, or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must submit a written open negotiation notice with the content specified in paragraph (b)(1)(ii) of this section to the other party and to the Secretary in the manner specified in paragraph (b)(3) of this section. The 30-business-day open negotiation period begins on the day on which the party first submits the open negotiation notice and the remittance advice documentation specified in paragraph (b)(1)(ii)(A)(*12*) of this section to the other party and the Secretary. The party in receipt of the open negotiation notice must provide to the other party and to the Secretary in the manner specified in paragraph (b)(3) of this section as soon as practicable, but no later than the 15th business day of the 30-business-day open negotiation period, a written notice and

supporting documentation in response to the open negotiation notice, as specified in paragraph (b)(1)(iii)(A) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include, with respect to the item or service that is the subject of the open negotiation notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or air ambulance provider to the plan or issuer, and the National Provider Identifier (NPI);

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 149.530, if the plan or issuer is registered under § 149.530, or an attestation from the party submitting the open negotiation notice that the plan or issuer was not registered prior to the date it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation notice is a plan or issuer, the plan type (for example, self-insured or fully-insured);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation;

(*4*) Information sufficient to identify the item or service, including: the date(s) the item or service was furnished and, if the party submitting the open negotiation notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for the item

or service from the plan or issuer; the type of item or service (specifically, whether the item or service is an emergency service as defined in § 149.110(c)(2)(i) or (ii), a non-emergency service as described in § 149.120(b), or an air ambulance service as defined in § 149.30); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location where the item or service was furnished (such as, place of service code or bill type code);

(*5*) The initial payment amount (including $0 if, for example, payment is denied);

(*6*) The qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the party submitting the open negotiation notice is a plan or issuer;

(*7*) An offer of an out-of-network rate for each item or service;

(*8*) If the party submitting the open negotiation notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*9*) If the party submitting the open negotiation notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at § 149.410(b) or § 149.420(c) through (i);

(*10*) A statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished;

(*11*) General information listed in the standard open negotiation notice developed by the Secretary pursuant to paragraph (b)(3) of this section describing the open negotiation period and the Federal IDR process (including a description of the purpose of the open negotiation period and Federal IDR process and key deadlines in the open negotiation period and Federal IDR process); and

(*12*) A copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under § 149.140(d)(1), with respect to the item or service.

(B) [Reserved]

(iii) *Open negotiation response notice*--(A) *Content.* The response to the open negotiation notice must include, with respect to the item or service that is the subject of the open negotiation response notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or provider of air ambulance services to the plan or issuer, and the NPI;

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 149.530 if the plan or issuer is registered under § 149.530, or an attestation from the party submitting the open negotiation response notice that the plan or issuer was not registered prior to the date it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation response notice is a plan or issuer, the plan type (for example, self-insured or fully-insured);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation response notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation;

(*4*) Information sufficient to identify the item or service included in the open negotiation notice, including the date(s) the item or service was furnished, and if the party submitting the open negotiation response notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number;

(*5*) If the party submitting the open negotiation response notice is a plan or issuer, a statement as to whether it agrees that the initial payment amount (including $0 if, for example, payment is denied) and the qualifying payment amount reflected in the open negotiation notice accurately reflect the initial payment amount and qualifying payment amount disclosed with the initial payment for the item or service, and if not, or if the open negotiation notice indicates that the initial payment amount or qualifying payment amount was not communicated by the plan or issuer with the initial payment or notice of denial of payment or other remittance advice, the initial payment amount (including $0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount);

(*6*) If the party submitting the open negotiation response notice is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*7*) A counteroffer for an out-of-network rate for each item or service or an acceptance of the other party's offer;

(*8*) If the party submitting the open negotiation response notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at § 149.410(b) or § 149.420(c) through (i);

(*9*) With respect to each item or service, either a statement and supporting documentation that explains why the item or service is not subject to the Federal IDR process or a statement agreeing that the item or service is subject to the Federal IDR process;

(*10*) A statement as to whether any of the information provided in the open negotiation notice is inaccurate and the basis for the statement, as well as supporting documentation; and

(*11*) A statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the party submitting the open negotiation notice under paragraph (b)(1)(ii)(A)(*12*) of this section is accurate, and if inaccurate, a copy of the accurate

initial payment or notice of denial of payment or other remittance advice required to include the disclosures under § 149.140(d)(1), with respect to the item or service.

(B) [Reserved]

(2) *Initiating the Federal IDR process*—(i) *In general.* Either party may initiate the Federal IDR process with respect to a qualified IDR item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period provided for under paragraph (b)(1) of this section. To initiate the Federal IDR process, a party (the initiating party) must submit a written notice of IDR initiation, consistent with paragraph (b)(2)(ii) of this section, to the other party to the dispute (the non-initiating party), and to the Secretary in the manner specified in paragraph (b)(3) of this section, during the 4-business-day period beginning on the first business day after the last day of the open negotiation period (unless it is otherwise required to be submitted in the timeframe specified in paragraph (c)(5)(vii)(C) of this section). The date of IDR initiation is the date that the Secretary receives the notice of IDR initiation described in paragraph (b)(2)(ii) of this section.

(A) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under §§ 149.410(b) or 149.420(c) through (i).

(B) [*Reserved*]

(ii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include, with respect to the item or service that is the subject of the notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name,

email address, phone number, and mailing address), and the NPI; and if the initiating party is a provider, facility, or provider of air ambulance services, the Tax Identification Number (TIN);

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 149.530 if the plan or issuer is registered under § 149.530, or an attestation from the initiating party that the plan or issuer was not registered prior to the date that it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the initiating party is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process;

(*4*) Information sufficient to identify whether the dispute being initiated includes batched or bundled qualified IDR items or services as described in paragraph (c)(4) of this section;

(*5*) Information sufficient to identify the qualified IDR item or service that is the subject of the notice of IDR initiation, including the date(s) the qualified IDR item or service was furnished; if the initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer; the date the open negotiation period under paragraph (b)(1) of this section began; the type of item or service (specifically, whether the qualified IDR item or service is an emergency service as defined in § 149.110(c)(2)(i) or (ii), a non-emergency service as described in § 149.120(b), or an air ambulance service as defined in § 149.30); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the

service code; and information to identify the location the item or service was furnished (including place of service code or bill type code);

(*6*) The initial payment amount (including $0 if, for example, payment is denied);

(*7*) The qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the initiating party is a plan or issuer;

(*8*) If the initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i);

(*9*) A statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished;

(*10*) Attestation that the item or service under dispute is a qualified IDR item or service, and the basis for the attestation;

(*11*) General information listed in the standard notice of IDR initiation developed by the Secretary pursuant to paragraph (b)(3) of this section describing the Federal IDR process (including a description of the purpose of the Federal IDR process and key deadlines in the Federal IDR process);

(*12*) A copy of the initial payment or notice of denial of payment or other remittance advice that is required to include the disclosures under § 149.140(d)(1), with respect to the item or service;

(*13*) Preferred certified IDR entity; and

(*14*) A statement describing the key aspects of the claim, such as patient acuity or level of training of the provider, facility, or provider of air ambulance services that furnished the qualified IDR item or service, discussed by the parties during open negotiation that relate to the payment for the disputed claim, whether the reasons for initiating the Federal IDR process are different from the aspects of the claim discussed during the open negotiation period, and an

explanation of why the party is initiating the Federal IDR process, including any of the permissible considerations described in §§ 149.510(c)(5)(iii) and 149.520(b)(2) that serve as the party's basis for initiating the Federal IDR process.

(B) [Reserved]

(iii) *Notice of IDR initiation response*. The non-initiating party must provide to the initiating party and to the Secretary in the manner specified in paragraph (b)(3) of this section within 3 business days after the date of IDR initiation, a written notice and supporting documentation in response to the notice of IDR initiation, as specified in paragraph (b)(2)(iii)(A) of this section.

(A) *Content*. The notice of IDR initiation response must include, with respect to the item or service that is the subject of the notice, information about the item or service and the parties including:

(*1*) Information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address), and the NPI; and if the non-initiating party is a provider, facility, or provider of air ambulance services, the TIN;

(*2*) Information sufficient to identify the plan or issuer, including the plan's or issuer's registration number, as required under § 149.530 if the plan or issuer is registered under § 149.530 or an attestation from the non-initiating party that the plan or issuer was not registered prior to the date that it submitted the notice; the legal business name of the plan or issuer, as well as the current contact information (name, email address, phone number, and mailing address) of the plan or issuer as provided with the initial payment or notice of denial of payment; and if the non-initiating party is a plan or issuer, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor);

(*3*) The name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the non-initiating party, and

an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process;

(*4*) Information sufficient to identify each item or service included in the notice of IDR initiation, including the date(s) the item or service was furnished. If the non-initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan or issuer, and the claim number;

(*5*) If the non-initiating party is a plan or issuer, a statement as to whether the non-initiating party agrees that the initial payment (including $0 if, for example, payment is denied) and the qualifying payment amount reflected in the notice of IDR initiation is accurate for the item or service that is the subject of the dispute, and if not, the initial payment amount (including $0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount);

(*6*) If the non-initiating party is a plan or issuer, the amount of cost sharing imposed for the item or service, if any;

(*7*) If the non-initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at § 149.410(b) or § 149.420(c) through (i);

(*8*) With respect to each item or service that is the subject of the dispute, either an attestation that the item or service is a qualified IDR item or service, or for each item or service that the non-initiating party asserts is not a qualified IDR item or service, an explanation and documentation to support the statement;

(*9*) A statement confirming that the initial payment or notice of denial of payment or other remittance advice provided by the initiating party under paragraph (b)(2)(ii)(A)(*12*) of this section is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of

payment or other remittance advice required to include the disclosures under § 149.140(d)(1), with respect to the item or service;

(*10*) A statement as to whether any of the information provided in the notice of IDR initiation is inaccurate and the basis for the statement as well as any supporting documentation; and

(*11*) A statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity. If the non-initiating party objects to the initiating party's preferred certified IDR entity, the notice of IDR initiation response must include the name of an alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the initiating party's preferred certified IDR entity.

(B) [Reserved].

(3) *Manner.* A party furnishing notices as required under paragraphs (b)(1)(ii) and (iii), and (b)(2)(ii) and (iii) of this section must furnish the notices using the standard forms developed by the Secretary and must furnish the notices and supporting documentation to the other party and the Secretary, through the Federal IDR portal.

(c) * * *

(1) *Selection of certified IDR entity*—(i) *Preliminary selection of the certified IDR entity.* Within 3 business days after the date of IDR initiation, the non-initiating party must agree or object to the preferred certified IDR entity identified in the notice of IDR initiation, as described in paragraph (b)(2)(iii)(A)(*11*) of this section.

(A) If the non-initiating party agrees, or fails to object, to the selection of the initiating party's preferred certified IDR entity in the manner described in paragraph (b)(2)(iii)(A)(*11*) of this section and within the timeframe specified in paragraph (c)(1)(i) of this section, the initiating party's preferred certified IDR entity will be considered jointly selected on the third business day after the date of IDR initiation.

(B) If the non-initiating party objects to the selection of the initiating party's preferred certified IDR entity by designating an alternative preferred certified IDR entity in the manner described in paragraph (b)(2)(iii)(A)(*11*) of this section and within the timeframe specified in paragraph (c)(1)(i) of this section, the initiating party may then agree or object to the non-initiating party's alternative preferred certified IDR entity by submitting the notice of certified IDR entity selection in the manner specified in paragraph (c)(1)(i)(D) of this section. If the initiating party agrees to the non-initiating party's alternative preferred certified IDR entity within 3 business days after the date of IDR initiation, or if the non-initiating party submits the notice of IDR initiation response on or before the second business day after the date of IDR initiation and the initiating party fails to respond within 3 business days after the date of IDR initiation, the alternative preferred certified IDR entity will be considered jointly selected by the parties. If the non-initiating party submits the notice of IDR initiation response on the third business day after the date of IDR initiation and the initiating party does not agree on the same day, selection will proceed under paragraph (c)(1)(i)(C) of this section.

(C) If a certified IDR entity is not jointly selected under paragraph (c)(1)(i)(A) or (B) of this section, either party may select an alternative preferred certified IDR entity by submitting the notice of certified IDR entity selection in the manner specified in paragraph (c)(1)(i)(D) of this section, until the earlier of the date that the parties agree on the alternative preferred certified IDR entity or the deadline for joint selection, which is 3 business days after the date of IDR initiation. Once a party submits a notice of certified IDR entity selection, it may not submit another notice of certified IDR entity selection until after it receives a responding notice of certified IDR entity selection from the other party.

(*1*) If a party submits a notice of certified IDR entity selection to the other party on the first or second day after the date of IDR initiation and the party in receipt of the notice agrees or fails to object to the alternative preferred certified IDR entity by the third business day after the

date of IDR initiation, the alternative preferred certified IDR entity will be considered jointly selected by the parties.

(*2*) If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice agrees to the alternative preferred certified IDR entity on the same day, the alternative preferred certified IDR entity will be considered jointly selected by the parties.

(*3*) If a party submits a notice of certified IDR entity selection to the other party on the third business day after the date of IDR initiation and the party last in receipt of the notice does not agree to the alternative preferred certified IDR entity on the same day, the parties will have failed to jointly select a certified IDR entity.

(D) To notify the other party and the Secretary of an agreement or objection to an alternative preferred certified IDR entity under paragraph (c)(1)(i)(C) of this section, a party must submit the notice of certified IDR entity selection. The party must furnish the notice of certified IDR entity selection using the standard form developed by the Secretary and must furnish the notice to the other party and the Secretary through the Federal IDR portal within 3 business days after the date of IDR initiation. However, in the event the conditions under paragraph (c)(1)(ii) of this section apply, the party may notify the Secretary of an agreement or objection to an alternative preferred certified IDR entity in accordance with paragraph (c)(1)(ii) of this section. The notice of certified IDR entity selection must include a statement indicating the party's agreement with or objection to the other party's alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the alternative preferred certified IDR entity. If the party in receipt of a notice of certified IDR entity selection objects to the other party's alternative preferred certified IDR entity and the party submits a notice of certified IDR entity selection by the end of the third business day after the date of IDR initiation, that party's notice of certified IDR entity selection reflecting the objection must include the name of another alternative preferred certified IDR entity.

(ii) *Failure to jointly select a certified IDR entity.* If the parties fail to jointly select a certified IDR entity within 3 business days after the date of IDR initiation, the Secretary will select a certified IDR entity. The parties will have failed to jointly select a certified IDR entity if, by the end of the third business day after the date of IDR initiation, the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection has objected to the other party's alternative preferred certified IDR entity, or if the notice of IDR initiation response or the notice of certified IDR entity selection is submitted to the other party on the third business day after the date of IDR initiation and the party in receipt of the notice does not agree to the alternative preferred certified IDR entity within 3 business days after the date of IDR initiation.

(A) In selecting the certified IDR entity, the Secretary will first confirm whether a party submitted the notice of IDR initiation response or the notice of certified IDR entity selection with an alternative preferred certified IDR entity on the third business day after the date of IDR initiation without the other party's agreement to the selection. If either notice was provided on the third business day after the date of IDR initiation without the other party's agreement to the alternative preferred certified IDR entity by the end of third business day after the date of IDR initiation, the Secretary will provide the party last in receipt of the applicable notice 2 additional business days to agree or object to the other party's alternative preferred certified IDR entity selection.

(*1*) If the party last in receipt of the notice of IDR initiation response or the notice of certified IDR entity selection agrees with the other party's alternative preferred certified IDR entity and notifies the Secretary of the agreement or fails to notify the Secretary of its objection in the Federal IDR portal by the fifth business day after the date of IDR initiation, the Secretary will select the final alternative preferred certified IDR entity selected in the applicable notice. In disputes where the applicable notice was submitted on the third business day after the date of

IDR initiation, the party last in receipt of the notice will not be allowed to select another alternative preferred certified IDR entity.

(*2*) If the party notifies the Secretary of its objection to the alternative preferred certified IDR entity by the fifth business day after the date of IDR initiation, the Secretary will proceed with the random selection of the certified IDR entity from among the certified IDR entities (other than the preferred certified IDR entity and any alternative preferred certified IDR entity previously selected in such dispute by a party, unless there is no other certified IDR entity available to select) that charge a fee within the allowed range of certified IDR entity fees on the sixth business day after the date of IDR initiation. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vii)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees. In either case, the Secretary will notify the parties of the preliminary selection of the certified IDR entity not later than 6 business days after the date of IDR initiation.

(B) [Reserved].

(iii) *Date of preliminary selection of the certified IDR entity*. The date of preliminary selection of the certified IDR entity will be:

(A) Three business days after the date of IDR initiation if the parties jointly selected a certified IDR entity, as specified in paragraph (c)(1)(i) of this section; or

(B) Six business days after the date of IDR initiation, if the parties fail to jointly select a certified IDR entity as specified in paragraph (c)(1)(ii) of this section.

(iv) *Final selection of the certified IDR entity*—(A) *Conflict-of-interest review*. The certified IDR entity preliminarily selected for a dispute must review the selection. The selection of the certified IDR entity will be finalized only if the certified IDR entity attests to the Secretary that it meets the following requirements:

(*1*) The certified IDR entity does not have a conflict of interest as defined in paragraph (a)(2)(iv) of this section;

(*2*) The certified IDR entity will only assign personnel to a dispute and make decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute in a manner that is not based upon the likelihood that the assigned personnel will support a particular party to the dispute; and

(*3*) The certified IDR entity will not assign any personnel to a dispute who would have any conflicts of interest, as defined in paragraph (a)(2)(iv) of this section, regarding any party to the dispute or whose relationship with a party within the 1 year immediately preceding the assignment to the dispute would violate the restrictions on aiding or advising a former employer or principal in a manner similar to the restrictions set forth in 18 U.S.C. 207(b).

(B) *Failure to meet conflict-of-interest requirements.* If the certified IDR entity notifies the Secretary within 3 business days of the date of preliminary selection of the certified IDR entity that it does not meet the requirements of paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section or if the certified IDR entity does not respond within 3 business days after the date of preliminary selection of the certified IDR entity, the Secretary will randomly select another certified IDR entity consistent with paragraph (c)(1)(ii) of this section. The Secretary will notify the parties of the new randomly preliminarily selected certified IDR entity no later than 1 business day after the previously selected certified IDR entity notifies the Secretary that it has a conflict of interest or, if the previously selected certified IDR entity fails to respond within 3 business days after the date of preliminary selection of the certified IDR entity, no later than 1 business day after the end of the 3-business-day period.

(C) *Date of final selection of the certified IDR entity*. If the certified IDR entity that has been preliminarily selected attests within 3 business days that it meets the requirements of paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section, the Secretary will notify the parties of the final selection of the certified IDR entity no later than 1 business day after the certified IDR

entity attests that it meets the conflict-of-interest requirements. The date of final selection of the certified IDR entity is the date that the Secretary provides this notice to the parties.

(2) *Federal IDR process eligibility review*—(i) *Federal IDR process eligibility determination by certified IDR entity*. Unless the departmental eligibility review described in paragraph (c)(2)(ii) of this section applies, the selected certified IDR entity must review the information in the notice of IDR initiation, notice of IDR initiation response, and any additional information described in paragraph (c)(2)(iii) of this section, and make a final determination as to whether the item or service is a qualified IDR item or service, as defined in paragraph (a)(2)(xi) of this section, that is eligible for the Federal IDR process. The certified IDR entity must make such a determination and notify the Secretary and both parties no later than 5 business days after the date of final selection of the certified IDR entity. If the certified IDR entity determines that the item or service is not a qualified IDR item or service, the dispute will be closed, and the selected certified IDR entity will not take any action with regard to the dispute.

(ii) *Departmental eligibility review for Federal IDR process eligibility determinations*. When the conditions for the departmental eligibility review set forth in paragraph (c)(2)(ii)(A) of this section are met, the Secretary will conduct the eligibility review and make the eligibility determination instead of the certified IDR entity. If the Secretary determines that the item or service is not a qualified IDR item or service, the dispute will be closed, and the selected certified IDR entity will not take any action with regard to the dispute. If the dispute is found to be eligible, the Secretary will inform the preliminarily selected certified IDR entity of the dispute's eligibility so that it may conduct its conflict-of-interest assessment, and the dispute will otherwise continue through the Federal IDR process, including notification of the eligibility determination to the disputing parties by the preliminarily selected certified IDR entity.

(A) *Application of the departmental eligibility review.* The departmental eligibility review will apply when the Secretary determines that any of the extenuating circumstances

described in paragraph (g)(1) of this section require application of the departmental eligibility review to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process.

(B) *Notification regarding applicability of the departmental eligibility review.* Before invoking the application of the departmental eligibility review, the Secretary will post advance public notification of the date on which the departmental eligibility review will take effect and the reasons for invoking the application of the departmental eligibility review. Before ending the application of the departmental eligibility review, the Secretary will post advance public notification of the date on which the departmental eligibility review will no longer be in effect and the reasons for ending the application of the departmental eligibility review.

(iii) *Request for additional information*. The Secretary or the selected certified IDR entity may request additional information from either party to a dispute at any time, including for the purpose of assessing whether a conflict of interest exists, conducting an eligibility determination, or making a payment determination.

(A) Upon request, a party must submit the additional information within 5 business days to the Secretary or the selected certified IDR entity, as applicable, through the Federal IDR portal. Following a request for additional information, the time period for the applicable stage of the Federal IDR process will be tolled until the earlier of the date either all of the requested information is provided or the 5-business-day period expires, and each subsequent timeframe in the Federal IDR process will be determined based on the date of completion of the stage of the Federal IDR process that was tolled for provision of the requested information.

(B) If a party fails to submit the additional information as required, the related determination, including the eligibility determination, conflict-of-interest review, or payment determination will be made without the requested information unless a good-cause extension of the 5-business-day period, as specified in paragraph (g)(1)(i) of this section, has been provided,

and the party subsequently submits the additional information requested within the extended period.

(3) *Authority to continue negotiations or withdraw*—(i) *Authority to continue to negotiate.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary required under paragraph (b)(2)(ii) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount and any cost sharing paid or required to be paid by the participant, beneficiary, or enrollee, or there was an initial denial of payment, payment must be made directly by the plan or issuer to the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant, beneficiary, or enrollee, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the dispute number, a statement of the out-of-network rate for the qualified IDR item or service, and signatures from authorized signatories for both parties.

(ii) *Withdrawals*. A dispute may be withdrawn from the Federal IDR process by the initiating party, the Secretary, or a certified IDR entity before a payment determination is made if one of the following conditions is met:

(A) The initiating party provides notification through the Federal IDR portal to the Secretary and the certified IDR entity (if selected) that both parties to the dispute agree to withdraw the dispute from the Federal IDR process without agreement on an out-of-network rate.

The notification must include the dispute number, a statement about both parties' agreement to withdraw and signatures from authorized signatories for both parties.

(B) The initiating party provides a standard withdrawal request notice through the Federal IDR portal to the Secretary, the certified IDR entity (if selected), and the non-initiating party of its request to withdraw the dispute from the Federal IDR process and the non-initiating party notifies the Secretary, certified IDR entity (if selected), and the initiating party through the Federal IDR portal of its agreement to withdraw from the Federal IDR process within 5 business days of the initiating party's request. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party will be considered to have agreed to the withdrawal, and the dispute will be withdrawn.

(C) The certified IDR entity or Secretary cannot determine eligibility because both parties to the dispute are unresponsive to any requests for additional information to determine eligibility as described in paragraph (c)(2)(iii) of this section, or

(D) The certified IDR entity cannot make a payment determination because both parties to the dispute have failed to submit an offer as described in paragraph (c)(5)(i) of this section.

(4) ***

(i) *In general.* A certified IDR entity may consider up to 25 qualified IDR items and services jointly as part of one payment determination that is subject to the certified IDR entity fee for batched determinations only if the qualified IDR items and services meet the requirements of this paragraph (c)(4)(i):

* * * * *

(B) Payment for the qualified IDR items and services is required to be made by the same group health plan or health insurance issuer. For group or individual health insurance coverage, this requirement is satisfied if the same issuer is required to make payment for the qualified IDR items and services, even if the qualified IDR items and services relate to claims from different group health plans or individual market policies. For self-insured group health plans, this

requirement is satisfied if the same self-insured group health plan is required to make payment for the qualified IDR items and services, including when the plan makes payments through a third party administrator; the requirement is not satisfied if multiple self-insured group health plans are required to make payments for the qualified IDR items and services, even if those group health plans make payments through the same third party administrator;

(C) The qualified IDR items and services meet any of the following criteria under which multiple qualified IDR items and services relate to the treatment of a similar condition and therefore are permitted to be considered jointly as a single payment determination for purposes of encouraging efficiencies (including minimizing costs) in the Federal IDR process:

(*1*) The qualified IDR items or services were furnished to a single patient during the same patient encounter. For purposes of this section, a single patient encounter is defined as a patient encounter on one or more consecutive days during which the qualified IDR items or services were furnished to the same patient and billed on the same claim form; or

(*2*) The qualified IDR items and services were furnished to one or more patients and were billed under the same service code or a comparable code under a different procedural coding system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) codes with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; or

(*3*) For anesthesiology, radiology, pathology, and laboratory qualified IDR items and services, the qualified IDR items and services were furnished to one or more patients and were billed under service codes belonging to the same Category I CPT code range, as specified in guidance published by the Secretary; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period following the date on which the first item or service included in the batched determination was furnished and were the subjects of a 30-business-day open negotiation period

that ended within 4 business days of IDR initiation, except as provided in paragraph (c)(5)(vii) of this section.

(ii) *Treatment of bundled payment arrangements.* Qualified IDR items and services that meet the definition of a bundled payment arrangement under § 149.30 may be submitted and considered as a single payment determination, and the certified IDR entity must make a single payment determination for the multiple qualified IDR items and services included in the bundled payment arrangement. Bundled payment arrangements as defined in § 149.30 and submitted under this paragraph (c)(4)(ii) are subject to the certified IDR entity fee for single determinations.

(5) * * *

(i) *Submission of offers*. Not later than 10 business days after the date of the final selection of the certified IDR entity as described in paragraph (c)(1)(iv)(C) of this section (or not later than 10 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section, when the Secretary determines that any of the extenuating circumstances described in paragraph (g)(1)(ii) of this section apply), the plan or issuer and the provider, facility, or provider of air ambulance services:

* * * * *

(ii) *Payment determination and notification*. Not later than 30 business days after the date of the final selection of the certified IDR entity as described in paragraph (c)(1)(iv)(C) of this section (or not later than 30 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section, when the Secretary determines that any of the extenuating circumstances described in paragraph (g) of this section apply), the certified IDR entity must:

(A) * * *

(*1*) *Prevailing party*. In the case of single determinations, the party whose offer is selected by the certified IDR entity is considered the prevailing party. In the case of batched

determinations, the party with the most determinations in its favor is considered the prevailing party; if each party prevails in an equal number of determinations, neither party will be considered the prevailing party, and the certified IDR entity fee will be split evenly between the parties.

(*2*) *Non-prevailing party*. In the case of single determinations, the party whose offer is not selected by the certified IDR entity is considered the non-prevailing party. In the case of batched determinations, the party with the fewest determinations in its favor is considered the non-prevailing party.

* * * * *

(vii) *Effects of determination*.

(A) * * *

(B) *Suspension of certain subsequent IDR requests*. In the case of a determination made by a certified IDR entity under paragraph (c)(5)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted*. If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(5)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

* * * * *

(d) *Costs of IDR process* —(1) *Certified IDR entity fee*—(i) *Timing of payment of certified IDR entity fee.* Each party to a dispute for which there is a final selection of the certified IDR entity and a determination that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section must pay to the certified IDR entity the predetermined certified IDR entity fee charged by the certified IDR entity. The certified IDR entity fee must be paid no later than the date a party submits its offer to the certified IDR entity, in accordance with paragraph (c)(5)(i) of this section.

(ii) *Failure to timely pay certified IDR entity fee*. If a party fails to pay the certified IDR entity fee as specified in paragraph (d)(1)(i) of this section, that party's offer will not be considered received. Such party will continue to be responsible for payment of the certified IDR entity fee.

(iii) *Method of allocation of the certified IDR entity fee after a payment determination.* After making a payment determination, the certified IDR entity shall retain the certified IDR entity fee described under paragraph (d)(1)(i) of this section paid by the non-prevailing party as defined in paragraph (c)(5)(ii)(A)(*2*) of this section. The certified IDR entity must return the fee paid by the prevailing party, as defined in paragraph (c)(5)(ii)(A)(*1*) of this section, within 30 business days following the date of the certified IDR entity's payment determination. In the event of a batched dispute in which each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. In that case, the certified IDR entity must return half the fee paid by each party within 30 business days following the date of the certified IDR entity's payment determination.

(iv) *Method of allocation of the certified IDR entity fee upon agreement or withdrawal after an eligibility determination.* For a dispute for which there is a final selection of the certified IDR entity and a determination that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, unless directed otherwise by both parties, the

certified IDR entity is required to return half of each party's certified IDR entity fee within 30 business days of the date both parties notify the certified IDR entity that they have:

(A) Reached an agreement on an out-of-network rate for qualified IDR items or services before the certified IDR entity has made its payment determination, as described in paragraph (c)(3)(i) of this section; or

(B) Withdrawn the dispute before the certified IDR entity has made its payment determination, as described in paragraph (c)(3)(ii) of this section.

(v) *Method of allocation of the certified IDR entity fee upon agreement or withdrawal before an eligibility determination.* When the parties reach an agreement on an out-of-network rate or withdraw a dispute for which there is a final selection of the certified IDR entity, but for which no eligibility determination has yet been made, unless directed otherwise by both parties, the certified IDR entity is required to return each party's full certified IDR entity fee within 30 business days of the date both parties notify the certified IDR entity that they have agreed on an out-of-network rate or agreed to withdraw the dispute.

(2) *Administrative fee*. (i) *In general.* Each party to a dispute for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay a non-refundable administrative fee to the Secretary for participating in the Federal IDR process.

(A) *Timing of payment of administrative fee*. The initiating party must pay the administrative fee within 2 business days of the date of preliminary selection of the certified IDR entity as described in paragraph (c)(1)(iii) of this section. The non-initiating party must pay the administrative fee within 2 business days of the date the non-initiating party receives notice that an eligibility determination for the Federal IDR process has been reached by either the certified IDR entity or the Departments in accordance with paragraph (c)(2) of this section.

(B) *Agreements and withdrawals.* In the case of an agreement, as described in paragraph (c)(3)(i) of this section, or a withdrawal, as described in paragraph (c)(3)(ii) of this section, the administrative fee will not be returned to the parties if preliminary selection of the certified IDR

entity has occurred, as described in paragraph (c)(1)(i) of this section; if not yet collected, the administrative fee must still be paid, except as provided in paragraph (d)(2)(i)(C) of this section for a dispute closed for nonpayment by an initiating party.

(C) *Failure to pay administrative fee*. If the initiating party fails to pay the administrative fee in accordance with paragraph (d)(2)(i)(A) of this section, the dispute will be closed due to nonpayment and neither party will be responsible for the administrative fee. If the non-initiating party fails to pay the administrative fee in accordance with paragraph (d)(2)(i)(A) of this section, that party's offer will not be considered received and the non-initiating party will continue to be responsible for payment of the administrative fee.

(D) *Collection of unpaid fees.* Any party that fails to pay the administrative fee owed in accordance with paragraph (d)(2)(i)(A) of this section is obligated to pay the administrative fee otherwise due and owing, except as provided in paragraph (d)(2)(i)(C) of this section for a dispute closed for nonpayment by an initiating party. The Secretary will pursue collection from a party to a dispute of any administrative fee that is not timely paid pursuant to applicable debt collection authorities, after netting any amounts owed by the Federal Government in accordance with § 156.1215 of this Title, as applicable.

(ii) *Administrative fee amount*. The administrative fee amount and method of payment will be established through notice and comment rulemaking in a manner such that the total administrative fees paid for a year, including administrative fees reduced under paragraph (d)(2)(iii) of this section, are estimated to be equal to the projected amount of expenditures made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(A) For disputes initiated on or after the later of the effective date of Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges final rules or January 1, 2024, the administrative fee amount is $150 per party per dispute, which will remain in effect until changed by subsequent rulemaking.

(B) [Reserved]

(iii) *Reducing the administrative fee amount*. For disputes initiated on or after January 1, 2025—

(A) The Secretary may reduce the administrative fee for both parties in accordance with paragraph (d)(2)(iii)(C) of this section when the highest offer made by either party during open negotiation for the dispute is less than the threshold established in notice and comment rulemaking pursuant to paragraph (d)(2)(ii) of this section. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph and for which a determination has been made that the dispute is eligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, the administrative fee amount may be reduced to 50 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section for each party to the dispute. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph and for which a determination has been made that the dispute is ineligible for the Federal IDR process in accordance with paragraph (c)(2) of this section, the administrative fee amount may be reduced to 50 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section for the initiating party and to 20 percent of the administrative fee amount for the non-initiating party.

(B) The Secretary may reduce the administrative fee for a non-initiating party in accordance with paragraph (d)(2)(iii)(C) of this section when the dispute is determined to be ineligible for the Federal IDR process in accordance with paragraph (c)(2) of this section. For a dispute that satisfies the requirements for a reduced administrative fee in accordance with this paragraph, the administrative fee amount for the non-initiating party may be reduced to 20 percent of the administrative fee amount as described in paragraph (d)(2)(ii) of this section.

(C) The reduced administrative fee amounts provided for in paragraphs (d)(2)(iii)(A) and (d)(2)(iii)(B) of this section shall be established in notice and comment rulemaking and will

remain in effect until changed by subsequent rulemaking, pursuant to paragraph (d)(2)(ii) of this section.

(e) * * *

(2) * * *

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees (if applicable) received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the certified IDR entity;

* * * * *

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party or a portion of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(3)(i) of this section, a withdrawal described in paragraph (c)(3)(ii) of this section, or a circumstance described under paragraph (d)(1)(iii) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees (if applicable) described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

* * * *

(g) * * *

(1) *In general.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(5)(ix) of this section) may be extended in extenuating

circumstances at the Secretary's discretion. Extenuating circumstances include, but are not limited to when:

(i) With respect to a specific dispute, the Secretary determines that the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of one or both parties or the certified IDR entity, or for other good cause. The certified IDR entity or either party may also submit a request for an extension due to extenuating circumstances to the Secretary through the Federal IDR portal. The requesting certified IDR entity or party must attest that it will take prompt action to ensure that the certified IDR entity's payment determination under this section may be made as soon as administratively practicable under the circumstances; or

(ii) The Secretary determines that the parties or certified IDR entity cannot meet applicable timeframes due to systematic delays in processing disputes under the Federal IDR process, such as an unforeseen volume of disputes or Federal IDR portal system failures. Extensions provided due to extenuating circumstances caused by an unforeseen volume of disputes will be applied to the timeframe for eligibility determinations under paragraph (c)(2) of this section. Extensions provided due to extenuating circumstances caused by systems failures within the Federal IDR portal will be applied to the Federal IDR process timeframe(s) determined relevant by the Secretary. The Secretary will post a public notice regarding any extensions of time periods pursuant to this paragraph (g)(1)(ii).

(A) *Timeframe following an extension to eligibility determination.* When an extension to the eligibility determination timeframe pursuant to paragraph (g)(1)(ii) of this section is in effect, the start date of the subsequent timeframes in the Federal IDR process will be determined based on the date of completion of the eligibility determination by the certified IDR entity or the Secretary.

(*1*) *Submission of offers.* The parties must submit their offers and certified IDR entity fees to the certified IDR entity not later than 10 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section.

(*2*) *Payment Determination.* The certified IDR entity must make the payment determination and notification of the payment determination to the parties not later than 30 business days after the qualified IDR items and services are determined eligible as described in paragraph (c)(2) of this section.

(B) *Timeframe following an extension to other timeframes in the Federal IDR process.* When an extension to any timeframe within the Federal IDR process, other than the eligibility timeframe, is in effect pursuant to paragraph (g)(1)(ii) of this section, the start date of each subsequent timeframe in the Federal IDR process will be determined based on the date of completion of the process for which the extension was granted.

(2) [Reserved]

(h) *Applicability date***.** (1) Paragraph (a) of this section is applicable with respect to plan years (or in the individual market, policy years) beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021, and the revised definition for batched qualified IDR items and services at paragraph (a)(2)(i) of this section is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(2) Paragraph (b) of this section is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(3) Paragraph (c)(1) of this section, regarding the selection of a certified IDR entity, is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule, except that paragraphs (c)(1)(iv)(A)(*1*) through (*3*) of this section, regarding the conflict-of-interest standards, are applicable with

respect to plan years (or in the individual market, policy years) beginning on or after January 1, 2022.

(4) Paragraph (c)(2) of this section, regarding the Federal IDR process eligibility review and paragraph (c)(3) of this section regarding the authority to continue negotiations or withdraw are applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule and paragraph (c)(4) of this section regarding the treatment of batched and bundled qualified IDR items and services is applicable 90 days after the effective date of the rule.

(5) Paragraphs (c)(5)(i) and (ii), and (c)(5)(vii)(B) and(C) of this section regarding the deadlines for the submission of offers, payment determination and notification, suspension of certain subsequent IDR requests, and subsequent submission of requests submitted are applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule. Paragraphs (c)(5)(iii) and (iv) of this section regarding considerations in payment determinations and the related examples and paragraph (c)(5)(vi)(B) of this section regarding written decisions are applicable with respect to items or services furnished on or after October 25, 2022, for plan years (or in the individual market policy years) beginning on or after January 1, 2022. Paragraphs (c)(5)(v) through (c)(5)(vi)(A), (c)(5)(vii)(A), and (c)(5)(viii) and (ix) are applicable with respect to plan years (or in the individual market, policy years) beginning on or after January 1, 2022.

(6) Paragraph (d) of this section regarding the costs of the IDR process is applicable to disputes initiated on or after January 1, 2025.

(7) Paragraph (e) of this section is applicable with respect to plan years (or in the individual market, policy years) beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (e)(1), (e)(2)(i) through (vi), (e)(2)(x) and (xi), and (e)(3) through (6) of this section are applicable beginning on October 7, 2021. Paragraphs (e)(2)(vi), (viii), and (ix) of this section regarding the certified IDR entity's controls to prevent

and detect improper financial activities, and procedures to retain the certified IDR entity fee and administrative fee are applicable upon the effective date of the rule.

(8) Paragraph (f) of this section is applicable with respect to plan years (or in the individual market, policy years) beginning on or after January 1, 2022, except that paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process is applicable with respect to items or services furnished on or after October 25, 2022, for plan years (or in the individual market policy years) beginning on or after January 1, 2022.

(9) Paragraph (g) of this section regarding the extension of time periods for extenuating circumstances is applicable to disputes with open negotiation periods beginning on or after the later of August 15, 2024, or 90 days after the effective date of the rule.

(10) Until the relevant applicability date for the requirements of this section, plans, issuers, providers, facilities, providers of air ambulance services and certified IDR entities are required to continue to comply with the corresponding section of § 149.510 in effect on October 25, 2022.

(i) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions of paragraphs (b)(1), (c)(2)(ii), (c)(4), (d)(2), and (g)(1) of this section are intended to be severable from one another, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in those paragraphs. The provisions in § 149.510 are intended to be severable from the provisions in §§ 149.100, 149.140, and 149.530, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 149.100, 149.140, and 149.530.

23. Section 149.530 is added to subpart F to read as follows:

§ 149.530 Federal independent dispute resolution registry of group health plans, health insurance issuers, and Federal Employees Health Benefits Carriers.

(a) *Establishment of Federal independent dispute resolution registry.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will establish a Federal IDR registry consisting of the information described in paragraph (b)(2) of this section and will assign a registration number for each group health plan, health insurance issuer offering group or individual health insurance coverage, and Federal Employees Health Benefits (FEHB) Program carrier. The information contained in the registry will be made available to parties seeking to initiate an open negotiation or a dispute through the Federal IDR portal, and will be searchable, including by registration number.

(b) *Federal IDR registration*—(1) *Registration requirement.* Each group health plan and health insurance issuer offering group or individual health insurance coverage subject to the Federal IDR process must register with the Federal IDR registry as specified by the Secretary in guidance. Initial registration must be completed by the later of the date that is 30 business days after the effective date of the final rule, the date that is 30 business days after the registry becomes available, or the date the group health plan or health insurance issuer begins offering a group health plan or individual health insurance coverage subject to the Federal IDR process.

(2) *Required data elements.* Group health plans and health insurance issuers offering group or individual health insurance coverage subject to the registration requirement must include the following information with their registration:

(i) The legal business name (if any) of the group health plan, issuer, or FEHB carrier and, if applicable, the legal business name of the group health plan sponsor;

(ii) Whether the plan or coverage is a self- or fully-insured group health plan subject to ERISA, individual health insurance coverage, a plan offered by a FEHB carrier, a self- or fully-insured non-Federal governmental plan, or a self- or fully-insured church plan;

(iii) The State(s) in which the plan or coverage is subject to a specified State law, as defined in § 149.30 for any items or services for which the protections of §§ 149.110, 149.120, and 149.130 apply;

(iv) The State(s) in which the plan or coverage is subject to an All-Payer Model Agreement under section 1115A of the Social Security Act for any items or services to which the protections in §§ 149.110, 149.120, and 149.130, apply;

(v) For self-insured group health plans not otherwise subject to State law, any State(s) in which the group health plan has properly effectuated an election to opt in to a specified State law as defined in § 149.30, if that State allows a plan not otherwise subject to the State law to opt-in; and for FEHB plans that adopt a specified State law pursuant to their FEHB carrier's contract terms, any State(s) in which they have made such an adoption;

(vi) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service;

(vii) The 14-digit Health Insurance Oversight System (HIOS) identifier; or if the 14-digit HIOS identifier has not been assigned, the 5-digit HIOS identifier; or if no HIOS identifier is available, the plan's or the plan sponsor's Employer Identification Number (EIN) and the plan's plan number (PN), if a PN is available, or for FEHB carriers, the applicable contract number(s) and plan code(s);

(viii) Additional information needed to identify the plan or issuer and the applicable Federal and State requirements for determining appropriate out-of-network payment rates for items or services to which the protections against balance billing in this part apply, as specified by the Secretary in guidance, or such additional information needed with respect to FEHB carriers as specified by OPM in guidance; and

(ix) Additional information needed for purposes of administrative fee collection, as specified by the Secretary in guidance, or such additional information needed with respect to FEHB carriers as specified by OPM in guidance.

(3) *Updating disclosures.* A plan or issuer must timely report to the Secretary changes to the information required under this section within 30 calendar days after the information changes. A plan or issuer must confirm the accuracy of its registration annually in the fourth quarter of each calendar year.

(*4*) *Third party authority.* The requirements of paragraphs (b)(1) through (3) of this section may be performed by a third party administrator or service provider with authority to act on behalf of the group health plan or health insurance issuer offering group or individual health insurance coverage subject to the Federal IDR process. If the registration requirements are performed by such third party administrator or service provider the group health plan or health insurance issuer offering group or individual health insurance coverage must require that such third party administrator or service provider clearly delineate each group health plan or health insurance issuer offering group health insurance coverage for which it has authority to act. If such third party administrator or service provider fails to provide the information in compliance with the requirements of paragraphs (b)(1) through (3) of this section the plan or issuer will be in violation of the requirements of this section.

(c) *Severability*. (1) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(2) The provisions in § 149.530 are intended to be severable from the provisions in §§ 149.100, 149.140, and 149.510, from any grant of forbearance from removal resulting from this subpart, and from any provision referenced in §§ 149.100, 149.140, and 149.510.

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