Individuals who want to testify in person at the public hearing must send an email to *publichearings@irs.gov* to have your name added to the building access list. The subject line of the email must contain the regulation number REG-105954-22 and the language TESTIFY In Person. For example, the subject line may say: Request to TESTIFY In Person at Hearing for REG-105954-22.

Individuals who want to testify by telephone at the public hearing must send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–105954–22 and the language TESTIFY Telephonically. For example, the subject line may say: Request to TESTIFY Telephonically at Hearing for REG–105954–22.

Individuals who want to attend the public hearing in person without testifying must also send an email to *publichearings@irs.gov* to have your name added to the building access list. The subject line of the email must contain the regulation number REG– 105954–22 and the language ATTEND In Person. For example, the subject line may say: Request to ATTEND Hearing In Person for REG–105954–22. Requests to attend the public hearing must be received by 5 p.m. ET by October 20, 2023.

Individuals who want to attend the public hearing by telephone without testifying must also send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–105954–22 and the language ATTEND Hearing Telephonically. For example, the subject line may say: Request to ATTEND Hearing Telephonically for REG–105954–22. Requests to attend the public hearing must be received by 5 p.m. ET by October 20, 2023.

Hearings will be made accessible to people with disabilities. To request special assistance during a hearing please contact the Publications and Regulations Branch of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–6901 (not a tollfree number) by October 20, 2023. Any questions regarding speaking at or attending a public hearing may also be emailed to *publichearings@irs.gov*.

Oluwafunmilayo A. Taylor,

Section Chief, Publications and Regulations Branch, Associate Chief Counsel, (Procedure and Administration). [FR Doc. 2023–20840 Filed 9–25–23; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG 115762-23]

RIN 1545-BQ94

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AC24

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 149

[CMS-9890-P]

RIN 0938-AV39

Federal Independent Dispute Resolution (IDR) Process Administrative Fee and Certified IDR Entity Fee Ranges

AGENCY: 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: Proposed rule.

SUMMARY: This document sets forth proposed rules related to the fees established by the No Surprises Act for the Federal independent dispute resolution (IDR) process, as established by the Consolidated Appropriations Act, 2021 (CAA). These proposed rules would amend existing regulations to provide that the administrative fee amount charged by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (the Departments) to participate in the Federal IDR process, and the ranges for certified IDR entity fees for single and batched determinations will be set by the

Departments through notice and comment rulemaking. These proposed rules would also set forth the methodology used to calculate the administrative fee and the considerations used to develop the certified IDR entity fee ranges. This document also proposes the amount of the administrative fee for disputes initiated on or after the later of the effective date of these rules or January 1, 2024. Finally, this document proposes the certified IDR entity fee ranges for disputes initiated on or after the later of the effective date of these rules or January 1, 2024. In accordance with 5 U.S.C. 553(b)(4), a summary of this rule 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 October 26, 2023.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments. 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 CMS–9890–P. 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–9890–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–9890–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:

Shira B. McKinlay, Internal Revenue Service, Department of the Treasury, 202–317–5500;

Shannon Hysjulien or Rebecca Miller, Employee Benefits Security Administration, Department of Labor, 202–693–8335; and

Jacquelyn Rudich or Nora Simmons, Centers for Medicare & Medicaid Services, Department of Health and Human Services, 301–492–5211.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received before the close of the comment period will be available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The Departments will post comments on the following website as soon as possible after they have been received: https://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 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,² section 716 of ERISA,³ and section 2799A–1 of the PHS Act,⁴ 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 for patient visits to participating health care facilities, generally defined as hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgical centers.⁵

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 outof-network rates under section 9816 of the Code,6 section 716 of ERISA,7 and section 2799A-1 of the PHS Act.8 Section 9816(c)(8) of the Code,⁹ section 716(c)(8) of ERISA,10 and section 2799A–1(c)(8) of the PHS Act¹¹ provide that each party to a determination under the Federal IDR process shall pay a fee for participating in the Federal IDR process, and the amount of the fee is an amount established by the Departments in a manner such that the total amount of fees paid by all parties is estimated to be equal to the amount of expenditures estimated to be made by the Departments for the year in carrying out the Federal IDR process.

Section 105 of the No Surprises Act added section 9817 of the Code,¹² section 717 of ERISA,¹³ and section

⁵ 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.

⁶ 26 U.S.C. 9816, et seq.
⁷ 29 U.S.C. 1185e, et seq.
⁸ 42 U.S.C. 300gg-111, et seq.
⁹ 26 U.S.C. 9816(c)(8).
¹⁰ 29 U.S.C. 1185e(c)(8).
¹² 26 U.S.C. 9817, et seq.
¹³ 29 U.S.C. 1185f, et seq.

2799A–2 of the PHS Act.¹⁴ 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 E¹⁵ 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 Health and Human Services (HHS) (the Departments), along with the Office of Personnel Management (OPM), have issued rulemakings in 2021 and 2022 to implement various provisions of the No Surprises Act. More specifically relevant to this proposed rulemaking, the Departments and OPM issued interim final rules (July 2021 interim final rules ¹⁶ and October 2021 interim final rules 17) and final rules (August 2022 final rules 18) implementing provisions of sections 9816 and 9817 of the Code,¹⁹ sections 716 and 717 of ERISA,20 and sections 2799A-1 and 2799A–2 of the PHS Act.²¹ These rules implement provisions to protect consumers from surprise medical bills for emergency services, non-emergency services furnished by nonparticipating providers for patient visits to participating facilities ²² 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-ofnetwork rate for these services if a specified State law as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45

¹⁵ 42 U.S.C. 300gg–131–139.

- 17 86 FR 55980 (October 7, 2021).
- ¹⁸87 FR 52618 (August 26, 2022).
- $^{19}\,26$ U.S.C. 9816, $et\,seq.$ and 26 U.S.C. 9817, $et\,seq.$
- ²⁰ 29 U.S.C. 1185e, *et seq.* and 29 U.S.C. 1185f, *et seq.*
- ²¹ 42 U.S.C. 300gg–111, *et seq.* and 42 U.S.C. 300gg–112, *et seq.*

²² 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.

¹ Public Law 116–260 (Dec. 27, 2020).

² 26 U.S.C. 9816, et seq.

³ 29 U.S.C. 1185e, et seq.

^{4 42} U.S.C. 300gg-111, et seq.

¹⁴ 42 U.S.C. 300gg–112, et seq.

^{16 86} FR 36872 (July 13, 2021).

CFR 149.30 or an applicable All-Payer Model Agreement under section 1115A of the Social Security Act 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, 2022.23 The August 2022 final rules became effective October 25, 2022, and are applicable for items or 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.

B. 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,²⁴ sections 716(c) and 717(b) of ERISA,²⁵ and sections 2799A–1(c) and 2799A-2(b) of the PHS Act.²⁶ The rules apply to emergency services, nonemergency services furnished by nonparticipating providers for patient visits to certain types of participating health care facilities 27 (unless an individual has been provided notice and waived the individual's surprise 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 situations in which neither a specified State law as

²⁷ A health care facility, in the context of nonemergency services, is defined as (1) a hospital (as defined in section 1861(e) of the Social Security Act), (2) a hospital outpatient department, (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act), or (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act. Code section 9816(b)(2)(A)(ii), ERISA section 716(b)(2)(A)(ii), and PHS Act section 2799A– 1(b)(2)(A)(ii). 26 CFR 54.9816–37, 29 CFR 2590.716–3, and 45 CFR 149.30. defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 nor an All-Payer Model Agreement under section 1115A of the Social Security Act applies.

To implement the Federal IDR process, the October 2021 interim final rules include requirements governing the costs of the Federal IDR process. Under section 9816(c)(5)(F)(i) of the Code,²⁸ section 716(c)(5)(F)(i) of ERISA,29 section 2799A-1(c)(5)(F)(i) of the PHS Act,30 and the October 2021 interim final rules, the party whose offer is not selected is responsible for the payment of the fee charged by the certified IDR entity (certified IDR entity fee).³¹ Under the October 2021 interim final rules, as a condition of certification, the certified IDR entity must notify the Departments of the amount of the certified IDR entity fees it intends to charge for payment determinations, which is limited to a fixed certified IDR entity fee amount for single determinations and a separate fixed certified IDR entity fee amount for batched determinations.³² Each of these fixed certified IDR entity fees must be within a range set forth in guidance by the Departments, unless the certified IDR entity receives written approval from the Departments to charge a certified IDR entity fee outside that range.³³ The October 2021 interim final rules describe the considerations that the Departments will use to develop the certified IDR entity fee ranges, including the anticipated time and resources needed for certified IDR entities to meet the requirements of those interim final rules, the volume of payment determinations, and the adequacy of the Federal IDR process capacity to efficiently handle the volume of IDR initiations and payment determinations, and discuss that the Departments will review and update the allowable fee ranges annually based on these factors, the impact of inflation, and other cost increases. Those rules also provide that on an annual basis, the certified IDR entity may update its certified IDR entity fees within the ranges set forth in current guidance and seek approval from the Departments to charge fixed

certified IDR entity fees beyond the upper or lower limits for certified IDR entity fees.³⁴

Additionally, pursuant to section 9816(c)(8) of the Code,³⁵ section 716(c)(8) of ERISA,³⁶ and section 2799A-1(c)(8) of the PHS Act,37 and under the October 2021 interim final rules, each party must pay an administrative fee for participating in the Federal IDR process. The administrative fee is established in guidance in a manner so that, in accordance with the requirements of section 9816(c)(8)(B) of the Code,³⁸ section 716(c)(8)(B) of ERISA,39 and section 2799A-1(c)(8)(B) of the PHS Act,⁴⁰ 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.⁴¹

Contemporaneously with the October 2021 interim final rules, the Departments released the Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act (October 2021 guidance), setting the administrative fee for both parties to a dispute at \$50 per party.⁴² The October 2021 guidance also established the range for fixed certified IDR entity fees for single determinations as \$200-\$500, and the range for fixed certified IDR entity fees for batched determinations as \$268–\$670, unless otherwise approved by the Departments. In October 2022, the Departments released the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act (October 2022 guidance), again setting the administrative fee for both parties to a dispute at \$50 per party.⁴³ The October 2022 guidance explained that the data available regarding take-up and usage of

⁴¹26 CFR 54.9816–8T(d)(2)(ii), 29 CFR 2590.716– 8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii).

⁴² Centers for Medicare & Medicaid Services (September 30, 2021). Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/CCIIO/Resources/Regulationsand-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf.

⁴³ Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulationsand-guidance/downloads/cy2023-fee-guidancefederal-independent-dispute-resolution-processnsa.pdf.

²³ 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.

²⁴ 26 U.S.C. 9816(c) and 26 U.S.C. 9817(b).

 ²⁵ 29 U.S.C. 1185e(c) and 29 U.S.C. 1185f(b).
 ²⁶ 42 U.S.C. 300gg–111(c) and 42 U.S.C. 300gg–112(b).

^{28 26} U.S.C. 9816(c)(5)(F)(i).

²⁹29 U.S.C. 1185e(c)(5)(F)(i).

^{30 42} U.S.C. 300gg-111(c)(5)(F)(i).

³¹In the case of a batched dispute, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. 86 FR 55980, 56001.

³² 26 CFR 54.9816–8T(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), and 45 CFR 149.510(e)(2)(vii). ³³ Id.

³⁴ Id.

³⁵ 26 U.S.C. 9816(c)(8).

³⁶ 29 U.S.C. 1185e(c)(8).

^{37 42} U.S.C. 300gg-111(c)(8).

³⁸26 U.S.C. 9816(c)(8)(B).

³⁹29 U.S.C. 1185e(c)(8)(B).

^{40 42} U.S.C. 300gg-111(c)(8)(B).

the Federal IDR process was not reliable enough to support a change to either the estimated number of payment determinations for which administrative fees would be paid or the estimated ongoing program costs for 2023; therefore, the 2023 administrative fee amount due from each party for participating in the Federal IDR process would remain the same as the 2022 administrative fee. The October 2022 guidance permits certified IDR entities to charge a fee between \$200 and \$700 for single determinations and between \$268 and \$938 for batched determinations, unless the Departments otherwise grant approval for the certified IDR entity to charge a fee outside of these ranges. In addition, to account for the heightened workload for batched determinations, the October 2022 guidance permits a certified IDR entity to charge the following percentage of its approved certified IDR entity batched determination fee ("batching percentage") for batched determinations, which are based on the number of line items initially submitted in the batch:

• *2–20 line items:* 100 percent of the approved batched determination fee;

• *21–50 line items:* 110 percent of the approved batched determination fee;

• 51–80 line items: 120 percent of the approved batched determination fee; and

• *81 line items or more:* 130 percent of the approved batched determination fee.

In December 2022, the Departments released the Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act (December 2022 guidance), which amended the \$50 per party administrative fee set in the October 2022 guidance to \$350 for calendar year 2023.44 The change in the administrative fee for 2023 reflected the additional costs to the Departments to carry out the Federal IDR process as a result of the Departments' enhanced role in calendar year 2023 in conducting preeligibility reviews to allow the certified IDR entities to complete their eligibility determinations more efficiently,⁴⁵ as

well as systemic improvements that allowed for the aggregation of data needed to estimate the rate at which disputes were determined eligible for the Federal IDR process and the rate at which one or both parties paid the administrative fee for purposes of calculating the administrative fee. The December 2022 guidance did not amend the certified IDR entity fee ranges.

C. Recent Litigation

On November 30, 2022, the Texas Medical Association, Tyler Regional Hospital, and a Texas physician filed a lawsuit (TMA III)⁴⁶ against the Departments and OPM, asserting that the July 2021 interim final rules 47 and certain related guidance documents were in conflict with the statutory language, including the regulations governing how the qualifying payment amount (QPA) should be calculated. On August 24, 2023, the U.S. District Court for the Eastern District of Texas (Texas 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 those portions that provided 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 guidance was unlawfully issued without notice and

⁵¹ Tex. Med. Ass n, v. U.S. Dep't of Health and Human Servs., Case No. 6:23-cv-00059-JDK (E.D. Tex. January 30, 2023). comment rulemaking.⁵² On August 3, 2023, the Texas District Court issued a memorandum opinion and order ⁵³ that vacated the portion of the December 2022 guidance ⁵⁴ that increased the administrative fee for the Federal IDR process to \$350 per party for disputes initiated during the calendar year beginning January 1, 2023. The Texas 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

As a result of the TMA IV opinion and order, on August 3, 2023, the Departments instructed certified IDR entities to pause all work in the Federal IDR portal until the Departments updated the Federal IDR process guidance, systems, and related documents to make them consistent with the TMA IV opinion and 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 to be eligible and administrative fees had been paid (or the deadline for collecting fees had expired) before August 3, 2023. 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

⁵⁴ Centers for Medicare & Medicaid Services (December 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/regulationsand-guidance/downloads/amended-cy2023-feeguidance-federal-independent-dispute-resolutionprocess-nsa.pdf.

⁵⁵ Specifically, the Texas 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.

⁴⁴ Centers for Medicare & Medicaid Services (December 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/regulationsand-guidance/downloads/amended-cy2023-feeguidance-federal-independent-dispute-resolutionprocess-nsa.pdf.

⁴⁵Centers for Medicare & Medicaid Services (November 21, 2022). Notice of the Federal Independent Dispute Resolution (IDR) Team Technical Assistance to Certified Independent

Dispute Resolution Entities (IDREs) in the Dispute Eligibility Determination Process. https:// www.cms.gov/files/document/idre-eligibilitysupport-guidance-11212022-final-updated.pdf.

⁴⁶ Tex. Med. Ass'n, v. U.S. Dep't of Health and Human Servs., Case No. 6:22–cv–00450–JDK (E.D. Tex. November 30, 2022).

⁴⁷ 86 FR 36872 (July 13, 2021).

⁴⁸ See Memorandum Opinion and Order, *Tex. Med. Ass'n.* v. *U.S. Dep't of Health & Hum. Servs*, No. 6:22–cv–00450–JDK (E.D. Tex. August 24, 2023).

⁴⁹ Specifically, the Texas District Court vacated certain subprovisions of 45 CFR 149.130 and 149.140, 26 CFR 54.9816–6T and 54.9817–1T, and 29 CFR 2590.716–6 and 2590.717–1. The Texas District Court also vacated 5 CFR 890.114(a).

⁵⁰ Specifically, the Texas District Court vacated FAQs 14 and 15 of FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 55 (August 19, 2022), as well as portions of Technical Guidance for Certified IDR Entities at 2–3 (August 18, 2022).

⁵² See Motion for Summary Judgment and Reply in Support of Summary Judgment, p. 1, Tex. Med. Ass'n.v. U.S. Dep't of Health & Hum. Servs, No. 6:23-cv-00059-JDK (E.D. Tex. March 27, 2023). https://ecf.txed.uscourts.gov/doc1/175113317945.

⁵³ See Memorandum Opinion and Order, Tex. Med. Ass'n. v. U.S. Dep't of Health & Hum. Servs, No. 6:23-cv-00059-JDK (E.D. Tex. August 3, 2023).

guidance ⁵⁶ to reflect the TMA IV decision related to the administrative fee and to clarify the applicability of the \$50 per party per dispute administrative fee amount for 2023, as provided in the October 2022 guidance. On the same date, the Departments directed 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 opinion and order issued on August 24, 2023, the Departments again paused all IDRrelated activities in order to evaluate the Texas District Court's order and review current Federal IDR processes, templates, and system updates that are necessary to comply with the order. As of the publication of this proposed rulemaking, the Departments have directed certified IDR entities only to perform limited Federal IDR process functions.

D. Scope and Purpose of Rulemaking

These rules propose amendments to 26 CFR 54.9816-8(d)(2)(ii) and (e)(2)(vii), 29 CFR 2590.716-8(d)(2)(ii) and (e)(2)(vii), and 45 CFR 149.510(d)(2)(ii) and (e)(2)(vii) to provide that the administrative fee amount and the ranges for certified IDR entity fees for single and batched disputes would be set by the Departments through notice and comment rulemaking, rather than in guidance published annually. This rulemaking also proposes to set forth the methodology used to calculate the administrative fee and the considerations used to develop the certified IDR entity fee ranges. These rules would also propose the administrative fee amount and certified IDR entity fee ranges for disputes initiated on or after the later of the effective date of these rules or January 1, 2024.

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

A. Administrative Fee Amount and Methodology

Under section 9816(c)(8)(A) of the Code,⁵⁷ section 716(c)(8)(A) of ERISA,⁵⁸ section 2799A-1(c)(8)(A) of the PHS Act,⁵⁹ and the October 2021 interim

final rules,⁶⁰ each party to a determination for which a certified IDR entity is selected must pay an administrative fee for participating in the Federal IDR process. Under section 9816(c)(8)(B) of the Code,⁶¹ section 716(c)(8)(B) of ERISA,62 section 2799A-1(c)(8)(B) of the PHS Act,63 and the October 2021 interim final rules,64 the administrative fee is established in a manner such 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.

In TMA IV,65 the Texas District Court issued an opinion and order holding that the process by which the Departments amended the 2023 administrative 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, 2023⁶⁶ 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.67 In light of the Texas 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 propose to establish the amount of the administrative fee through notice and comment rulemaking. To reflect this, the Departments propose to amend 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 state that the Departments will set the administrative fee through notice and comment rulemaking.

The Departments also propose at 26 CFR 54.9816–8(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR

⁶⁴ 26 CFR 54.9816–8T(d)(2)(ii), 29 CFR 2590.716– 8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii).

⁶⁵ 6:23-cv-00059-JDK (E.D. Tex. Jan. 30, 2023). ⁶⁶ Centers for Medicare & Medicaid Services (December 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/regulationsand-guidance/downloads/amended-cy2023-feeguidance-federal-independent-dispute-resolutionprocess-nsa.pdf.

⁶⁷ See Memorandum Opinion and Order, Tex. Med. Ass'n. v. U.S. Dep't of Health & Hum. Servs, No. 6:23–cv–00059–JDK (E.D. Tex. August 3, 2023). https://ecf.txed.uscourts.gov/doc1/175113317945.

149.510(d)(2)(ii) that, for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, the proposed administrative fee amount would be \$150 per party per dispute, which would remain in effect until changed by subsequent rulemaking. Under this proposed rule, the Departments propose to retain the flexibility to update the administrative fee more frequently or less frequently than annually. With this flexibility, the Departments intend to update the administrative fee amount when the total projected amount of administrative fees paid or projected expenditures made by the Departments to carry out the Federal IDR process changes, such that a new administrative fee amount would be required for the Departments to cover the costs of carrying out the Federal IDR process. For example, the Departments' expenditures may be impacted by changes to regulations governing the Federal IDR process or the implementation of that process, the volume of disputes initiated and closed under the Federal IDR process, and the Departments' costs. In such cases, the Departments would propose a different administrative fee amount in notice and comment rulemaking before applying a new administrative fee amount. Thus, the proposal to amend the current regulation to remove the requirement to set the administrative fee amount annually would help mitigate the risk of the Departments being unable to collect administrative fees sufficient to carry out the Federal IDR process in response to evolving conditions, such as the rates at which disputes are being initiated and closed. Additionally, the Departments could determine that the projected amount of administrative fees paid at the current fee amount will equal the projected expenditures made to carry out the Federal IDR process in a subsequent year, and therefore, no adjustment of the fee amount in rulemaking would be necessary. This proposed approach would comport with the statutory requirement to set the administrative fee amount in a manner such that the total amount of fees paid in a year is estimated to be equal to the amount of expenditures estimated to be made by the Departments in such year in carrying out the Federal IDR process.

The Departments propose to set the administrative fee amount 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. The Departments project the number of administrative fees to be paid

⁵⁶Centers for Medicare & Medicaid Services (August 11, 2023). Federal Independent Dispute Resolution (IDR) Process Administrative Fee FAQs. https://www.cms.gov/cciio/resources/regulationsand-guidance/downloads/no-surprises-actindependent-dispute-resolution-administrative-feefrequently-asked-questions.pdf.

^{57 26} U.S.C. 9816(c)(8)(A).

^{58 29} U.S.C. 1185e(c)(8)(A).

^{59 42} U.S.C. 300gg-111(c)(8)(A).

⁶⁰ 26 CFR 54.9816–8T(d)(2)(i), 29 CFR 2590.716– 8(d)(2)(i), and 45 CFR 149.510(d)(2)(i).

^{61 26} U.S.C. 9816(c)(8)(B).

^{62 29} U.S.C. 1185e(c)(8)(B).

^{63 42} U.S.C. 300gg-111(c)(8)(B).

based on the total volume of disputes to be closed. Under the current Federal IDR process and the policies proposed in these proposed rules, both the initiating and non-initiating parties to a dispute are required to pay the nonrefundable administrative fee in full, and therefore the total amount of administrative fees paid is calculated to reflect that both parties to a dispute pay the administrative fee. In calculating the Departments' estimated administrative fee, the Departments 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 is more indicative of the total volume of disputes for which fees are paid under the Departments' current collections process.⁶⁸

For the purposes of calculating the administrative fee amount proposed in this rulemaking, the Departments project approximately 225,000 disputes will be closed annually. This projection is based on Federal IDR process data from February 2023 through July 2023, which is the most recent 6-month period before Federal IDR process operations were temporarily paused in August 2023.⁶⁹ Using this projected volume of disputes, the Departments assume a prospective reduction of approximately 25 percent in the volume of closed disputes to account for the impact of the TMA IV opinion and order'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 anticipate that the vacatur of the batching regulations as a result of TMA IV discussed in sections I.C. and II.B. of this preamble may result in the initiation and closure of fewer disputes due to the possibility that batched disputes may involve more line items and take more time to close.

Additionally, to calculate the administrative fee amount proposed in this rulemaking, the Departments projected the expenditures to carry out the Federal IDR process. These projected expenditures include the Federal resources needed to carry out the Federal IDR process, such as personnel costs, as well as activities included as part of contract costs, such as resources used for targeted improvements of the overall process. The costs to the Departments for carrying out the Federal IDR process in 2024 are projected to be approximately \$70 million,⁷⁰ which includes contract costs and Federal resources associated with:

• Maintaining the Federal IDR portal, 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, improving the speed of eligibility and payment determinations, and to assist the Departments in understanding where some 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 program integrity of the Federal IDR process by reducing and preventing errors in the Federal IDR process;

• Investigating relevant complaints, which is intended to ensure compliance with the Federal IDR process;

• 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, which is intended to operationalize, maintain, and oversee administrative fee collections from certified IDR entities;

• Assisting with eligibility determinations when the volume of disputes submitted exceeds the capacity of certified IDR entities to perform those determinations, which is intended to expedite and facilitate eligibility reviews conducted by certified IDR entities; ⁷¹ and

• Retaining and making available Federal personnel dedicated to carrying out Federal IDR process activities.

Using this methodology, as proposed in paragraphs 26 CFR 54.9816-8(d)(2)(ii), 29 CFR 2590.716–8(d)(2)(ii), and 45 CFR 149.510(d)(2)(ii), the proposed administrative fee for disputes initiated on or after the later of the effective date of these rules or on January 1, 2024, and continuing until changed by subsequent rulemaking, would be calculated by dividing the projected annual expenditures of approximately \$70 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. As previously explained, the projected total number of administrative fees is calculated using the projected volume of disputes closed and reflects that both parties to a dispute pay the administrative fee. We project 225,000 closed disputes in calendar year 2024. Therefore, 450,000 administrative fees would be paid by the parties in the year, because initiating and non-initiating parties to a dispute are required to pay the full administrative fee under the current Federal IDR process. This would result in a proposed administrative fee amount of \$150 per party per dispute.72 This administrative fee amount is based on the most current collections data (February through July 2023), which the Departments have determined to be the best available data for estimation of future collections, and the Departments' projected expenditures as of the publication of these proposed rules. 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 methodology proposed here, as finalized, using the updated data, if applicable.

The Departments continue to consider improvements to the Federal IDR process, including how collection of the administrative fee could be more efficient and how the administrative fee amount could better ensure equitable access to the Federal IDR process across the various parties seeking to initiate disputes. Accordingly, the Departments intend to propose additional policies related to the administrative fee in future notice and comment rulemaking, including policies that would change the manner and timeframe in which the

⁶⁸ Under current policy and guidance, the administrative fee may be collected by certified IDR entities up until the time the parties submit their offers, and therefore the administrative fee is not collected for all disputes initiated. *See*, for example, Centers for Medicare & Medicaid Services (March 2023). *Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities. https://www.cms.gov/files/document/federal-idrguidance-idr-entities-march-2023.pdf.*

⁶⁹ For this calculation, we used our Federal IDR process collections data from February 2023 through July 2023 to calculate the average monthly volume of disputes closed. We applied the 25 percent reduction described in this rule to the average monthly volume and multiplied this number by 12 to project the annual volume of closed disputes.

⁷⁰ Because the Departments generally are not permitted to publicly provide information that is confidential due to trade secrets associated with future contracting, the Departments are limited in their ability to provide detailed information about projected total Federal IDR process expenditures. *See* 45 CFR 5.31(d).

⁷¹Centers for Medicare & Medicaid Services (November 21, 2022). Notice of the Federal Independent Dispute Resolution (IDR) Team Technical Assistance to Certified Independent Dispute Resolution Entities (IDREs) in the Dispute Eligibility Determination Process. https:// www.cms.gov/files/document/idre-eligibilitysupport-guidance-11212022-final-updated.pdf.

⁷² As described later in this rule, we estimate that the proposed administrative fee of \$150 per party, per dispute would result in an estimated annual collection approximately equal to the projected annual expenditures of approximately \$70 million.

administrative fee is paid, reduce the administrative fee amount for disputes that are determined ineligible or that involve low-dollar claims, and codify the consequences of failing to pay the administrative fee. Therefore, it is likely that these potential future proposals could require changes to the administrative fee amount, and any such change would be set forth in future notice and comment rulemaking.

The Departments solicit comments on this proposal, including the methodology used to calculate the administrative fee amount and the proposed administrative fee amount for disputes initiated on or after the later of the effective date of these rules or on January 1, 2024, as well as any potential effects on interested parties as a result of increasing the administrative fee from \$50 to \$150 per party. For example, the Departments solicit comments on whether this proposed administrative fee amount could be cost prohibitive for certain parties disputing low-dollar items and services, and whether it would reduce the number of disputes initiated in calendar year 2024 and beyond. The Departments also solicit comment on the proposal to set the administrative fee amount more frequently or less frequently than annually and whether the Departments should instead retain the current policy that the administrative fee amount is set annually. Additionally, the Departments seek comment on any implications of TMA III and TMA IV that could impact these administrative fee proposals that are not already noted in this proposed rulemaking.

Finally, the Departments solicit comment on whether, in future years, they should apply an inflationary adjustment, such as the consumer price index for all urban consumers (CPI–U), to the projected expenditures to be made by the Departments in carrying out the Federal IDR process when calculating the administrative fee amount each year and set forth the adjusted administrative fee amount in guidance, rather than in notice and comment rulemaking, as long as there are no other changes to the methodology.

B. Certified IDR Entity Fee Ranges

Under current regulations 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), the certified IDR entity fees for single determinations and batched determinations are set by the certified IDR entities within the upper and lower limits of ranges for each as set forth in guidance issued annually by the Departments.

The Departments propose to amend the provisions of the regulations establishing the ranges for certified IDR entity fees for single and batched disputes to refer to the ranges being established in notice and comment rulemaking, rather than in guidance. These changes would be reflected at 26 CFR 54.9816-8(e)(2)(vii), 29 CFR 2590.716-8(e)(2)(vii), and 45 CFR 149.510(e)(2)(vii), which would specify that certified IDR entities must, on an annual basis, provide a fixed fee for single determinations and separate fixed fees for batched determinations within the upper and lower limits for each as set in notice and comment rulemaking. Further, the proposed rules would provide that the certified IDR entity fee ranges established by the Departments in rulemaking would remain in effect until new certified IDR entity fee ranges are changed by a subsequent notice and comment rulemaking. Under this approach, the Departments would retain the discretion to update the certified IDR entity fee ranges more or less frequently than annually. Consistent with the current process, the certified IDR entity could not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits. Finally, the Departments propose that the certified IDR entity or IDR entity seeking certification may seek advance written approval from the Departments to update its fees more frequently than once annually.

The Departments propose that for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, certified IDR entities would be permitted to charge a fixed certified IDR entity fee for single determinations within the range of \$200 to \$840. This fee range represents a 20 percent increase to the upper limit from the 2023 single determination fee range.⁷³ The Departments anticipate that the proposed range for single determinations would only minimally impact the fixed fees selected by certified IDR entities. This is because the process of arbitrating single determinations should remain relatively predictable in 2024, as these disputes

have not been impacted by the *TMA IV* decision. The Departments expect that certified IDR entities would continue to price their single determination fees competitively despite the proposed increase in range. Nonetheless, the Departments are of the view that an increase to the upper limit of the range is necessary to allow certified IDR entities flexibility to set their fees in alignment with their operating costs.

The Departments propose that for disputes initiated on or after the later of the effective date of these proposed rules, or January 1, 2024, certified IDR entities would be permitted to charge a fixed certified IDR entity fee for batched determinations within the range of \$268 to \$1,173, unless a fee not within that range is approved by the Departments pursuant to paragraphs 26 CFR 54.9816-8T(e)(2)(vii)(A) and (B), 29 CFR 2590.716-8(e)(2)(vii)(A) and (B), and 45 CFR 149.510(e)(2)(vii)(A) and (B). This fee range represents a 25 percent increase to the upper limit from the 2023 batched determination fee range.74 The Departments propose to continue to use a tiered fee structure based on the number of line items within the batch.75 Under this proposed rule, the certified IDR entities would be permitted to charge a fixed tiered fee within the range of \$75 to \$250 for every additional 25 line items within a batched dispute beginning with the 26th line item. A certified IDR entity's batched determination fee would be applied to all batched disputes that have between 2 and 25 line items. For batched disputes with more than 25 line items, the certified IDR entity fee would be able to increase the base amount for every additional 25 line items by a fixed value between \$75 and \$250, as determined by the certified IDR entity. Unlike the fixed certified IDR entity fee for single and batched determinations, certified IDR entities would not be able

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⁷³ Beginning January 1, 2023, certified IDR entities are permitted to charge a certified IDR entity fee for single determinations within the range of \$200-\$700. See Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulationsand-guidance/downloads/cy2023-fee-guidancefederal-independent-dispute-resolution-processnsa.pdf.

⁷⁴ Beginning January 1, 2023, certified IDR entities are permitted to charge a certified IDR entity fee for batched determinations within a range of \$268–\$938. See Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulationsand-guidance/downloads/cy2023-fee-guidancefederal-independent-dispute-resolution-processnsa.pdf.

⁷⁵ This was first proposed in the Calendar Year 2023 Fee Guidance *for the* Federal Independent Dispute Resolution Process *under* the No Surprises Act and implemented for all disputes initiated as of January 1, 2023. See Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/ resources/regulations-and-guidance/downloads/ cy2023-fee-guidance-federal-independent-disputeresolution-process-nsa.pdf.

to seek approval to charge a fee outside of the tiered fee range for batched determinations. It is the Departments' view that the ability to seek approval to charge a fee outside of the fixed certified IDR entity batched fee range is sufficiently flexible to address any potential cost concerns. This is because the certified IDR entities only need the ability to set a fee outside one of the two batched ranges' upper and lower limits to set their overall batched fee in a manner that allows them to cover their expenses. Further, for batched determinations, the fee range would not restrict the application of the additional fixed tiered fee for batched disputes. For example, if a certified IDR entity had, in 2024, set its batched determination fee at \$1,000 (which would be within the fee range of \$268 to \$1,173) and its tiered fee at \$200 (which would be within the tiered fee range of \$75 to \$250) for each additional increment of 25 line items, and were to be selected for a batched determination with 53 line items (which corresponds to 2 increments of 25 line items within the tiered fee structure plus the batched determination fee) it would be permitted to charge \$1,400 (\$1,000 + $($200 \times 2)$) as its batched determination fee in calendar year 2024.

Further, the Departments propose that the batched determination fee would continue to be based on the number of line items included in the initiating party's initial submission of the batched dispute to the Federal IDR process. This would account for the time and effort required of certified IDR entities in determining eligibility for all line items within a batched dispute such that they can ultimately make a payment determination. These fee ranges would apply until another set of fee ranges were proposed and finalized through subsequent notice and comment rulemaking.

If a certified IDR entity wishes to charge a fee outside either of these proposed ranges, it would continue to follow the existing process for requesting written approval from the Departments to do so outlined in 26 CFR 54.9816–8T(e)(2)(vii)(A) and (B), 29 CFR 2590.716–8(e)(2)(vii)(A) and (B), and 45 CFR 149.510(e)(2)(vii)(A) and (B), which the Departments do not propose to change in this rulemaking.

During calendar year 2023, certified IDR entities continue to incur high administrative costs due to the volume of disputes and the complexity in determining eligibility, as described in the December 2022 guidance.⁷⁶ These

proposed ranges reflect the significant administrative burden, ongoing eligibility determination challenges,77 and the Departments' desire to allow more flexibility for certified IDR entities to determine a fee that best reflects their operating costs. Given the wide variability of certified IDR entities' operations, structures, staffing patterns, and expenses, it is the Departments' position that the ranges should not overly restrict the certified IDR entities' ability to set their fees commensurate with their costs. Instead, broad ranges that allow certified IDR entities flexibility to set their fees in accordance with their own circumstances would allow them to remain financially viable and encourage their continued participation in the Federal IDR process. The Departments acknowledge that broadening the certified IDR entity fee ranges could have some impact on the cost to parties to engage in the Federal IDR process (discussed in section IV.D.2. of this preamble) which could implicate access to the Federal IDR process. However, access to the Federal IDR process is dependent on certified IDR entities' voluntary participation in that process. Voluntary participation by certified IDR entities is only possible if they are able to set their fees within ranges necessary to cover their operating expenses. If the Departments were to set fee ranges that could not support the certified IDR entities' financial viability and certified IDR entities declined to participate in the Federal IDR process altogether, the goal of access would be impaired.⁷⁸ Therefore, the Departments

77 Between April 15, 2022 and March 31, 2023, disputing parties initiated 334,828 disputes through the Federal IDR portal. During that time, noninitiating parties challenged the eligibility of 122,781 disputes. Even if the non-initiating party does not challenge eligibility of the dispute, the certified IDR entity must review the dispute and confirm that it is eligible before the dispute can proceed in the Federal IDR process. These reviews involve complex eligibility determinations that require certified IDR entities to expend considerable time and resources. Eligibility challenges are described in the following documents: Centers for Medicare & Medicaid Services (August 19, 2022) Federal Independent Dispute Resolution Process Status Update. https://www.cms.gov/files/ document/federal-idr-process-status-update-august-2022.pdf and Centers for Medicare & Medicaid Services (April 27, 2023). Federal Independent Dispute Resolution—Status Update. https:// www.cms.gov/files/document/federal-idrprocessstatus-update-april-2023.pdf.

⁷⁸ Indeed, during the early implementation of the Federal IDR process, some certified IDR entities did temporarily halt their operations before the Departments provided additional batching guidance have endeavored to judiciously balance access concerns with certified IDR entities' interests and seek comment on the balance proposed. In setting the certified IDR entity ranges for disputes initiated on or after the later of the effective date of these rules or on January 1, 2024, the Departments considered:

• The anticipated time and resources needed for certified IDR entities to make payment determinations meeting the requirements of the statute, rules, and guidance;

• The anticipated time and resources needed for data reporting;

• The anticipated time and resources needed for complying with audit requirements;

• The anticipated volume of Federal IDR initiations and payment determination quality assessments;

• The anticipated volume of Federal IDR initiations ineligible for the Federal IDR process; and

• The level of complexity in determining the eligibility of items and services for the Federal IDR process.

After reviewing these considerations, the Departments are of the opinion that a 20 percent increase in the upper limit of the certified IDR entity fee range for single determinations (from \$200 to \$840), would provide certified IDR entities an appropriate amount of flexibility in setting a fixed fee for single determinations, taking into account the anticipated increase in operational cost. The Departments relied on these same considerations to develop the proposed 25 percent increase in the upper limit of the certified IDR entity fee range for batched determinations, but also took into account the TMA IV opinion and order when proposing the range for batched determinations and the associated tiered fee based on the number of line items. In particular, the Departments have considered the impact of the TMA IV opinion and order on the anticipated complexity of batched determinations to inform the proposed increased base range of \$268 to \$1,173 and proposed tiered fee range of \$75 to \$250 based on the number of line items in a batched dispute. Section 9816(c)(3)(A) of the Code,⁷⁹ section 716(c)(3)(A) of the ERISA,⁸⁰ and section

⁷⁶ See Centers for Medicare & Medicaid Services (December 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/regulationsand-guidance/downloads/amended-cy2023-feeguidance-federal-independent-dispute-resolutionprocess-nsa.pdf.

in August 2022, see: 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 Independent Dispute Resolution Entities. https://www.hhs.gov/ guidance/sites/default/files/hhs-guidancedocuments/Technical-Assistance-IDR-Entities-August-2022.pdf.

⁷⁹26 U.S.C. 9816(c)(3)(A).

^{80 26} U.S.C. 9816(c)(3)(A).

2799A-1(c)(3)(A) of the PHS Act 81 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 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 are 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.

Since the TMA IV opinion and order vacated 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), which established standards for determining when multiple items or services relate to "the treatment of a similar condition" for the purpose of batched disputes,82 the certified IDR entities may no longer rely on the regulatory guidance provided to assist certified IDR entities when reviewing batched disputes. Certified IDR entities must now only rely upon statutory language when determining whether multiple items or services are related to the treatment of a similar condition and are therefore appropriate to batch.

As explained in the preamble to the October 2021 interim final rules, the Departments originally adopted the batching standards in those rules to avoid combinations of unrelated claims of providers, facilities, providers of air ambulance services and plans and issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies in the Federal IDR process. The Departments further intended to reduce redundant IDR proceedings and streamline the certified

IDR entities' decision-making processes. The Departments anticipate that the change in batching parameters introduced by the vacatur of 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) will make certified IDR entities' responsibilities and processes for eligibility and payment determinations under the Federal IDR process more complex and less certain. This unpredictability increases the systemic burden for certified IDR entities in the administration of their duties. In addition, the vacatur of 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) will also likely increase the number of items or services batched. Certified IDR entities have indicated to the Departments that making determinations on large batches of dissimilar items and services is particularly complex and burdensome. Based on certified IDR entities' experiences during the early stages of implementing the Federal IDR process, prior to the Departments having provided guidance regarding the batching parameters in August 2022,83 the Departments observed that confusion related to the batching standards for the same or similar items or services contributed to increased complexity in determining eligibility. which added time and cost for certified IDR entities and contributed to processing delays.⁸⁴ The Departments anticipate that the changes to batching standards will require certified IDR entities to update their operations, processes, and systems, demand greater staff resources, and increase the time needed to render eligibility determinations, including determinations of whether items or services may be submitted as a batch. Therefore, the proposal to increase the fee range for batched determinations and apply a tiered fee for batched disputes based on the number of line items would allow certified IDR entities to be appropriately compensated and ensure that Federal IDR process costs are clear to parties in advance of initiating the Federal IDR process.

In finalizing the fee amounts, the Departments intend to take into account any updated data or assumptions as

applied to the factors considered in this preamble to set the fee ranges.

The Departments do not propose to change the process for certified IDR entities to set their fees.85 Certified IDR entities will continue to be permitted to set their fees within the ranges proposed in these proposed rules, if finalized. Under these proposed rules, a certified IDR entity must receive the Departments' advance written approval to modify its fixed fees more than once annually. If requesting to set its fee more than once annually, the certified IDR entity must submit to the Departments for approval: (1) the fixed fee that the certified IDR entity is seeking to charge; (2) a description that reasonably explains the circumstances that require a change to its fee; and (3) a detailed description that reasonably explains how the change to its fee will be used to mitigate the effects of these circumstances. The Departments would use their discretion to determine if the explanations included in the request demonstrate that the change would ensure the certified IDR entity's financial viability and would not impose on parties an undue barrier to accessing the Federal IDR process. It is appropriate to permit certified IDR entities to change their fees more than once annually, with advance approval from the Departments, as some certified IDR entities may adopt more efficiencies throughout the year that would allow them to charge a lower fee, or if conditions of the Federal IDR process fluctuate throughout the year, some certified IDR entities may need to increase their fees to cover operating expenses.

The Departments seek comment on these proposals, including the proposed fee ranges themselves. The Departments solicit comment on whether in future years they should apply an inflationary adjustment consideration, such as the CPI–U, to the considerations used to develop the certified IDR entity fee ranges each year and set forth the adjusted fee amount in guidance, rather than notice and comment rulemaking. The Departments also seek comment on whether certified IDR entities should be allowed to set their fees based on a structure other than a fixed fee range for single disputes and tiered fees for batched disputes within the ranges proposed in these rules. Specifically, the Departments seek comment on whether certified IDR entities should have flexibility to set a per line item fee or a per unique service code fee. The Departments have considered that allowing a per line item fee or a per

⁸¹42 U.S.C. 300gg–111(c)(3)(A).

⁸² See Memorandum Opinion and Order, Tex. Med. Ass'n. v. U.S. Dep't of Health & Hum. Servs, No. 6:23-cv-00059-JDK (E.D. Tex. August 3, 2023). https://ecf.txed.uscourts.gov/doc1/175113317945.

⁸³ See 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 Independent Dispute Resolution Entities. https://www.hhs.gov/ guidance/sites/default/files/hhs-guidancedocuments/Technical-Assistance-IDR-Entities-August-2022.pdf. ⁸⁴ Id.

^{85 45} CFR 149.510(e)(2)(vii).

unique service code fee could better address the concern of unpredictable batching practices imposing high burdens on certified IDR entities. However, the Departments acknowledge that these pricing structures for batching could decrease the accessibility of the Federal IDR process for parties, particularly small providers. In addition, the Departments seek comment on the proposed number of line items in each additional batched tier. The Departments seek comment on whether the tiers should be set at 10 line items, 50 line items, or a different number than the proposed tiered increments of 25 line items. The Departments acknowledge the need to strike the correct balance between the line item increment and the amount of resources expended by the certified IDR entities to review those line items. The Departments have considered if increments of 25 line items or higher might impose too great a burden on the certified IDR entities so as not to be commensurate with the proposed tiered fee range available to them. However, the Departments also acknowledge that setting the line item increments lower than 25 line items would further impact the cost to parties of submitting a dispute, and that the proposed tiered fee range of \$75 to \$250 may not be appropriate at smaller line item increments. The Departments seek comment on whether the tiered fee for batched disputes should be set at a percentage of the certified IDR entity's batched determination fee, similar to how the tiering for the 2023 calendar year were implemented, rather than a dollar value range. The Departments also seek comment on whether to provide a fixed fee that all certified IDR entities must charge beyond the proposed 25 line items per additional 25 line items rather than permitting a range for certified IDR entities to choose from. More specifically, the Departments seek comment on whether certified IDR entities should be permitted to set their batched determination fee between \$268 and \$1,173 and then be permitted to charge only an additional fixed dollar amount (for example, \$125, \$150, \$200, etc.) per additional 25 line items. The Departments seek comment on the appropriateness of setting a fixed dollar tiered fee structure for batched disputes, since this could impact the certified IDR entities' operational flexibility, and would limit their ability to competitively price their fees. However, the Departments are considering whether establishing a fixed dollar tiered fee might mitigate the risk of one or a few certified IDR entities pricing

their tiered fee for batched disputes so low that they become inundated with large batches and thus provide greater consistency across certified IDR entities. The Departments are considering if this alternate approach would provide more consistency regarding the fees charged by different certified IDR entities and avoid potentially overburdening IDR entities that select a low tiered fee for batched disputes.

III. Severability

In the event that any portion of these proposed rules, if finalized as proposed, is declared invalid, the Departments intend that the various aspects of the administrative fee proposals and certified IDR entity fee proposals, as finalized, be severable. For example, if a court were to find unlawful all of the administrative fee proposals, the Departments would still intend for the certified IDR entity fee proposals to stand, and vice versa. As another example, if a court were to find unlawful the proposals to establish both the administrative fee and the certified IDR entity fee ranges more or less frequently than annually, the Departments would still intend for the administrative fee amount and certified IDR entity fee ranges to be (1) established through notice and comment rulemaking and (2) established in the amount and ranges as proposed in these proposed rules. Likewise, if a court were to find unlawful the proposed administrative fee amount or methodology or the certified IDR entity fee ranges or considerations used to determine the fee ranges as proposed in these proposed rules, the Departments would still intend for the administrative fee amount and certified IDR entity ranges to be (1) established through notice and comment rulemaking and (2) established more or less frequently than annually.

Thus, the Departments propose at new paragraph 26 CFR 54.9816-8(d)(3)(i), 29 CFR 2590.716-8(d)(3)(i), and 45 CFR 149.510(d)(3)(i) that any provision of paragraph (d) or paragraphs (e)(2)(vii) through (e)(2)(ix) held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of these paragraphs is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of these paragraphs and shall not affect the remainder thereof. The

Departments further propose at new paragraph 26 CFR 54.9816–8(d)(3)(ii), 29 CFR 2590.716–8(d)(3)(ii), and 45 CFR 149.510(d)(3)(ii) that the provisions in paragraphs (d) and (e)(2)(vii) through (ix) are intended to be severable from each other.

The Departments are of the view that each of the proposals for the administrative fee amount and the certified IDR entity fee ranges would still function sensibly even if one or more of the proposals in these proposed rules, as finalized, were found unlawful. For example, the proposals to establish the administrative fee amount and certified IDR entity fee ranges in notice and comment rulemaking would not depend on either the lawfulness of the methodology used to determine the administrative fee amount or the lawfulness of the considerations used in determining the certified IDR entity fee ranges, or whether both would be established on an annual basis or more or less frequently than annually. The proposal to use notice and comment rulemaking to establish the fees specifies only the method the Departments would use and does not determine how frequently the fees would be established or the methodology for the administrative fee amount or the considerations used to determine the certified IDR entity fee ranges.

The Departments seek comment on this approach.

IV. Economic Impact and Paperwork Burden

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

These proposed rules would establish the administrative fee amount and the certified IDR entity fee ranges in notice and comment rulemaking, as well as propose the methodology for setting both fees.

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); Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023); 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. 1102(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 Federal 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" (hereinafter, the Modernizing E.O.) 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) (\$200 million or more in any 1 year). Although based on the Departments' estimates, OMB's OIRA has determined these rules are not significant under section 3(f)(1), 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

The Departments propose to amend the certified IDR entity and administrative fee provisions of the rules for the Federal IDR process to set the administrative fee and the certified IDR entity fee ranges in notice and comment rulemaking, as well as propose the methodology for setting the administrative fee and the considerations for developing the certified IDR entity fee ranges. The Departments are of the view that these proposals would ensure that disputing and other parties are sufficiently notified and provided an opportunity to comment on the fees associated with the Federal IDR process.

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 1 and discussed in this section of the preamble. In accordance with OMB Circular A-4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers 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 nonquantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these proposed rules.

TABLE 1—ACCOUNTING TABLE

Accounting statement

About hing statement						
Benefits:						
 Non-Quantified: Increased interested party transparency as a result of the proposals to establish in notice and comment rulemaking, as well as the methodology for calculated developing the certified IDR entity fee ranges. 						
Costs:	Estimate (million)	Year dollar	Discount rate (percent)	Period covered		
Annualized Monetized (\$/Year)	\$0.09 \$0.08	2023 2023	7 3	2023–2027 2023–2027		
Quantified						

Quantified:

• Costs to interested parties of \$438,543 to review and interpret these rules in 2023.

Transfers:	Estimate (million)	Year dollar	Discount rate (percent)	Period Covered
Annualized	\$41.69	2023	7	2023–2027
Monetized (\$/year)	\$42.55	2023	3	2023–2027

Quantified:

• Transfers from disputing parties to the Federal government of approximately \$45 million annually beginning in 2024 as a result of the proposal to set the administrative fee amount at \$150 per party per dispute initiated on or after the later of the effective date of these rules or January 1, 2024.

• Transfers from disputing parties to certified IDR entities of approximately \$9 million annually beginning in 2024 as a result of the proposal to set the certified IDR entity fee ranges at \$200-\$840 for single determinations, \$268-\$1,173 for batched determinations, and an additional \$75-\$250 for each 25 line items in excess of the first 25 line items.

1. Benefits

The primary benefit of this rulemaking would be to allow the Federal IDR process to function through establishing the administrative fee amount and certified IDR entity fee ranges in rulemaking and establishing the amounts of these fees for disputes initiated on or after the later of the effective date of these rules or January 1, 2024. In response to the opinion and order in TMA IV, these proposed rules are necessary in order to set the administrative fee amount. The primary non-quantifiable benefit of these proposed rules would be the continuation of a functioning Federal IDR process, which helps to protect consumers from surprise medical bills and helps providers to receive compensation. Additional benefits specific to each Federal IDR process fee type appear in the following sections.

a. Administrative Fee Amount and Methodology

The Departments are proposing to establish the amount of the administrative fee in notice and comment rulemaking for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, as well as the methodology for determining the administrative fee. Utilizing notice and comment rulemaking would increase transparency of the administrative fee setting process and allow interested parties to provide feedback to the Departments prior to the Departments setting the administrative fee amount. The Departments seek comment on these assumptions.

b. Certified IDR Entity Fee Ranges

The Departments are proposing to establish the certified IDR entity fee ranges for single and batched determinations, which include a tiered fee range for batched determinations for disputes that exceed 25 dispute line items, in notice and comment rulemaking for disputes initiated on or after the later of the effective date of these rules or January 1, 2024. Utilizing notice and comment rulemaking to set the appropriate ranges for certified IDR entity fees would increase transparency for parties interested in the certified IDR entity fee ranges and allow interested parties to identify in advance the impacts of changing the certified IDR entity fee ranges. The Departments seek comment on these assumptions.

2. Costs

a. Administrative Fee Amount and Methodology

The Departments are proposing to establish the amount of the administrative fee in notice and comment rulemaking for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, as well as proposing the methodology for setting the administrative fee amount, in response to the opinion and order in TMA IV and to ensure that disputing and other parties are sufficiently notified and provided an opportunity to comment on the certified IDR entity fee ranges. The Departments are also proposing the administrative fee amount for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, at \$150 per party per dispute.

The current administrative fee is \$50 per party per dispute.⁸⁶ Based on Federal IDR process data from February through July 2023, as discussed in section II.A. of this preamble, the Departments estimate that approximately 225,000 disputes are closed per year. Therefore, if the current administrative fee were to remain applicable, disputing parties would pay approximately \$22.5 million in administrative fees annually (225,000 disputes $\times 2$ parties per dispute \times \$50 per party).⁸⁷ As the Departments are now proposing an administrative fee of \$150 for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, the Departments estimate that disputing parties would pay approximately \$67.5 million in administrative fees annually beginning in 2024 (225,000 disputes $\times 2$ parties per dispute × \$150 per party), assuming the number of disputes remains stable year over year and the

administrative fee amount is not subsequently changed through notice and comment rulemaking. Therefore, the costs associated with this proposal would be approximately \$45 million (\$67.5 million if this proposal is finalized - \$22.5 million if the status quo were to continue).

The Departments seek comment on these estimates and assumptions.

b. Certified IDR Entity Fee Ranges

The Departments are proposing to set the certified IDR entity fee ranges for single and batched determinations, with a tiered fee range for batched determination for disputes that exceed 25 line items, in notice and comment rulemaking for disputes initiated on or after January 1, 2024 in response to the opinion and order in TMA IV and to ensure that disputing and other parties are sufficiently notified and provided an opportunity to comment on the certified IDR entity fee ranges. The proposed certified IDR entity fee range for single determinations for disputes initiated on or after the later of effective date of these rules or January 1, 2024, would be \$200 to \$840. The proposed certified IDR entity fee range for batched determinations for disputes initiated on or after the later of the effective date of these rules or January 1, 2024 would be \$268 to \$1,173. Further, the proposed tiered fee range for batched determination for disputes initiated on or after the later of the effective date of these rules or January 1, 2024 would be \$75 to \$250. While the certified IDR entities are responsible for setting their fees for single and batched determinations, the Departments acknowledge that the proposed changes to the fee ranges may impact the cost to participate in the Federal IDR process for the parties. The Departments anticipate that the vacatur of batching standards by the Texas District Court's opinion and order in TMA IV could result in initiating parties submitting single and batched disputes in proportions similar to those prior to the issuance of the August 2022 guidance, which interpreted the standards for batching qualified IDR items or services. Based on internal data prior to the establishment of the now vacated batching criteria that was released in August 2022, approximately 70 percent of disputes were single disputes and approximately 30 percent were batched disputes.⁸⁸ The Departments anticipate that, as a result of TMA IV, initiating

⁸⁶ As a result of the opinion and order in TMA *IV,* which vacated the portion of the December 2022 guidance that increased the administrative fee to \$350 per party per dispute for disputes initiated during calendar year 2023, the administrative fee amount reverted to the administrative fee amount established in the October 2022 guidance. See Centers for Medicare & Medicaid Services (August 11, 2023). Federal Independent Dispute Resolution (IDR) Process Administrative Fee FAQs. https:// www.cms.gov/cciio/resources/regulations-andguidance/downloads/no-surprises-act-independentdispute-resolution-administrative-fee-frequentlyasked-questions.pdf. Also see Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/ resources/regulations-and-guidance/downloads/ cy2023-fee-guidance-federal-independent-disputeresolution-process-nsa.pdf.

⁸⁷ The numbers in this analysis assume that all parties pay the requisite administrative fee in all closed disputes.

⁸⁸ The Departments estimate that currently approximately 80 percent of disputes are single disputes and 20 percent of disputes are batched disputes.

parties will likely resume the batching practices they engaged in prior to issuance of the August 2022 guidance, such as initiating a higher proportion of batched disputes and including more items or services within those batched disputes.

As discussed in section II.A. of this preamble, the Departments estimate that approximately 225,000 disputes are closed annually. Further, the Departments assume that certified IDR entities collect a certified IDR entity fee on approximately 135,000 of those 225,000 closed disputes annually.89 Therefore, for the purposes of this analysis, the Departments estimate that certified IDR entities would collect certified IDR entity fees on approximately 94,500 single disputes and 40,500 batched disputes closed annually (135,000 × 0.70 and 135,000 × 0.30, respectively). The Departments acknowledge that each party must pay a certified IDR entity fee to the certified IDR entity no later than the time that party submits its offer. However, because the non-prevailing party is ultimately responsible for the full certified IDR entity fee, which is retained by the certified IDR entity for the IDR services it performed, it is the Departments' position that providing a per-dispute calculation reasonably captures the overall cost of the dispute without implicating false precision on the amount of certified IDR fee costs that initiating and non-initiating parties ultimately may incur.

To develop a reasonable estimate for the certified IDR entity fee amount for both single and batched disputes, the Departments assume that the certified IDR entities would set single determination fixed fees approximate to the median value of the proposed fee range and would set batched determination fixed fees approximate to the 75th quartile of the proposed fee range.⁹⁰ Therefore, for the purposes of

⁹⁰ Currently, the median of the calendar year 2023 certified IDR entity fees is \$549 for single determinations and \$770 for batched determinations, which are approximately the upper quartiles of the 2023 certified IDR entity fee ranges for single determinations (\$200-\$700) and batched determinations (\$268–\$938). The Departments anticipate that, due to the uncertainty around batching practices as a result of the *TMA IV* opinion and order, the certified IDR entities will likely choose to increase their batched determination fee.

this analysis, the Departments estimate that the average single determination fixed fee (range \$200–\$840) would be approximately \$520, and that the average batched determination fixed fee (range \$268-\$1,173) would be approximately \$947. At an estimated cost of \$520 per single determination for approximately 94,500 single determinations annually, the Departments estimate that single determinations would cost disputing parties approximately \$49,140,000 annually (\$520 × 94,500). At an estimated cost of \$947 per batched determination for approximately 40,500 batched determinations annually, the Departments estimate that batched determinations would cost disputing parties approximately \$38,353,500 annually (\$947 × 40,500).

Further, the Departments estimate that using the proposed tiered fee range for batched determinations, certified IDR entities would set and apply a fixed fee approximate to the median of the proposed range (\$75-\$250) for batched determinations based on the number of dispute line items. The Departments estimate that certified IDR entities would set their tiered fee at \$163 on average. The Departments acknowledge the uncertainty surrounding the number of line items that may be submitted in batched disputes due to the TMA IV opinion. However, to produce an estimate, and for the purposes of this analysis, the Departments estimate that a subset of approximately 4,455 batched determinations would potentially be subject to at least 2 applications of the tiered fee ($$163 \times 2 = 326).⁹¹ As such, the Departments estimate that this subset of approximately 4,455 batched determinations exceeding 25 line items would cost disputing parties approximately \$1,452,330 annually $($326 \times 4,455)$. In total, assuming the number of disputes remains stable year over year, the Departments estimate the parties would pay approximately \$89 million in certified IDR entity fees annually if these proposals are finalized as proposed (\$49,140,000 for single determinations + \$38,353,500 for batched determinations + \$1,452,330 for the subset of batched determinations subject to the tiered fee).

The calendar year 2023 certified IDR entity fee ranges for single determinations and batched

determinations are \$200-\$700 and \$268-\$938, respectively. Certified IDR entities currently charge a median fixed fee of \$549 for single determinations and \$770 for batched determinations in 2023. As such, for approximately 108,000 single determinations and 24,840 batched determinations annually,92 if current certified IDR entity fixed fees remained applicable, the Departments estimate that disputing parties would pay approximately \$59,292,000 for single determinations (\$549 × 108,000) and \$19,126,800 for batched determinations ($$770 \times 24,840$). Current guidance permits certified IDR entities to charge a batching percentage on batched determinations based on the number of dispute line items.⁹³ For the purposes of this analysis, the Departments assume that a subset of approximately 8 percent of batched determinations potentially subject to the batched percentages would at least receive a 120 percent increase from the median batched determination fixed fee $($770 \times 1.20)$. As such, the Departments estimate that disputing parties would pay approximately \$2 million for this subset of batched determinations potentially subject to a batching percentage $(2,160 \times \$924)$, resulting in a total cost of approximately \$80 million under the current calendar year 2023 certified IDR entity fee structure (\$59,292,000 for single determinations + \$19,126,800 for batched determinations + \$2 million for the subset of batched determinations subject to the tiered fee). Therefore, taking into account the current costs to the parties associated

 $\bullet\,$ 2–20 line items: 100 percent of the approved batched determination fee;

 $\bullet\,$ 21–50 line items: 110 percent of the approved batched determination fee;

 $\bullet~51{-}80$ line items: 120 percent of the approved batched determination fee; and

• 81 line items or more: 130 percent of the approved batched determination fee.

⁸⁹ The Departments use the number of closed disputes for this analysis, as the certified IDR entity fee is due from the parties at the time the parties submit their offers, in accordance with 26 CFR 54.9816–87(d)(1)(ii), 29 CFR 2590.716–8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii). Therefore, using the number of initiated disputes for this analysis would be inappropriate as not all initiated disputes proceed to the offer submission stage if, for example, they are determined to be ineligible for the Federal IDR process.

Therefore, using the 75th percentile of the proposed fee range to calculate the cost of batched determinations provides a reasonable approximation of the expected increase.

⁹¹ The Departments estimate that approximately 11 percent of batched disputes submitted prior to the establishment of the batching criteria released in August 2022 exceeded 25 dispute line items.

 $^{^{92}}$ The Departments estimate that 80 percent of disputes are single disputes and 20 percent are batched disputes (135,000 \times 0.80 and 135,000 \times 0.20, respectively). For the purpose of this analysis, the Departments estimate that a subset of approximately 8 percent, or 2,160 batched determinations would be subject to a batching percentage (27,000 \times 0.08).

⁹³ Without the need to seek further approval, to account for the differential in the workload of batched determinations, a certified IDR entity may charge the following percentage of its approved certified IDR entity batched determination fee ('batching percentage'') for batched determinations, which are based on the number of line items initially submitted in the batch:

See Centers for Medicare & Medicaid Services (October 31, 2022). Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act. https://www.cms.gov/cciio/resources/regulationsand-guidance/downloads/cy2023-fee-guidancefederal-independent-dispute-resolution-processnsa.pdf.

with the current certified IDR entity fee structure, the total costs to disputing parties associated with this proposal is approximately \$9 million (\$89 million if finalized as proposed – \$80 million if the status quo fee ranges were to continue).

The Departments seek comments on these estimates and assumptions.

3. Uncertainties

It is unclear whether the Federal IDR process would experience the same operating conditions, such as the number of disputes initiated, future policy changes finalized after future notice and comment rulemaking, and increased or decreased costs by the Departments to carry out the Federal IDR process. Due to the need to take point-in-time estimates of volume and expenditures for the purposes of developing the analyses in these rules, there is inherent uncertainty in the estimates in these analyses as the data are constantly changing. It is difficult to project the impact on the administrative fee amount charged to the parties if the Federal IDR process landscape changes. Although the Departments have analyzed the Federal IDR process data available to inform their projections, it is uncertain whether the trends in this data will remain applicable. The Federal IDR process is still in an early phase of implementation and has not yet achieved the stabilization that would likely occur with long-term uptake of the process. Initially, the Departments estimated that approximately 22,000 disputes would be submitted to the process each year; 94 uptake of the process, however, rapidly outpaced that estimate, as dispute initiations have grown exponentially since implementation, and analysis has revealed an estimated number closer to 340,000 annual initiated disputes is currently more accurate. At the same time, the Departments do not know what impact changes to the batching policy as a result of the Texas District Court's opinion and order in TMA IV will have on the number of disputes being initiated and the time that it will take certified IDR entities to close those disputes.

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 third party administrators (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 median 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 \$130.52 per hour.⁹⁵ The Departments estimate, based on an estimated rule length of approximately 22,000 words and an average reading speed of 200 to 250 words per minute, that it would take each reviewing entity approximately 1.6 hours to review these proposed rules, with an associated cost of approximately \$208.83 (1.6 hours × \$130.52 per hour). Therefore, the Departments estimate that the total burden to review these proposed rules will be approximately 3,360 hours $(2,100 \text{ reviewers} \times 1.6 \text{ hours per})$ reviewer), with an associated cost of approximately \$438,543 (2,100 reviewers \times \$208.83 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. Administrative Fee Amount and Methodology (26 CFR 54.9816–8(d)(2), 29 CFR 2590.716–8(d)(2), and 45 CFR 149.510(d)(2))

In *TMA IV*, the Texas District Court indicated that notice and comment rulemaking is necessary to set the administrative fee amount. In light of

the Texas District Court opinion and order, as well as the Departments' assessment regarding the practicability of determining the administrative fee amount through notice and comment rulemaking, the Departments are of the view that alternative approaches would lead to unwarranted uncertainty. In addition, the Departments are of the view that providing a description of the methodology used to calculate the fee amount and proposing the administrative fee amount in these proposed rules would increase transparency for the parties and provide interested parties the opportunity to be included in the fee setting process. The Departments considered that guidance has historically set the administrative fee amount based on concerns that the requirement to collect fees sufficient to fund the Federal IDR process, and the lead time required to set the fee amount in notice and comment rulemaking, could constrain the Departments' responsiveness to program needs and artificially inflate the administrative fee amount due to the need to ensure adequate funding of the process. However, in light of TMA IV, the Departments are of the view that the increased transparency and opportunity for interested parties to provide feedback on the administrative fee methodology and amount would outweigh the potential concern that the administrative fee might be artificially inflated by the need to make conservative estimates to set the administrative fee amount further in advance through notice and comment rulemaking.

2. Certified IDR Entity Fee Ranges (26 CFR 54.9816–8(e)(2), 29 CFR 2590.716– 8(e)(2), and 45 CFR 149.510(e)(2))

The Departments considered maintaining the current policy that the allowable ranges for certified IDR entity fees would be set in guidance yearly instead of through notice and comment rulemaking. The Departments considered whether continuing to set the certified IDR entity fee ranges in guidance would preserve necessary flexibility for the certified IDR entities to choose their fees within the allowable ranges and submit those fees for approval to the Departments, and would allow the Departments time to review and approve each certified IDR entity's fees and publish them in advance of the year to which the fees apply. The Departments balanced several considerations, including that certified IDR entities are ultimately able to choose their own fee within the ranges established in guidance by the Departments, and that setting the fee

⁹⁴ 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.

⁹⁵U.S. Bureau of Labor Statistics (May 1, 2022). May 2022 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/ oes nat.htm.

ranges through guidance was intended to create a competitive market among the certified IDR entities to keep fees affordable, while ensuring that those entities are able to cover their costs. Setting the allowable ranges for certified IDR entity fees through notice and comment rulemaking is appropriate because it would increase transparency and provide an opportunity for the Departments to consider comments from interested parties.

F. Paperwork Reduction Act

These proposed rules are not subject to the requirements of the Paperwork Reduction Act of 1995,96 because they do not contain a collection of information as defined in 44 U.S.C. 3502(3). Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

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 and 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 would 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 their 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 jurisdictions.

The provisions in these proposed rules would affect plans (or their TPAs),⁹⁷ health insurance issuers offering group or individual health insurance coverage, and providers, facilities, and providers of air ambulance services.

For purposes of analysis under the RFA,⁹⁸ the Departments consider an employee benefit plan with fewer than

100 participants to be a small entity.99 The basis of this definition is found in section 104(a)(2) of ERISA,¹⁰⁰ which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3),101 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),¹⁰² the Department of Labor 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 certain requirements.¹⁰³ 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 104 in accordance with the Small Business Act.¹⁰⁵

In 2021, there were 1,500 issuers in the U.S. health insurance market ¹⁰⁶ and 205 TPAs.¹⁰⁷ 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,¹⁰⁸ 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

103 29 CFR 2520.104-20, 2520.104-21, 2520.104-41, 2520.104-46, and 2520.104b-10.

from Medical Loss Ratio (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.¹⁰⁹ However, it should be noted that 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. For the purposes of this analysis, the Departments assume 8.6 percent, or 128 issuers, and 18 TPAs are considered small entities.

These proposed rules would also affect health care providers due to the proposed requirements related to the certified IDR entity and administrative fees. 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.¹¹⁰ These proposed rules are also expected to affect nonphysician providers who bill on an outof-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 subsector. In 2020, the total revenue of providers of air ambulance services was estimated to be \$4.2 billion, with 1.114 air ambulance bases.¹¹¹ This results in an industry average of \$3.8 million per air ambulance base. Accordingly, the Departments are of the view that most providers of air ambulance services are likely to be small entities.

The proposed policies that would result in an increased burden to small entities are described below.

The Departments propose to establish the administrative fee amount in notice and comment rulemaking, and the

¹¹⁰ 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. United States Census Bureau (May 2021). 2017 SUSB Annual Data Tables by Establishment Industry. https://www.census.gov/data/tables/2017/ econ/susb/2017-susb-annual.html.

¹¹¹ 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.

^{96 44} U.S.C. 3501 et seq.

⁹⁷ The Departments expect that most self-insured group health plans will work with a TPA to meet the requirements.

^{98 5} U.S.C. 601, et seq.

⁹⁹ The Departments 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.

^{100 29} U.S.C. 1024(a)(2).

^{101 29} U.S.C. 1024(a)(3).

^{102 29} U.S.C. 1024(a)(3).

^{104 13} CFR 121.201 (2011).

¹⁰⁵ 15 U.S.C. 631 et seq. (2011). ¹⁰⁶Centers for Medicare & Medicaid Services (2022). Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/ Data-Resources/mlr.

¹⁰⁷ Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.

¹⁰⁸ United States Small Business Administration (March 17, 2023). Table of Size Standards. https:// www.sba.gov/document/support-table-sizestandards.

¹⁰⁹Centers for Medicare & Medicaid Services (2022). Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/ Data-Resources/mlr.

Departments propose that the administrative fee amount for disputes initiated on or after of the effective date of these rules or on January 1, 2024, would be \$150 per party. The total annual burden associated with this proposal is \$45 million, split evenly between plans and issuers and providers, facilities, and providers of air ambulance services (\$22.5 million each). For more details, please refer to the Regulatory Impact Analysis in these proposed rules.

The Departments propose to establish the certified IDR entity fee ranges in notice and comment rulemaking, and the Departments propose that the ranges would be \$200-\$840 for single determinations and \$268-\$1,173 for batched determinations, with a \$75-\$250 tiered fee range for disputes that contain more than 25 line items. The total annual burden associated with this proposal is approximately \$9 million, 30 percent (\$2.7 million) for providers, facilities, and providers of air ambulance services ¹¹² and 70 percent (\$6.3 million) for plans and issuers.¹¹³ For more details, please refer to the Regulatory Impact Analysis in these proposed rules.

To estimate the proportion of the total costs that would fall on small entities, the Departments assume that the proportion of costs is proportional to the industry receipts. Applying data from the Census Bureau of receipts by size for each industry, the Departments estimate that small issuers would incur 0.2 percent of the total costs incurred by all issuers and small providers would incur

¹¹³ Data from the first full year of Federal IDR process operations show that initiating parties prevail in approximately 70 percent of disputes. See Centers for Medicare & Medicaid Services (April 27, 2023). Federal Independent Dispute Resolution Process—Status Update. Therefore, as the prevailing party's certified IDR entity fee is refunded per 26 CFR 54.9816-8T(d)(1)(ii), 29 CFR 2590.716-8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii), initiating parties only pay the certified IDR entity fee for 30 percent of disputes, while non-initiating parties pay for the other 70 percent.https:// www.cms.gov/files/document/federal-idrprocessstatus-update-april-2023.pdf. Therefore, as the prevailing party's certified IDR entity fee is refunded per 26 CFR 54.9816-8T(d)(1)(ii), 29 CFR 2590.716-8(d)(1)(ii), and 45 CFR 149.510(d)(1)(ii), initiating parties only pay the certified IDR entity fee for 30 percent of disputes, while non-initiating parties pay for the other 70 percent.

42.4 percent of the total cost by all providers.¹¹⁴

For the proposal to set the administrative fee amount at \$150 per party for disputes initiated on or after the later of the effective date of these rules or January 1, 2024, the Departments estimate that the total annual cost for small providers ¹¹⁵ would be \$9,540,000.¹¹⁶ This results in a per-entity cost for small providers of \$144.09.¹¹⁷ The Departments estimate that the total annual cost for small issuers and TPAs would be \$45,000.¹¹⁸ This results in a per-entity cost for small issuers and TPAs of \$308.22.¹¹⁹

For the proposal to set the certified IDR entity fee ranges at \$200–\$840 for single determinations and \$268–\$1,173 for batched determinations, with a \$75–\$250 tiered fee range for disputes that contain more than 25 line items, the Departments estimate that the total annual cost for small providers 120 would be \$1,144,800. 121 This results in a per-entity cost for small providers of \$17.29. 122 The Departments estimate that the total annual cost for small providers of \$17.29. 122 The Departments estimate that the total annual cost for small issuers and TPAs would be \$12,600. 123

¹¹⁵ 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. U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of Treasury (n.d.) *Initial Report on the Federal Independent Dispute Resolution (IDR) Process, April 15–September 30, 2022. https:// www.cms.gov/files/document/initial-report-idrapril-15-september-30-2022.pdf.*

¹¹⁶ The total annual cost for small providers is estimated as: $22.5 \text{ million} \times 42.4 \text{ percent} =$ 9,540,000.

 117 The annual per-entity cost is estimated as: \$9,540,000/66,207 small providers = \$144.09.

 118 The total annual cost for small issuers and TPAs is estimated as: \$22.5 million $\times 0.2$ percent = \$45,000.

 119 The annual per-entity cost for small issuers and TPAs is estimated as: \$45,000/(128 issuers + 18 TPAs) = \$308.22.

¹²⁰ 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. U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of Treasury (n.d.) *Initial Report on the Federal Independent Dispute Resolution (IDR) Process, April 15–September 30, 2022. https:// www.cms.gov/files/document/initial-report-idrapril-15-september-30-2022.pdf.*

¹²¹The total annual cost for small providers is estimated as: \$2,700,000 × 42.4 percent = \$1,144,800.

 122 The annual per-entity cost is estimated as: \$1,144,800/66,207 small providers = \$17.29.

 123 The total annual cost for small issuers and TPAs is estimated as: $6,300,000\times0.2$ percent = \$12,600.

This results in a per-entity cost for small issuers and TPAs of \$86.30.¹²⁴

Thus, the total estimated annual cost for small issuers and TPAs is \$57,600, and the total estimated annual cost for small providers is \$10,684,800. The perentity annual cost for small issuers and TPAs is \$394.52, and the per-entity annual cost for small providers is \$161.38.

The Departments seek comment on this analysis and seek information on the number of small plans (or TPAs), issuers, or providers that may be affected by the provisions in these proposed rules.

The number of impacted small health plans is not significant compared to the total universe of 1.9 million small health plans. Assuming that 340,000 disputes are submitted to the Federal IDR process each year, 18 percent of small health plans would be impacted.¹²⁵ The number of impacted plans and issuers may be even smaller if some plans and issuers have multiple disputes that are batched in the Federal IDR process. 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.126

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. The Departments are of the view that this threshold will not be reached by the requirements in these proposed rules, given that the annual per-entity cost of \$413.70 per small issuer/TPA represents 0.02 percent of the average annual receipts for a small issuer/TPA and the annual per-entity cost of \$165.23 per small provider represents 0.01 percent of the average annual receipts for a small provider.127 Therefore, the Secretary has certified that these proposed rules will not have

¹²⁶ 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/uscbrookings-schaeffer-on-health-policy/2021/03/16/ recommendations-for-implementing-the-nosurprises-act/.

¹²⁷ United States Census Bureau (March 2020). 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size. https:// www.census.gov/data/tables/2020/econ/susb/2020susb-annual.html.

¹¹² 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. U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of Treasury (n.d.) *Initial Report on the Federal Independent Dispute Resolution (IDR) Process, April 15–September 30, 2022. https:// www.cms.gov/files/document/initial-report-idrapril-15-september-30-2022.pdf.*

¹¹⁴ United States Census Bureau (March 2020). 2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size. https:// www.census.gov/data/tables/2020/econ/susb/2020susb-annual.html.

 $^{^{124}}$ The annual per-entity cost for small issuers and TPAs is estimated as: 12,600/(128 issuers + 18 TPAs) = 886.30.

 ¹²⁵ 340,000 claims/1,927,786 ERISA health plans
 = 18 percent (*Source:* 2020 Medical Expenditure Panel Survey-Insurance Component).

a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Paperwork Reduction 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.¹²⁸ For purposes of section 1102(b) of the Paperwork Reduction 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. While these proposed rules are not subject to section 1102 of the Paperwork Reduction Act, the Departments have determined that these proposed rules will not affect small rural hospitals. Therefore, the Secretary has certified that these proposed rules will not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Special Analyses—Department of the Treasurv

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,129 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) 130 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, and providers, facilities, and providers of air ambulance services would incur costs to comply with the 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 federalism implications or limit the policy-making discretion of the States in compliance with the requirement of Executive Order 13132.

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-ofnetwork emergency services and to outof-network providers for patient visits to in-network facilities for non-emergency services. Where a State has a specified State law, the State law, rather than the Federal IDR process, would apply.

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.

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

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Child support, Employee benefit plans, Health care, Health insurance, Infants and children, Maternal and child health, Penalties, Pensions, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 149

Administrative practice and procedure, Health care, Health insurance, Insurance companies, Penalties, Reporting, and recordkeeping requirements.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

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Accordingly, the Department of the Treasury and the IRS proposes to amend 26 CFR part 54 as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 is amended by adding an entry for § 54.9816-8 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * * * * * * *

Section 54.9816-8 also issued under 26 U.S.C. 9816.

■ 2. Section 54.9816–8 is amended by revising paragraphs (a) through (e) and the headings for paragraphs (f) and (g) to read as follows:

§ 54.9816–8 Independent dispute resolution process.

(a) Scope and definitions. For further guidance, see § 54.9816-8T(a).

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^{128 5} U.S.C. 603.

^{129 26} U.S.C. 7805(f).

^{130 2} U.S.C. 1511.

(b) Determination of payment amount through open negotiation and initiation of the Federal IDR process. For further guidance, see § 54.9816-8T(b).

(c) Federal IDR process following *initiation.* For further guidance, see §54.9816-8T(c).

(d) Costs of IDR process. (1) Certified IDR entity fee. For further guidance, see §54.9816-8T(d)(1).

(2) Administrative fee. (i) For further guidance, see § 54.9816–8T(d)(2)(i).

(ii) The administrative fee amount will be established through notice and comment rulemaking in a manner such that the total administrative fees paid for a year 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. 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 and will remain in effect until changed by subsequent rulemaking.

(3) Severability. (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) through (ix) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of these paragraphs is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of these paragraphs and shall not affect the remainder thereof.

(ii) The provisions in paragraphs (d) and (e)(2)(vii) through (ix) of this section are intended to be severable from each other.

(e) Certification of IDR entity-(1) In general. For further guidance see §54.9816-8T(e)(1).

(2) *Requirements*. (i) through (vi). For further guidance, see § 54.8616-8T(e)(2)(i) through (vi).

(vii) Provide, on an annual basis, a fixed fee for single determinations and separate fixed fees for batched determinations, as well as additional fixed tiered fees for batched disputes, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until

changed by subsequent rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits. The certified IDR entity or IDR entity seeking certification may also seek advance written approval from the Secretary to update its fees more frequently than once annually. If a certified IDR entity or IDR entity seeking certification submits to the Secretary a request to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking, the Secretary will use their discretion to determine if the information submitted by a certified IDR entity or IDR entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the certified IDR entity's financial viability and would not impose on parties an undue barrier to accessing the Federal IDR process. In order for the certified IDR entity to receive the Secretary's written approval to charge a fee beyond the upper or lower limits for fees as set forth in rulemaking, or to modify the fixed fees more than once annually, it must satisfy the conditions in both paragraphs (e)(2)(vii)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(1) If requesting to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking:

(*i*) The alternative fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*ii*) A description of the circumstances that require the alternative fee; and

(*iii*) A description that reasonably explains how the alternative fixed fee will be used to mitigate the effects of those circumstances; or

(2) If requesting to modify the fixed fee more than once annually:

(*i*) The fixed fee the certified IDR entity is seeking to charge;

(*ii*) A description of the circumstances that require a change to its fixed fee; and

(*iii*) Å detailed description that reasonably explains how the change to its fixed fee will be used to mitigate the effects of those circumstances.

(B) Receive from the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) 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, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of \$200 to \$840, unless a fee not within that range is approved by the Secretary pursuant to paragraphs (e)(2)(vii)(A) and (B) of this section. The range for the certified IDR entity fee for single determinations will remain in effect until changed by subsequent rulemaking.

(ix) 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, certified IDR entities are permitted to charge a fixed certified IDR entity fee for batched determinations within the range of \$268 to \$1,173, unless a fee not within that range is approved by the Secretary pursuant to paragraphs (e)(2)(vii)(A) and (B) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of \$75 to \$250 for every additional 25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for batched determinations will remain in effect until changed by subsequent rulemaking.

(x) through (xiii). For further guidance, see § 54.9816-8T(e)(2)(x) through (xiii).

(f) Reporting of information relating to the Federal IDR process. * *

(g) Extension of time periods for extenuating circumstances. * *

- 3. Section 54.9816–8T is amended by:
- a. Revising paragraph (d)(2)(ii);
- b. Adding paragraph (d)(3);
- c. Revising paragraph (e)(2)(vii)

* * *

- d. Redesignating paragraphs
- (e)(2)(viii) through (xi) as paragraphs (e)(2)(x) through (xiii);
- e. Adding new paragraphs (e)(2)(viii) and (ix).

The revisions and additions read as follows:

§ 54.9816–8T Independent dispute resolution process (temporary). *

- * * (d) * * *
- . (2) * * *

(ii) For further guidance, see § 54.9816–8(d)(2)(ii).

(3) Severability. For further guidance, see § 54.9816-8(d)(3).

(e) * * * (2) * * * (vii) and (ix). For further guidance, see § 54.9816–8(e)(2)(vii) and (ix).

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DEPARTMENT OF LABOR

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Employee Benefits Security Administration

29 CFR Chapter XXV

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

■ 4. 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).

- 5. Section 2590.716–8 is amended by:
- a. Revising paragraph (d)(2)(ii);
- b. Adding paragraph (d)(3);
- c. Revising paragraph (e)(2)(vii);
- d. Redesignating paragraphs

(e)(2)(viii) through (xi) as paragraphs (e)(2)(x) through (xiii); and

 e. Adding new paragraphs (e)(2)(viii) and (ix).

The revisions and additions read as follows:

§2590.716–8 Independent dispute resolution process.

* * *

- (d) * * *
- (2) * * *

(ii) The administrative fee amount will be established through notice and comment rulemaking in a manner such that the total administrative fees paid for a year 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. 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.

(3) Severability. (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) through (ix) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of these paragraphs is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of these paragraphs and shall not affect the remainder thereof.

(ii) The provisions in paragraphs (d)(2) and (e)(2)(vii), (viii), and (ix) of this section are intended to be severable from each other.

(e) * * * (2) * * *

(vii) Provide, on an annual basis, a fixed fee for single determinations and separate fixed fees for batched determinations, as well as additional fixed tiered fees for batched disputes, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until changed by subsequent rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits. The certified IDR entity or IDR entity seeking certification may also seek advance written approval from the Secretary to update its fees more frequently than once annually. If a certified IDR entity or IDR entity seeking certification submits to the Secretary a request to charge a fixed fee beyond the upper or lower limited for fees set forth in rulemaking, the Secretary will use their discretion to determine if the information submitted by the certified IDR entity or entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the certified IDR entity's financial viability and would not impose on parties an undue barrier accessing the Federal IDR process. In order for the certified IDR entity to receive the Secretary's written approval to charge a fee beyond the upper or lower limits for fees as set forth in rulemaking, or to modify the fixed fees more than once annually, it must satisfy the conditions in both paragraphs

(e)(2)(vii)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(1) If requesting to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking:

(*i*) The alternative fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(ii) A description of the circumstances that require the alternative fee; and

(*iii*) Å description that reasonably explains how the alternative fixed fee will be used to mitigate the effects of those circumstances; or

(2) If requesting to modify the fixed fee more than once annually:

(*i*) The fixed fee the certified IDR entity is seeking to charge;

(*ii*) A description of the circumstances that require a change to its fixed fee; and

(*iii*) A detailed description that reasonably explains how the change to its fixed fee will be used to mitigate the effects of those circumstances.

(B) Receive from the Secretary, the Secretary of the Treasury, and the Secretary of Health and Human Services, written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) 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, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of \$200 to \$840, unless a fee not within that range is approved by the Secretary pursuant to paragraphs (e)(2)(vii)(A) and (B) of this section. The range for the certified IDR entity fee for single determinations will remain in effect until changed by subsequent rulemaking.

(ix) 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, certified IDR entities are permitted to charge a fixed certified IDR entity fee for batched determinations within the range of \$268 to \$1,173, unless a fee not within that range is approved by the Secretary pursuant to paragraphs (e)(2)(vii)(A) and (B) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of \$75 to \$250 for every additional

25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for batched determinations will remain in effect until changed by subsequent rulemaking.

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

■ 6. 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.

- 7. Section 149.510 is amended by:
- a. Revising paragraph (d)(2)(ii);
- b. Adding paragraph (d)(3);

■ c. Revising paragraph (e)(2)(vii);

■ d. Redesignating paragraphs

(e)(2)(viii) through (xi) as paragraphs

(e)(2)(x) through (xiii); and ■ e. Adding new paragraphs (e)(2)(viii) and (ix).

The revisions and additions read as follows:

§149.510 Independent dispute resolution process.

- *
- (d) * * *
- (2) * * *

(ii) The administrative fee amount will be established through notice and comment rulemaking in a manner such that the total administrative fees paid for a year 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. 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.

(3) Severability. (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) through (ix) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of these paragraphs is invalid and unenforceable in all circumstances, in which event the provision shall be

severable from the remainder of these paragraphs and shall not affect the remainder thereof.

(ii) The provisions in this paragraph (d) and paragraphs (e)(2)(vii) through (ix) of this section are intended to be severable from each other.

- (e) * * *
- (2) * * *

(vii) Provide, on an annual basis, a fixed fee for single determinations and a separate fixed fee for batched determinations, as well as an additional fixed tiered fee for batched disputes, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until changed by subsequent rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits. The certified IDR entity or IDR entity seeking certification may also seek advance written approval from the Secretary to update its fees more frequently than once annually. If a certified IDR entity or IDR entity seeking certification submits to the Secretary a request to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking, the Secretary will use their discretion to determine if the information submitted by a certified IDR entity or IDR entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the certified IDR entity's financial viability and would not impose on parties an undue barrier to accessing the Federal IDR process. In order for the certified IDR entity to receive the Secretary's written approval to charge a fee beyond the upper or lower limits for fees as set forth in rulemaking, or to modify the fixed fees more than once annually, it must satisfy the conditions in both paragraphs (e)(2)(vii)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(1) If requesting to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking:

(i) The alternative fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(ii) A description of the circumstances that require the alternative fee; and

(*iii*) A description that reasonably explains how the alternative fixed fee will be used to mitigate the effects of those circumstances; or

(2) If requesting to modify the fixed fee more than once annually:

(i) The fixed fee the certified IDR entity is seeking to charge;

(*ii*) A description of the circumstances that require a change to its fixed fee; and

(*iii*) A detailed description that reasonably explains how the change to its fixed fee will be used to mitigate the effects of those circumstances.

(B) Receive from the Secretary, the Secretary of the Treasury, and the Secretary of Labor, written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) 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, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of \$200 to \$840, unless a fee not within that range is approved by the Secretary, pursuant to paragraphs (e)(2)(vii)(A) and (B) of this section. The range for the certified IDR entity fee for single determinations will remain in effect until changed by subsequent rulemaking.

(ix) 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, certified IDR entities are permitted to charge a fixed certified IDR entity fee for batched determinations within the range of \$268 to \$1,173, unless a fee not within that range is approved by the Secretary pursuant to paragraphs (e)(2)(vii)(A) and (B) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of \$75 to \$250 for every additional 25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for batched determinations will remain in effect until changed by subsequent rulemaking.

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