SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT OF 1995: INDEPENDENT DISPUTE RESOLUTION PROCESS

This ICR seeks approval for an extension of an existing control number.

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was signed into law. The No Surprises Act provides Federal consumer protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.

The CAA added provisions applicable to group health plans and health insurance issuers in the group and individual markets in new Part D of title XXVII of the Public Health Service Act (PHS Act) and also added new provisions to part 7 of the Employee Retirement Income Security Act (ERISA), and Subchapter B of chapter 100 of the Internal Revenue Code (Code). Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A-1, which contain limitations on cost sharing and requirements regarding the timing of initial payments and notices of denial of payment for emergency services furnished by nonparticipating providers and emergency facilities, and for non-emergency services furnished by nonparticipating providers with respect to patient visits to participating health care facilities, defined as hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgical centers. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A-1 to establish a Federal independent dispute resolution (IDR) process that nonparticipating providers or facilities and group health plans and health insurance issuers in the group and individual market may use following the end of an unsuccessful open negotiation period to determine the out-of-network rate for certain qualified items and services. More specifically, the Federal IDR process may be used to determine the out-of-network rate for services furnished by nonparticipating emergency facilities and nonemergency items and services furnished by nonparticipating providers at participating facilities where an All-Payer Model Agreement or specified State law does not apply. Section 105 of the No Surprises Act added Code section 9817, ERISA section 717, and PHS Act section 2799A-2, which contain limitations on cost sharing and requirements for initial payments for air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process. CAA provisions that apply to health care providers and facilities and providers of air ambulance services, such as requirements around cost

sharing, prohibitions on balance billing for certain items and services, and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in new part E.

The Departments of the Treasury, Labor, and Health and Human Services (the Departments) previously issued interim final rules implementing provisions of sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A-1 and 2799A-2 of the PHS Act to protect consumers from surprise medical bills for emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services. The interim final rules also implement provisions requiring the Departments to create a Federal IDR process to determine payment amounts when there is a dispute between payers and providers or facilities over the out-of-network rate due for emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services.[1]

July 2021 and October 2021 Interim Final Rules

To implement these provisions, the Departments published in the Federal Register the July 2021 interim final rules on July 13, 2021 (86 FR 36872) and the October 2021 interim final rules on October 7, 2021 (86 FR 55980).

The July 2021 interim final rules implemented provisions of the No Surprises Act to protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to certain participating facilities, and air ambulance services provided by nonparticipating providers of air ambulance services.

The October 2021 interim final rules expand on the July 2021 interim final rules and implement the Federal IDR process.[2] The October interim final rules also provided good faith estimate (GFE) requirements for uninsured (or self-pay) individuals, the patient-provider dispute resolution (PPDR) process, and the external review provisions of the No Surprises Act.

1 The Federal IDR process does not apply if an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law applies.

2 The July 2021 and October 2021 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. The rules apply to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022.

The July 2021 interim final rules and October 2021 interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; and to health care providers and facilities, and providers of air ambulance services with respect to items and services provided during plan years (in the individual market, policy years) beginning on or after January 1, 2022.[3]

The final rules issued in October 2021, titled Requirements Related to Surprise Billing; Part II (October 2021 interim final rules) also include interim final regulations under 5 U.S.C. 8902(p) issued by the Office of Personnel Management (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 (FEHB) Act. The OPM interim final rules amend existing 5 CFR 890.114(a) to provide that FEHB carriers are subject to the Federal IDR process set forth in those regulations with respect to a qualified item or service eligible for determination through open negotiation and the Federal IDR process furnished by a carrier offering a health benefits plan in the same manner as those provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5 U.S.C. 8902(m)(1) and the provisions of the carrier's contract.

On February 23, 2022 and July 26, 2022, the United States District Court for the Eastern District of Texas, in the cases of *Texas Medical Association, et al. v. United States Department of Health and Human Services, et al.*, Case No. 6:21-cv-425 (E.D. Tex.) (*TMA I*), and *LifeNet, Inc. v. United States Department of Health and Human Services, et al.*, Case No. 6:22-cv-162 (E.D. Tex.) (*LifeNet*), vacated portions of the October 2021 interim final rules.[4] On August 3, 2023, the United States District Court for the Eastern District of Texas, in the case of *Tex. Med. Ass'n., et al. v. U.S. Dep't of Health and Human Servs.*, Case No. 6:23–cv–00059–JDK, (E.D. Tex. Jan. 30, 2023) (*TMA IV*), vacated certain provisions of the October 2021 interim final rules.

On August 24, 2023, the United States District Court for the Eastern District of Texas, in the case *Tex. Med. Ass'n., et al.* v. *U.S. Dep't of Health and Human Servs.*, Case No. 6:22-cv-00450-JDK (E.D. Tex.) (*TMA III*), vacated portions of the October 2021 interim final rules. The Department of Justice partially appealed the district court's decision

3 86 FR 36872 (July 13, 2021); 86 FR 55980 (October 7, 2021). These provisions apply to carriers in the Federal Employees Health Benefits 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.
4 86 FR 55980 (October 7, 2021).

in *TMA III* to the United States Court of Appeals for the Fifth Circuit. On October 30, 2024, the Fifth Circuit partially reversed the district court's decision. On May 30, 2025, the Fifth Circuit granted a rehearing *en banc*. Oral arguments were held on September 24, 2025.

August 2022 Final Rules

After consideration of comments and in light of the District Court's February and July 2022 decisions, in conjunction with this ICR Revision submission, the Departments' published in the Federal Register the August 2022 final rules (2022 final rules) on August 26, 2022 as a joint rule that finalized select provisions under the July and October 2021 interim final rules to address certain requirements related to consideration of information when a certified IDR entity makes a payment determination, including the requirements for the certified IDR entity to provide a written decision.[5] The 2022 final rules also specify the information required to be provided where a qualifying payment amount (QPA) is calculated based on a downcoded service code, in addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules.

On February 6, 2023, the United States District Court for the Eastern District of Texas, in the case of *Tex. Med. Ass'n, et. al. v. U.S. Dep't of Health and Human Servs.*, Case No. 6:22–cv–372 (E.D. Tex. February 06, 2023) (*TMA II*), vacated portions of the 2022 final rules.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The October 2021 interim final rules and the August 2022 final rules associated with this ICR Revision submission, together set forth 27 required components, applicable to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans)[6], providers, and facilities. These requirements include of notices necessary for the Federal IDR process, requirements associated with the certification of IDR entities, and reporting requirements for certified IDR entities. These notices also pertain to health care provider and facility requirements to inform uninsured (or self-pay) individuals both verbally and in writing of the availability of a good faith estimate of expected charges (45 CFR 149.610) as well as a patient-provider dispute resolution process for uninsured (or self-pay) individuals who

5 87 FR 52618 (August 26, 2022).
6 These rules also apply to FEHB carriers.

receive a final bill from a provider or facility that is substantially in excess than the furnished good faith estimate (45 CFR 149.620).

i. *Additional Information to Be Shared with the Initial Payment or Notice of Denial of Payment.* The final rules specify that where a QPA is calculated based on a downcoded service code, in addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules at 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d), a plan or issuer must provide, if applicable, a statement that all or a portion of the claim was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and a description of any modifiers that were altered or added; and the amount that would have been the QPA had the service code or modifier not been downcoded.

ii. *Open Negotiation Notice*. Before accessing the Federal IDR process to determine the out-of-network rate for a qualified item or service, the parties must engage in a 30-business-day open negotiation period to attempt to reach an agreement regarding the total out-of-network rate (including any cost sharing). To initiate the open negotiation period, the initiating party must provide notice to the other party within 30 business days of the receipt of the initial payment or notice of denial of payment for the qualified item or service. The Departments have provided a standard notice that the parties must use to satisfy the open negotiation notice requirement. The "Open Negotiation Notice" must include information sufficient to identify the items or services subject to negotiation, including a description of the item or service, claim number, the name of the provider, facility, or provider of air ambulance services and National Provider Identifier (NPI), the date the item or service was furnished or provided, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and contact information for the party sending the "Open Negotiation Notice."

iii. *Notice of IDR Initiation.* When the parties do not reach an agreed-upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process by submitting the "Notice of IDR Initiation" to the other party and to the Departments during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period (or within 30 business days of the end of the 90-calendar-day cooling off period). An FEHB carrier must also notify the OPM Director. The Departments have provided a standard notice that the parties must submit through the Federal IDR portal. The "Notice of IDR Initiation" must include: (1) information sufficient to identify the qualified IDR item or service (and whether the qualified IDR items or services are designated as batched items and services), including the

date(s) and location(s) in which the items or services were provided or furnished, the type of qualified IDR items or services (such as emergency services, post-stabilization services, professional services, hospital-based services), corresponding service and place-of-service codes, the amount of cost sharing allowed, and the amount of the initial payment made by the plan or issuer for the qualified IDR item or service, if applicable; (2) the names and contact information of the parties involved, including email addresses, phone numbers, mailing addresses, the type of plan and the NPI for the health care provider/health care facility/provider of air ambulance services; (3) the State where the qualified IDR item or service was provided or furnished; (4) the commencement date of the open negotiation period; (5) the initiating party's preferred certified IDR entity; (6) an attestation that the item or service is a qualified IDR item and service within the scope of the Federal IDR process; (7) the QPA; (8) information about the QPA as described in 26 CFR 54.9816-6T(d), 26 CFR 54.9816-6(d), 29 CFR 2590.716-6(d), and 45 CFR 149.140(d);[7] and (9) general information describing the Federal IDR process.

iv. *Notice of Certified IDR Entity Selection.* The parties to the Federal IDR process may jointly select a certified IDR entity not later than 3 business days following the date of initiation of the Federal IDR process. The initiating party must notify the Departments of the mutually selected certified IDR entity or of the parties failure to select a certified IDR entity by electronically submitting the "Notice of the Certified IDR Entity Selection (or failure to select)", no later than 1 business day after the end of the 3-business-day period following IDR initiation (or, in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal.[8] In addition, in instances in which the non-initiating party believes that the Federal IDR process is not applicable, that party must notify the Departments through the Federal IDR portal on the same timeframe that the "Notice of Certified IDR Entity Selection" is required and provide information regarding the lack of applicability. If the parties have agreed on a certified IDR entity, the "Notice of the Certified IDR Entity Selection" must include the following information: (1) the name of the certified IDR entity; (2) the certified IDR entity number; (3) an attestation by both parties (or by the initiating party if the other party did not respond) that the selected certified IDR entity does not have a conflict of interest, and that the Federal IDR process applies; (4) and the signature of both parties. If the parties have failed to agree on a certified IDR entity, notice of such failure must include a statement that the parties have failed to select a certified IDR entity, including an attestation that the Federal IDR process applies; and the signature of the initiating party.

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8 https://nsa-idr.cms.gov/paymentdisputes/s/

v. *Notice of Agreement on an Out-of-Network Rate.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing a "Notice of IDR Initiation" to the Departments, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically in a form and manner specified by the Departments in guidance, such as through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate (that is, the total payment amount, including both cost sharing and the total plan or coverage payment) and signatures from an authorized signatory for each party.

vi. *Notice of Offer.* Not later than 10 business days after the selection of the certified IDR entity, the plan, issuer, or FEHB carrier and the nonparticipating provider, emergency facility, or provider of air ambulance services must each submit a written offer to the certified IDR entity. This offer must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, to facilitate the certified IDR entity reporting the offer as a percentage of the QPA to the Departments. Where batched items and services have different QPAs, the parties should provide these different QPAs and may provide different offers for these batched items and services, provided that the same offer should apply for all items and services with the same QPA. Parties to the Federal IDR process must also submit information requested by the certified IDR entity relating to the offer. Parties must include the dispute reference number, their organization name, primary and secondary points of contact (including mailing address, phone numbers and emails) and plan types. The provider must specify whether the provider, practice, or organization has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. Providers and facilities must also provide information on the practice specialty or type, respectively (if applicable). Plans and issuers must provide the coverage area of the plan or issuer, the relevant geographic region for purposes of the QPA, and, for group health plans, whether they are fully insured, or partially or fully self-insured (or an FEHB carrier, if the item or service relates to FEHB coverage). Parties may also submit any additional information relating to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination except that the information may not include information related to usual and customary charges, the amount that would have been billed if the protections of the No Surprises Act

had not applied, or the payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor. The Departments intend for the Federal IDR portal to collect this information as part of the offer submission process, such that certified IDR entities will not have to directly request this information.

vii. *IDR Payment Determination.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must notify the plan, issuer, or FEHB carrier and the provider, facility, or provider of air ambulance services of the selection of the offer and provide the written decision to the parties and the Departments. The certified IDR entity's written decision must include an explanation of what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted in accordance with the final rules. If the certified IDR entity relies on any additional information in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

viii. *Request of Extension of Time Periods for Extenuating Circumstances.* The time periods specified in the October 2021 interim final rules (other than the timing of the payments following a final determination or settlement) may be extended in the case of extenuating circumstances at the Departments' discretion on a case-by-case basis if an extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Parties may request an extension by submitting a request for an extension due to extenuating circumstances through the Federal IDR portal, including an explanation of the extenuating circumstances that necessitate an extension and which Federal IDR process time period(s) is the subject of the request. The party requesting the extension must attest that prompt action will be taken to ensure that the certified IDR entity can make a payment determination as soon as administratively practicable.

ix. *IDR Certification.* The October 2021 interim final rules require that an IDR entity provide written documentation to the Departments that demonstrates that the entity satisfies certain standards and procedures outlined in the October 2021 interim final rules and guidance issued by the Departments. The guidance indicates the types of documentation that should be submitted for each certification standard, in what manner they should be submitted, and what the Departments will require for certification. The required certification documentation should be submitted by entities seeking certification through an

application on the Federal IDR portal. An entity that satisfies the required standards set forth in the October 2021 interim final rules and guidance issued by the Departments will be assigned a certified IDR entity number and will be certified for a 5-year period and will need to be recertified every 5 years.

x. *Petition for Denial or Revocation*. An individual, provider, facility, provider of air ambulance services, plan, issuer, or FEHB carrier may petition for the denial of a certification of an IDR entity or a revocation of a certification of a certified IDR entity for failure to meet the requirements of Code section 9816(c), ERISA section 716(c), PHS Act section 2799A-1(c), or the October 2021 interim final rules. The petitioner must submit a written petition to the Departments that identifies the IDR entity seeking certification or the certified IDR entity that is the subject of the petition and outlines the reasons for the petition. The petition must also specify whether the petition seeks denial or revocation of a certification and must be signed by the petitioner. The petitioner must use the standard petition notice issued by the Departments and submit any supporting documentation for consideration by the Departments. The Departments will make public the list of IDR entities seeking certification, as well as the list of certified IDR entities, to help facilitate the petition process.

xi. *Administrative Fee*. Under Code section 9816(c)(8), ERISA section 716(c)(8), PHS Act section 2799A-1(c)(8), and the interim final rules, each party to a determination must pay an administrative fee for participating in the Federal IDR process. The October 2021 interim final rules require each party to pay the administrative fee to the certified IDR entity at the time the certified IDR entity is selected, regardless of whether that certified IDR entity was selected by the parties or by the Departments.

xii. *Breach and Incident Notification*. A certified IDR entity must report any actual or suspected breach of unsecured individually identifiable health information (IIHI) to the CMS IT Service Desk by telephone at (410) 786-2580 or 1-800-562-1963 or via email notification at cms_it_service_desk@cms.hhs.gov within 24 hours upon discovery of the breach. Incidents, as defined below, must be reported to the CMS IT Service Desk by the same means as breaches within 72 hours from discovery of the actual or suspected incident. For this purpose, "security incident" or "incident" has the meaning contained in OMB Memoranda M 17-12 (January 3, 2017) and means an occurrence that, in relation to a certified IDR entity's information technology system that stores and maintains unsecured IIHI: (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or the information system; or (2)

constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.

An certified IDR entity must, following the discovery of a breach or potential breach of unsecured IIHI, notify the applicable provider, facility, or provider of air ambulance services; the applicable plan, issuer, or FEHB carrier; the Departments; OPM in instances where the breach relates to IIHI of FEHB covered individuals, as applicable.

If an actual or attempted acquisition, access, use, or disclosure of unsecured IIHI in a manner not permitted under 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is discovered, a certified IDR entity must, within five business days from discovery of the breach, conduct a risk assessment as described in 26 CFR 54.9816-8T(a)(2)(ii)(B), 29 CFR 2590.716-8(a)(2)(ii)(B), and 45 CFR 149.510(a)(2)(ii)(B), and notify the Departments of the potential or actual breach and provide to the Departments (and OPM, if applicable), in written form through the federal IDR portal, its risk assessment determination as to whether any actual or suspected breach of unsecured IIHI occurred and whether there is likely a high or low probability this breach occurred. Further, the certified IDR Entity must notify the CMS IT Service Desk, within five business days from discovery of the breach, by telephone at (410) 786-2580 or 1-800-562-1963 or via email notification at cms_it_service_desk@cms.hhs.gov, regarding its risk assessment determination as to whether any actual or suspected breach of unsecured IIHI occurred and whether there is likely a high or low probability this breach occurred.

If an actual or attempted acquisition, access, use, or disclosure of unsecured IIHI in a manner not permitted under 26 CFR 54.9816-8T(e)(2)(v), 29 CFR 2590.716-8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is discovered and a certified IDR entity finds there is a high probability that the security or privacy of unsecured IIHI has been compromised based on a risk assessment as described in 26 CFR 54.9816-8T(a)(2)(ii)(B), 29 CFR 2590.716-8(a)(2)(ii)(B), and 45 CFR 149.510(a)(2)(ii)(B), then a certified IDR entity must provide notification of the breach or potential breach, without unreasonable delay and in no case later than 60 calendar days after the discovery of the breach or potential breach, to: the Departments (and OPM, if applicable); the plan, issuer, or FEHB carrier; the provider, facility, or provider of air ambulance services, as applicable; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach. Additionally, a certified IDR entity must share the results of any risk assessment, including the probability that the security or privacy of IIHI has been compromised, with the Departments (and OPM, if applicable).

xiii. *Recordkeeping Requirements*. A certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for 6 years. This recordkeeping requirement will help ensure that State and Federal oversight agencies are able to audit past determinations of certified IDR entities and that parties are able to obtain records of the determinations. Certified IDR entities must make these records available for examination by all parties to the dispute, except when disclosure would violate State or Federal privacy laws and regulations, as well as to State or Federal oversight agencies upon request for oversight purposes.

xiv. *Monthly Certified IDR Entity Reporting Requirements for Items and Services that are not Air Ambulance Services.* Within 30 business days of the close of each month, each certified IDR entity must report certain data and information in a form and manner specified by the Departments. The report will be submitted through the Federal IDR portal. This information is to be processed by the Departments and published on the Departments' websites for each calendar quarter. For qualified IDR items and services that are not air ambulance services, certified IDR entities must report the number of Notices of IDR Initiation submitted to the certified IDR entity during the preceding month and the number of Notices of IDR Initiation for which the certified IDR entity made a final determination. In instances in which the provider or facility submits the "Notice of IDR Initiation," the certified IDR entity must submit information on the size of the provider practices or facilities submitting notifications. With respect to each "Notice of IDR Initiation," the certified IDR entity should provide a description of the items and services included with respect to the notification, including the relevant billing and service codes. The certified IDR entity must also report the relevant geographic region for purposes of the QPA for the qualified IDR items and services with respect to which the "Notice of IDR Initiation" was provided. Certified IDR entities must also report, for each determination, the offers submitted by the disputing parties expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, and whether the offer selected by the certified IDR entity was submitted by the plan or issuer, FEHB carrier, or the provider or facility. The certified IDR entity must report the amount of the selected offer expressed as a dollar amount and as a percentage of the QPA. Where batched items and services have multiple QPAs, the certified IDR entities must report the offer as a percentage of each QPA with respect to the batched items and services to which the offer applied. The certified IDR entity must report the number of times the out-of-network rate it determined exceeded the QPA. The certified IDR entity must report the rationale for the determination, including the extent to which the decision relied on the additional

credible information regarding the relevant factors. For each determination, the certified IDR entity must also report the practice specialty or type of each provider or facility involved in furnishing the items and services at issue as well as each party's name and address. For each determination, the certified IDR entity must also report the number of business days between the selection of the certified IDR entity and the payment determination. Finally, the certified IDR entity must report the total amount of certified IDR entity fees paid to the certified IDR entity during the preceding month for determinations involving qualified IDR items and services that are not air ambulance services. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to the prevailing party or the administrative fees that are collected on behalf of the Departments.

xv. *Monthly Certified IDR Entity Reporting Requirements for Items and Services that are Air Ambulance Services*. With respect to claims involving air ambulance services, the certified IDR entity must report the number of notifications submitted to the certified IDR entity that pertain to air ambulance services during the preceding month; the number of such notifications with respect to which a final determination was made; and the number of times the out-of-network rate determined (or agreed to) exceeded the QPA for air ambulance services. With respect to each "Notice of IDR Initiation", the certified IDR entity must provide a description of the air ambulance service, including the relevant billing and service codes and point of pick-up (as defined in 42 CFR 414.605) for the service included in such notification, the amount of the offer submitted by the group health plan, health insurance issuer, or FEHB carrier and by the nonparticipating provider of air ambulance services expressed as a dollar amount and as a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer or by the provider of air ambulance services; and the amount of the offer so selected, expressed as a dollar amount and as a percentage of the QPA. The certified IDR entity must report the rationale for the determination including the extent to which the decision relied on the additional credible information regarding the relevant factors. Additionally, the certified IDR entity must identify the air ambulance vehicle type, including whether the vehicle is fixed wing or rotary wing (information which should be included in the relevant service code), and the clinical capability level of such vehicle (if the parties have provided such information); the identity of the plan, issuer, carrier, FEHB carrier, or provider of air ambulance services with respect to such notification, providing each party's name and address; and the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity. Finally, the certified IDR entity must also report the total amount of certified IDR entity fees paid to

the certified IDR entity for the preceding month for determinations involving air ambulance services. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to prevailing parties.

xvi. *Standard Form: "Good Faith Estimate for Health Care Items and Services" Under the No Surprises Act.* This form may be used by the health care providers and facilities to inform uninsured (or self-pay) individuals of the expected charges for receiving certain health care items and services. A good faith estimate must be provided within 3 business days upon request. Information regarding scheduled items and services must be furnished within 1 business day of scheduling an item or service to be provided in at least 3 business days; and within 3 business days of scheduling an item or service to be provided in at least 10 business days.

xvii. *Standard Form: Patient-Provider Dispute Resolution (PPDR) Dispute Initiation Form.* This notice will be used by uninsured (or self-pay) individuals (or their authorized representatives) to initiate a payment dispute. The eligibility of the dispute for the PPDR process will be verified. It will also be determined whether any conflict of interest exists with the selected dispute resolution (SDR) entity assigned to decide the dispute.

xviii. *Standard Form: Online PPDR Initiation Form.* This online notice will be used by uninsured (or self-pay) individuals to initiate a payment dispute. The eligibility of the dispute for the PPDR process will be verified. It will also be determined whether any conflict of interest exists with the SDR entity selected to decide the dispute.

xix. *Standard Notice: Ineligible for PPDR or Additional Information Needed.* This notice will be used by the SDR entities to inform an uninsured (or self-pay) individual or their authorized representative that the uninsured (or self-pay) individual is not eligible for dispute resolution or that their submission to initiate dispute resolution was incomplete. If the submission is incomplete, the notice informs the uninsured (or self-pay) individual or their authorized representative of what is required to establish eligibility for dispute resolution.

xx. *Patient-Provider SDR Entity Certification Application Data Elements.* This document identifies data elements that an organization seeking to become an SDR entity is required to include in the contracting process. The SDR entity must be certified by the Secretary under 45 CFR 149.620(d).

xxi. *Independent Dispute Resolution and PPDR; Vendor Management Data Elements.* This document identifies data elements that a certified IDR or SDR Entity will be

required to provide to HHS so that the certified IDR or SDR Entity can pay the required administrative fee.

xxii. *PPDR Process Data Elements.* This document identifies the data elements that an uninsured (or self-pay) individual, provider, or facility is required to include in the patient-provider dispute resolution process under 45 CFR 149.620.

xxiii. *Standard Notice: SDR Determination Notice to Parties Provided Under the No Surprises Act.* This notice is to be used by the SDR entities to notify the uninsured (or self-pay) individual and the health care provider or health care facility whether the difference between the billed amount and the "Good Faith Estimate" is justified or not in accordance with the regulatory determination process and what amount the uninsured individual is to pay the health care provider or health care facility.

xxiv. *Standard Notice: SDR Entity Notification to Health Care Providers and Facilities and Uninsured (or Self-Pay) Individuals.* This is a standard notice so that providers or facilities and uninsured (or self-pay) individuals are informed of the SDR entity selection. Once HHS assigns an SDR entity to a dispute, the SDR entity must inform both parties (the uninsured (or self-pay) individual and the health care provider or health care facility) of the selection. Additionally, the SDR entity must request that the health care provider submit specific information within 10 business days of receipt of the notice so the SDR entity can use the data to make a determination on the dispute. To use this standard notice, the SDR entity, must fill in the blanks with the appropriate information.

xxv. *Standard Notice: Uninsured (or Self-Pay) Individual and Provider or Facility Settle on a Payment Amount After Initiating Patient Provider Dispute Resolution.* This notice is for use by the health care provider or facility to notify the SDR entity in the event that both parties agree to settle on a payment amount after the patient-provider dispute resolution process has been initiated and prior to the SDR entity making a determination. While the determination by the SDR entity is pending, the two (2) parties to the patient-provider dispute resolution process (the uninsured (or self-pay) individual and their authorized representative and the health care provider or health care facility) may agree to resolve the dispute by settling on a payment amount. When the parties settle on the amount, federal standards require the provider or facility to notify the SDR entity no later than three (3) business days after the date of the agreement.

xxvi. *Standard Notice: SDR Entity Notification to Health Care Provider or Facility and Uninsured (or Self-Pay) Individual Confirming Receipt of Dispute Settlement and*

Action. This notice is for use by the SDR entity to notify the health care provider or facility and uninsured (or self-pay) individual that the settlement agreement has been received and the dispute is closed or the SDR entity requires additional information from the parties. Any point after the dispute resolution process has been initiated but before the date on which a determination is made by the SDR entity, the parties can settle the payment amount through either an offer of financial assistance or an offer to accept a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full. In the event that the parties agree to settle on a payment amount, the provider or facility should notify the SDR entity through the Federal IDR Portal, electronically, or in paper form, as soon as possible, but no later than 3 business days after the date of the agreement.

xxvii. Standard Notice: Uninsured (or Self-Pay) Individual, Provider or Facility's Notification to Secretary of Health and Human Services Requesting Extension. This notice can be used by the uninsured or (self-pay) individual or the provider or facility to request an extension from HHS. An uninsured (or self-pay) individual can request an extension at any step in the patient-provider dispute resolution process by submitting a request due to extenuating circumstances to the Secretary of HHS via the Federal IDR portal, or electronic or paper mail. If the uninsured (or self-pay) individual is able to demonstrate the extension is necessary to address delays due to matters beyond their control or for good cause, the Secretary has the discretion to provide such an extension. A provider or facility may request an extension after the patient-provider dispute resolution has started. Once a dispute has been initiated, the parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, or electronic or paper mail if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Extensions cannot be granted on payment-related deadlines, including payment of the administrative fee. Once the patient-provider dispute resolution process has started, the Secretary will consider granting extensions in the following circumstance: (i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and (ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances. To use this standard notice, the uninsured or (self-pay) individual or the provider or facility must provide the asked for information in the space allotted.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.

The October 2021 interim final rules and the August 2022 final rules do not restrict plans, issuers, or FEHB carriers from using electronic technology to provide notices. Parties may provide the "Open Negotiation Notice," and the "Notice of IDR Initiation" to the other party electronically if the initiating party has a good faith belief that the electronic method is readily accessible by the other party, and the notice is provided in paper form free of charge upon request.

Additionally, many of the requirements described above, including notices, petitions, and reporting will be submitted electronically through the Federal IDR portal. The Departments have established the Federal IDR portal to administer the Federal IDR Process, available at https://www.nsa-idr.cms.gov. The Federal IDR portal must be used to satisfy various requirements, including initiation of the Federal IDR process, selection of a certified IDR entity, and the submission of offers. Use of the Federal IDR portal will allow certified IDR entities and the Departments to ensure the timeline and process requirements of the Federal IDR process are being met.

The Government Paperwork Elimination Act (GPEA) requires agencies to allow customers the option to submit information or transact with the government electronically, when practicable. Where feasible, and subject to resource availability and resolution of legal issues, the DOL has implemented the electronic acceptance of information submitted by customers to the Federal government.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

Submitting documents once through the electronic Federal IDR portal satisfies related information collection requirements for all three agencies without duplication of effort.

The October 2021 interim final rules and final rules and the No Surprises Act amend and add provisions to existing rules under the PHS Act, ERISA, and the Code. Several States already have their own balance billing protections or IDR processes. However, only HHS has jurisdiction over non-Federal government plans and small group and individual market plans in States that do not enforce the applicable provisions of the PHS Act, and the DOL has jurisdiction over ERISA-covered group health plans. The Internal Revenue

Service has exclusive jurisdiction over certain church plans. OPM has jurisdiction over the FEHB plans, which are Federal governmental plans, and OPM both contracts with and regulates the carriers with respect to those plans. To limit duplication, qualified IDR items or services under the regulations are limited to items or services for which an out-of-network rate is not determined by reference to a specified State law or an All-Payer Model Agreement. Thus, there will be no duplication of effort with other Federal government agencies or State governments.

5. If the collection of information impacts small businesses or other small entities describe any methods used to minimize burden.

Small issuers, plans, FEHB carriers, providers, facilities, providers of air ambulance services, and certified IDR entities, regardless of size, will need to satisfy requirements under the October 2021 interim final rules and final rules; however, these costs are scalable to the number of Federal IDR process payment determinations an entity is involved in. The interim final rules permit same or similar items and services to be batched together in a single arbitration proceeding to encourage efficiency. Batched items and services must be billed by the same provider or group of providers or facility or same provider of air ambulance services; payment for the items and services must be made by the same group health plan or health insurance issuer; the items and services must be the same or similar items or services; and all the items and services must have been furnished within the same 30-business-day period (or otherwise fall within the same 90-calendar-day cooling off period). By batching similar claims, the October 2021 interim final rules may reduce the per-service cost of arbitration and potentially the aggregate administrative costs, since the arbitration process is likely to exhibit at least some economies of scale. For example, the per-service cost of an arbitration case involving ten claims is likely to be less costly than the per-service cost of an arbitration case involving five claims. Accordingly, the costs for batching multiple claims, compared to batching one claim, are likely to be lower for smaller providers and entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The October 2021 interim final rules and August 2022 final rules implement certain provisions of the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260). Accordingly, not conducting these information collections or conducting these information collections less frequently will prevent the Departments from fulfilling the requirements of these provisions.

Because the Federal IDR process depends on the sending and receiving of notices, discontinuing or reducing the frequency of these notices will not be possible. Without these notices, the Departments will be unable to meet the statutory requirements of PHS Act sections 2799A-1(c) and 2799A-2(b); ERISA sections 716(c) and 717(b); and Code sections 9816(c) and 9817(b).

The certification of IDR entities and the ability of parties to petition for denial of an IDR entity's certification or the revocation of a certified IDR entity's certification ensure that certified IDR entities meet and maintain a certain quality level. Certified IDR entities are required to be recertified every 5 years; extending this time period would decrease oversight of the performance of certified IDR entities.

The October 2021 interim final rules and August 2022 final rules require certified IDR entities to report data on a monthly basis to the Departments. If certified IDR entities were required to report their activity less frequently, the Departments would not be able to monitor the Federal IDR process as closely, which could harm individuals, plans, issuers, FEHB carriers, providers, facilities, and providers of air ambulance services, and could cause harms to the wider health care market. This would also affect the ability of the Departments to report certain information on their public websites as is required under the No Surprises Act.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and 2 copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The October 2021 interim final rules and August 2022 final rules require each certified IDR entity to report specified information on the Federal IDR process payment determinations to the Departments on a monthly basis. Additionally, for certification, IDR entities must submit descriptions of their organizational structures and capabilities, including an organizational chart, and the credentials, responsibilities, and number of personnel employed to make payment determinations. Finally, the October 2021 interim final rules and final rules require the parties participating in the Federal IDR process to provide the required notices to the certified IDR entities, the opposing party, and to the Departments. This information is required to efficiently conduct the Federal IDR process within the timeframes required by statute.

Also, per 26 CFR 54.9816-8T(c)(4)(viii), 29 CFR 2590.716-8(c)(4)(viii), and 45 CFR 149.510(c)(4)(viii), a certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for 6 years.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The Departments' notice required by 5 CFR 1320.8(d), which provided the public with 60 days to comment on the information collection under the October 2021 interim final rules, was published in the Federal Register on January 6, 2025 (90 FR 671). One

comment on this ICR was received. Below is the comment and the Departments response.

Barrier: The IDR process is complex and difficult to navigate, particularly for small providers and out-of-network mental health professionals, who often lack resources to dispute unfair reimbursements.

Proposed Improvements:
• Simplify submission process with pre-filled data: Many providers struggle with entering claim data manually. IDR submissions should allow automatic population of claim details from existing provider billing records.
• Ensure parity enforcement in mental health claims disputes: The IDR process should explicitly require examiners to evaluate claims under the Mental Health Parity and Addiction Equity Act (MHPAEA) when applicable.
• Direct contact for IDR escalation: Provide a dedicated email address or escalation process for disputes that remain unresolved beyond the mandated timeline.

These changes would streamline the dispute process and ensure mental health and substance use disorder claims are adjudicated fairly, in compliance with MHPAEA

Response to Comment: The Departments recognize the comments related to streamlining the dispute process and improving disputing parties' communications and have proposed updates to the IDR process to require more direct and frequent contact between disputing parties. The No Surprises Act sets forth the information certified IDR entities must consider when making determinations. Specifying additional information certified IDR entities must consider is beyond the Departments' authority.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

In order to meet the requirements of certification, certified IDR entities are required to maintain the confidentiality of IIHI obtained in the course of conducting payment determinations.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than 1 form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

Group health plans, health insurance issuers, FEHB carriers, providers, and facilities are responsible for complying with the October 2021 interim final rules and final rules. The Departments assume that the burden would primarily fall on plans, issuers, FEHB carriers, providers and facilities, as they would be sending the notifications. Accordingly, in the discussion below, the Departments refer to costs for plans, issuers, FEHB carriers, providers, and facilities. However, it is expected that most self-insured group health plans will work with a third-party administrator (TPA) to meet the requirements of the interim final rules and final rules.

The Departments recognize the potential that some of the largest self-insured plans may seek to meet the requirements of the October 2021 interim final rules and final rules in-house and not use a TPA or other third party; in such cases, those plans will incur the

estimated burden and cost directly. The Department notes that the burden of the certified IDR entities will be fully allocated toward the cost burden in Question 13.

The Departments estimate that 1,380 issuers[9] and 205 TPAs[10] would incur a burden to comply with this provision. The Departments also estimate that 2,000,000 claims will be submitted annually as part of the Federal IDR process each year.[11] Please see Table 1 to see the number of claims that are expected to go through each stage of the Federal IDR process. Further details on how these estimates were calculated are discussed below.

The following wage rates were used in this analysis: $143.56 (general or operations manager), $75.14 (clerical worker), $186.44 (compensation and benefits manager), $135.80 (medical billing specialist), $135.80 (medical billing specialist), and $218.22 (physician).[12]

Table 1. Number of Claims that are Expected to go through Each Stage of Federal IDR Process

	Number of Claims
Notice of Open Negotiation	3,000,000
Notice IDR Initiation	2,000,000
Notice of Offer by Provider	2,000,000
Notice of Offer by Insurer	2,000,000
Notice of Agreement on an Out-of-Network Rate	20,000
Notice for Request of Extension	20

Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities and Provider of Air Ambulance Services

Notice of Open Negotiation

9 Based on data from MLR annual report for the 2023 MLR reporting year. See https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr. Issuers are defined as health insurance company/State combination and refers to the legal entities or subsidiaries that are licensed and operate within a specific State.
10 Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.
11 Over 850,000 disputes were initiated in the last 6 months of 2024. The Departments project this number forward to arrive at an annual estimate of 2 million. See the Supplemental Background on Federal Independent Dispute Resolution Public Use Files July 1, 2024 – December 31, 2024 (May 28, 2025) available at: *https://www.cms.gov/files/document/federal-idr-supplemental-background-2024-q3-2024-q4.xlsx*
12 Internal DOL calculation based on 2025 labor cost data. For a description of DOL's methodology for calculating wage rates, see https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.

The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. The Departments estimate that, on average, it will take a medical and health services manager 30 minutes to write each "Open Negotiation Notice" and a clerical worker 15 minutes to prepare and send the notice. The "Open Negotiation Notice" must be sent within 30 business days beginning on the day the provider or facility receives an initial payment or a notice of denial of payment from the plan or issuer regarding such item or service. Please see Table 2 for calculations and burden totals.

Notice of IDR Initiation

When the parties do not reach an agreed-upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process by submitting the "Notice of IDR Initiation" to the other party and to the Departments during the 4-business day period beginning on the 31st business day after the start of the open negotiation period (or within 30 business days of the end of the 90-calendar-day cooling off period). The Departments estimate that it will take 30 minutes for a medical and health services manager to write the "Notice of IDR Initiation" and 15 minutes for a clerical worker to prepare and send the initiating notice. Please see Table 2 for calculations and burden totals.

Notice of Agreement on Out-of-Network Rate

If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing notice to the Departments of initiation of the Federal IDR process, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically through the Federal IDR portal, in a form and manner specified by the Departments, as soon as possible, but no later than 3 business days after the date of the agreement. This notification should include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties. The Departments assume that 1 percent of IDR payment determinations will be resolved by an agreement on an out-of-network rate after the Federal IDR process has been initiated. The Departments estimate that, on average, it will take a medical and health services manager 30 minutes to write each "Open Negotiation Notice" and a clerical worker 15 minutes to submit the notice to the Federal IDR portal. Please see Table 2 for calculations and burden totals.

Notice of Certified IDR Entity Selection

If the parties select a certified IDR entity, or if they fail to select a certified IDR entity,

they must notify the Departments of their selection no later than 1 business day after the selection or failure to select. To the extent the non-initiating party does not believe that the Federal IDR process applies, the non-initiating party must also provide information that demonstrates the lack of applicability by the same date that the notice of selection or failure to select must be submitted. The Departments estimate that in 25 percent of IDR payment determinations, there will be a failure to select a certified IDR entity. The Departments assume that it will take 30 minutes for a medical and health services professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. Please see Table 2 for burden and calculations.

The Departments estimate that in 75 percent of IDR payment determinations, a certified IDR entity will be selected by the disputing parties. Additionally, the Departments assume that it will take 30 minutes for a medical and health services professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. Please see Table 2 for burden and calculations.

If the parties fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity costs (or, if there is an insufficient number of certified IDR entities available that charge a fee within the allowed range, the Departments will select a certified IDR entity that has approval to charge a fee outside of that range) through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Notice of Offer

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a payment determination for a qualified IDR item or service, the parties must submit to the certified IDR entity (1) an offer for a payment amount for the qualified IDR service furnished by the provider of air ambulance services, expressed both as a dollar amount and as a percentage of the QPA; and (2) information as requested by the certified IDR entity relating to the offer. The Departments estimate that for providers, issuers, providers, and facilities it will take 30 minutes for a medical and health services manager to write the offer and 15 minutes for a clerical worker to prepare and send the offer. Please see Table 2 for burden and calculations.

Table 2. Hour Burden of Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities and Providers of Air Ambulance Services

	Number of Entities	Number of Hours per Entity	Total Hour Burden	Wage Rate	Hour Equivalent of Cost Burden
	(A)	(B)	(A x B)	(C)	(A x B x C)
Open Negotiation Notice					
Compensation and benefits manager prepare open negotiation notice	3,000,000	0.50	1,500,000	$186.44	$279,660,000
Clerical workers prepare additional material for open negotiation notice	3,000,000	0.25	750,000	$70.29	$52,717,500
IDR Initiation Notice					
Compensation and benefits manager prepare IDR initiation notice	2,000,000	0.50	1,000,000	$186.44	$186,440,000
Clerical workers prepare IDR initiation notice	2,000,000	0.25	500,000	$70.29	$35,145,000
Notice of Agreement on an Out-of-Network Rate					
Compensation and benefits managers prepare and submits agreement before the IDR entity gives a decision	20,000	0.50	10,000	$186.44	$1,864,400
Clerical workers prepare and submit agreement before the IDR entity gives a decision	20,000	0.25	5,000	$70.29	$351,450
Notice of Offer					
Compensation and benefits managers prepare provider's offer, which will be sent to the IDR entity	2,000,000	0.5	1,000,000	$186.44	$186,440,000
Clerical workers prepare provider's offer, which will be sent to the IDR	2,000,000	0.25	500,000	$70.29	$35,145,000

entity					
Compensation and benefits managers prepare insurer's offer, which will be sent to the IDR entity	2,000,000	0.5	1,000,000	$186.44	$186,440,000
Clerical workers prepare insurer's offer, which will be sent to the IDR entity	2,000,000	0.25	500,000	$70.29	$35,145,000
Total	**7,020,000**	**-**	**6,765,000**	**-**	**$999,348,350**

Request of Extension of Time Periods for Extenuating Circumstances

The Departments has limited data on how often entities will request an extension; however, the Departments are of the view that extenuating circumstances will be rare. The Departments assume that 20 plans, issuers, FEHB carriers, providers, facilities, air ambulance services providers, and air ambulance facilities will annually request an extension by completing the "Request for Extension due to Extenuating Circumstances" form and attesting that prompt action will be taken to ensure the payment determination under this section is made as soon as administratively practical. The Departments estimate that it will take a clerical worker 15 minutes to prepare and send the notice. Please Table 3 for calculations and burden.

Table 3. Hour Burden of Request of Extension of Time Periods for Extenuating Circumstances

	Number of Entities	**Number of Hours per Entity**	**Total Hour Burden**	**Wage Rate**	**Hour Equivalent of Cost Burden**
	(A)	**(B)**	**(A × B)**	**(C)**	**(A × B × C)**
Clerical workers prepare notice for request of extension	20	0.25	5	$75.14	376
Total	**20**	**-**	**5**	**-**	**$376**

Total Hour Burden Summary

Please see Table 4 for total hour burden.

Table 4. Total Hour Burden

	Total for All Agencies	DOL Total
Total Hour Burden (First Year)	10,519,488	1,691,251
Equivalent Cost of Hour Burden (First Year)	$1,348,831,555	$249,837,176
Total Hour Burden (Subsequent Years)	10,519,488	$1,691,251
Equivalent Cost of Hour Burden (Subsequent Years)	$1,348,831,555	$249,837,176
Hour Burden (Three-Year Average)	**10,519,488**	**1,691,251**
Equivalent Cost of Hour Burden (Three-Year Average)	**$1,348,831,555**	**$249,837,176**

Table 5. Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Equivalent Cost of Hour Burden
Federal IDR Process for Services relating to Nonparticipating Providers or Nonparticipating Emergency Facilities and Providers of Air Ambulance Services							
Open Negotiation Notice							
Compensation and benefits manager write the Open Negotiation Notice	750,000	1	750,000	0.5	375,000	$186.44	$69,915,000
Clerical workers prepare and send Open Negotiation Notice	750,000	1	750,000	0.25	187,500	$70.29	$13,179,375
IDR Initiation Notice							
Compensation and benefits manager write the Notice of IDR Initiation	500,000	1	500,000	0.5	250,000	$186.44	$46,610,000
Clerical workers prepare and send Notice of IDR Initiation	500,000	1	500,000	0.25	125,000	$70.29	$8,786,250
Notice of Agreement on an Out-of-Network Rate							

Compensation and benefits managers write the Notice of Agreement on an Out-of-Network Rate	5,000	1	5,000	0.5	2500	$186.44	$466,100
Clerical workers prepare and send Notice of Agreement on an Out-of-Network Rate	5,000	1	5,000	0.25	1250	$70.29	$87,863
Notice of Offer							
Compensation and benefits managers prepare provider's offer, which will be sent to the IDR entity	1,000,000	1	1,000,000	0.5	500,000	$186.44	$93,220,000
Clerical workers prepare provider's offer, which will be sent to the IDR entity	1,000,000	1	1,000,000	0.25	250,000	$70.29	$17,572,500
Compensation and benefits managers prepare insurer's offer, which will be sent to the IDR entity	1,000,000	1	1,000,000	0.5	500,000	$186.44	$93,220,000
Clerical workers prepare insurer's offer, which will be sent to the IDR entity	1,000,000	1	1,000,000	0.25	250,000	$70.29	$17,572,500
Request for Extension							
Clerical workers prepare and submit the Request for Extension	5	1	5	0.25	1	$75.14	$94
Total (3-year average)	**2,000,012**	**-**	**2,755,048**		**1,691,251**		**$249,837,417**

* The total number of respondents was calculated in the following manner: 2,000,000 (Federal IDR process for items and services relating to nonparticipating providers or nonparticipating emergency facilities and air ambulance providers) + 5 (Request for Extension) + 7 (Certified IDR Entity) = 680,012.

**The total number of responses in the first year was calculated in the following manner: 2,755,000 (Federal IDR Process for Services relating to nonparticipating providers or nonparticipating emergency facilities and air ambulance providers) 5 (Request for Extension) + 44 (Certified IDR Entity) = 2,755,049. The total number of responses in subsequent years was calculated in the following manner: 2,755,000 (Federal IDR process for items

and services relating to nonparticipating providers or nonparticipating emergency facilities and air ambulance providers) + 5 (Request for Extension) + 42 (Certified IDR Entity) = 2,755,047. Thus, the three-year average number of responses is 2,755,048.
***Please note that the numbers in the table are rounded.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 or 14).

- **The cost estimate should be split into 2 components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

Group health plans, health insurance issuers, FEHB carriers, facilities, providers, providers of air ambulance services, and certified IDR entities are responsible for complying with the October 2021 interim final rules and final rules.

In the discussion below, the Departments refer to costs incurred by plans, issuers, and FEHB carriers. However, it is expected that most self-insured group health plans will work with a TPA to meet the requirements of the rules. Accordingly, issuers and TPAs

are assumed to incur this cost and burden for most group health plans. The Departments recognize the potential that some of the largest self-insured plans may seek to meet the requirements of the October 2021 interim final rules and final rules in-house and not use a TPA or other third party; in such cases those plans will incur the estimated burden and cost directly.

Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities and Providers of Air Ambulance Services

The majority of the costs will be incurred from the distribution of notices. The Departments assume that five percent of these notices would be mailed and will incur a mailing cost of $0.05 per page and $1.00 for material cost. Please see Table 6 for mailing cost calculations and burden totals.

Table 6. Cost Burden of Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities and Providers of Air Ambulance Services

	Number of Notices	**Percent of Notices that will be mailed**	**Postage Cost**	**Material Cost**	**Mailing Cost**
	(A)	**(B)**	**(C)**	**(D)**	**[A x B x (C x D)]**
Open Negotiation Notice	3,000,000	5%	$1.00	$0.05	$157,500
IDR Initiation Notice	2,000,000	5%	$1.00	$0.05	$105,000
Notice of Provider's Offer to the IDR entity	2,000,000	5%	$1.00	$0.05	$105,000
Notice of Insurer's Offer to the IDR entity	2,000,000	5%	$1.00	$0.05	$105,000
Notice of Out-of-Network Agreement before the IDR entity gives a decision	20,000	5%	$1.00	$0.05	$1,050
Total	**3,000,000**	**-**	**-**	**-**	**$473,550**

Notice of IDR Payment Determination

The Departments classify the burden borne by certified IDR entities as a cost burden.

After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the parties of the payment determination no later than 30 business days after certified IDR entity selection, in a form and manner specified by the Departments.[13] The Departments assumes that a physician and medical billing specialist will take 30 minutes to prepare the payment determination notice at a composite wage rate of $163.27.[14] Please see Table 8 for calculations and burden totals.

Additionally, the certified IDR entity must provide the payment determination to both parties of the dispute and the Departments. The Departments also assume that the cost of preparing and delivering this written decision is included in the certified IDR entity fee paid by the provider, facility, plan, issuer, or FEHB carrier.

After a final determination, the certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process for 6 years. The certified IDR entity must store the documents in a manner necessary to meet the requirements of the interim final rules. The certified IDR entities must make such records available for examination by the plan, issuer, FEHB carrier, provider, facility, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws. The Department assumes that a clerical worker will take 30 minutes to maintain recordkeeping. Please see Table 7 for calculations and burden totals.

Table 7. Cost Burden of Federal IDR Process for Certified IDR Entities

	Number of Entities	**Number of Hours per Entity**	**Total Hour Burden**	**Wage Rate**	**Cost**
	(A)	**(B)**	**(A × B)**	**(C)**	**(A × B × C)**
Physicians and medical billing specialists prepare the payment determination notice	2,000,000	0.50	1,000,000	$163.27	$163,270,000
Clerical workers maintain recordkeeping	2,000,000	0.50	1,000,000	$70.29	$70,290,000
Total	**4,000,000**	**-**	**2,000,000**	**-**	**$233,560,00**

13 IDR Payment Determination Notification (ERISA 716(c)(5)(A))

14 The Department of Labor uses a composite wage rate because different professionals will review different types of claims and groups of individuals. The wage rate of a physician is $218.22, and the wage rate of a medical billing specialist is $135.80. (Internal DOL calculation based on 2025 labor cost data. For a description of the Department's methodology for calculating wage rates, see https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.) The composite wage rate is estimated in the following manner: ($218.22 x (1/3) + $135.80 x (2/3) = $163.27)

					0

Request of Extension of Time Periods for Extenuating Circumstances

The Departments assume that 20 plans, issuers, FEHB carriers, providers, facilities, or providers of air ambulance services will annually request an extension by completing the Request for Extension due to Extenuating Circumstances form and attesting that prompt action will be taken to ensure the payment determination under this section is made as soon as administratively practical. The Departments expect these requests to be submitted through the Federal IDR portal, and therefore have not estimated an associated mailing cost.

IDR Entity Certification

An IDR entity must be certified under standards and procedures set forth in guidance promulgated by the Departments. The Departments estimate that there will be 13 entities that seek IDR certification.[15] The Departments estimate that, on average, it will take a medical and health services manager 5.10 hours and a clerical worker 15 minutes to satisfy these requirements for certifications. Please see Table 8 for calculations and burden totals.

When a certified IDR entity is selected, the certified IDR entity must submit the administrative fee to the Departments on behalf of the parties to the Federal IDR process. The Departments estimate that, on average, the time required for a clerical worker to complete the information collection is 18 hours annually, including the time to review instructions, search existing data resources, gather required data, and complete and review the information collection. Please see Table 8 for calculations and burden totals.

Certified IDR entities are required to be recertified every 5 years. The Departments estimate that, on average, one-fifth of certified IDR entities will need to be recertified each year. Similar to the initial certification process, these certified IDR entities must ensure the processes are established and complete the corresponding paperwork, including the certification agreement, through the Federal IDR portal. The Departments estimate that, on average, it will take a medical and health services manager 2.10 hours and a clerical worker 15 minutes to satisfy the requirement. Please see Table 8 for calculations and burden totals.

15 According to the Center for Medicare and Medicaid Services, there are 13 certified IDR entities..(*See* Center for Medicare and Medicaid Services,. *List of Certified Independent Dispute Resolution Entities*, https://www.cms.gov/nosurprises/Help-resolve-payment-disputes/certified-IDRE-list.)

The interim final rules permit an individual, provider, facility, provider of air ambulance services, group health plan, issuer, or FEHB carrier to petition for a denial of a certification for an IDR entity seeking certification or for the revocation of certification of a certified IDR entity for failure to meet certain requirements set forth in the interim final rules.

The Departments do not have data on how often such a petition might occur; however, the Departments assume that such a petition will be a rare occurrence. The Departments assume that there will be 1 petition each year, and it will take, on average, a medical and health services manager 2 hours and a clerical worker and 15 minutes to prepare the petition. Please see Table 8 for calculations and burden totals.

IDR Entity Monthly Reporting

For each month, certified IDR entities will be required to report information on their activities to the Departments. The report will be submitted through the Federal IDR portal. The Departments estimate it will take a medical and health services manager 1 hour, on average, to prepare the reports and a clerical worker 15 minutes to prepare and send the report to the Departments each month. Please see Table 8 for calculations and burden totals

The certified IDR entities are required, following the discovery of a breach of unsecured IIHI, to notify of the breach the provider, facility, or provider of air ambulance services; the plan or issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible. The Departments estimate that three certified IDR entities will have a breach each year. In addition, the Departments estimate that it will take a medical and health services manager 1 hour, on average, to handle the initial breach and follow the required protocols, and that it will take a general and operations manager 45 minutes, on average, to ensure the protocol is executed and adapt policies accordingly. Please see Table 8 for calculations and burden totals.

Table 8. Cost Burden for IDR Entity Certification and Certified IDR Entity Monthly Reporting

	Number of Entities	Number of Hours per Entity	Total Hour Burden	Wage Rate	Cost
	(A)	(B)	(C)	(D)	(A x B x D)
IDR Entity Certification					
Compensation and benefits	13	5.10	66	$186.44	$12,361

managers prepare IDR entity certification (first year)					
Clerical workers prepare and submit IDR entity certification (first year)	13	0.25	3	$70.29	$228
IDR Entity Re-certification					
Compensation and benefits managers prepare IDR entity re-certification (subsequent years)	3	2.10	5	$186.44	$1,018
Clerical workers prepare and submit IDR entity re-certification (subsequent years)	3	0.25	1	$70.29	$46
Administrative Fee					
Clerical worker submits the administrative fee	13	18.00	234	$70.29	$16,448
Petition for Denial or Withdrawal of IDR Entities					
Compensation and benefits managers prepare petition for denial or withdrawal of IDR Entities	5	2	10	$186.44	$1,864
Clerical workers prepare and submit petition for denial or withdrawal of IDR entities	5	0.25	1	$70.29	$88
IDR Entity Monthly Reporting					
Compensation and benefits managers prepare IDR entity monthly report	156	1	156	$186.44	$29,085
Clerical workers prepare and submit IDR entity monthly report	156	0.25	39	$70.29	$2,741
IDR Entity Breach					
IDR entity managers handle the initial breach and follow the set procedures	3	1	3	$186.44	$559
CAC Senior Officials ensure the protocol is executed and adapt the policies accordingly	3	0.75	2	$143.56	$323
Total (First-Year)	**177**	**-**	**-**	**-**	**$47,250**
Total (Subsequent-Years)	**167**	**-**	**-**	**-**	**$35,724**
Total (Three-Year Average)	**170**	**-**	**-**	**-**	**$56,014**

Total Cost Burden Summary

Please see Table 9 for total cost burden.

Table 9. Total Cost Burden

	Total for All Agencies	**DOL Total**
Total Cost Burden (First Year)	$234,509,656	$58,519,953
Total Cost Burden (Subsequent Years)	$234,498,128	$58,517,071
Total Cost Burden (Three-Year Average)	**$234,501,971**	**$58,518,032**

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

The Federal government will incur costs to build and maintain the Federal IDR portal and to implement and administer the Federal IDR process. The annual costs associated with the Federal IDR portal and administering the Federal IDR process was estimated to be $70 million for 2024.

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).

15. Explain the reasons for any program changes or adjustments reporting in Items 13 or 14.

The Departments have made the following changes to the estimates of the burden of the information collection:

- The Department have updated the average hour burden for the IDR notices from 2 hours to 30 minutes.
- The Departments have updated the wage rates and the number of IDR claims that

are expected to go through the Federal IDR process.
- The Departments have combined the hour and cost burden for nonparticipating providers or nonparticipating emergency facilities and air ambulance providers.
- The Departments have also removed the hour burden for the additional information to be shared with the initial payment or notice of denial of payment, as the form has been included in OMB Control Number 0938-1433.

As a result, the number of responses has increased by 2,591,502 responses, the hour burden has increased by 1,601,731 hours, and the cost burden has increased by $57,961,885.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

For each calendar quarter, the Departments will publish information regarding the Federal IDR process on a public website.

The information will include aggregate statistics, such as the number of notifications submitted; the size of the provider practices and facilities submitting notifications; the number of notifications for which a determination was made; the information basis for such a determination; the number of times the payment amount determined under this subsection exceeds the qualifying payment amount, by items and services; the amount of expenditures made by the Departments during such calendar quarter to carry out the Federal IDR process; the total amount of fees paid; and the total amount of compensation paid to certified IDR entities.

Additionally, for each "Notice of IDR Initiation", the Departments will publish a a description of the items and services included with respect to the notification, including the relevant billing and service codes; the relevant geographic region for purposes of the QPA; the amount of the offer submitted by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable); the amount of the selected offer expressed as a dollar amount and a percentage of the QPA; the rationale for the certified IDR entity's decision; the practice specialty or type of each provider or facility, respectively, involved in furnishing each item or service; the identity for each plan or issuer, and provider or facility, with respect to the notification; and for each determination, the number of business days elapsed between selection of the

certified IDR entity and the selection of the out-of-network rate by the certified IDR entity.

The Departments will also publish the number of Notices of IDR Initiation submitted under the Federal IDR process that pertain to air ambulance services during the month submitted to the certified IDR entity; the number of such notifications with respect to which a final determination was made; the number of times the payment amount exceeded the QPA; and the total amount of certified IDR fees paid to the certified IDR entity during the month that data was collected with regard to air ambulance services. With respect to each "Notice of IDR Initiation" involving air ambulance claims, the Departments will publish a description of each air ambulance service, the point of pick-up (as defined in 42 CFR 414.605) for which the services were provided; the amount of the offer submitted by the group health plan, health insurance issuer, or FEHB carrier and by the nonparticipating provider of air ambulance services expressed as a a dollar amount and percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by such plan, issuer or carrier or by the provider or facility; the amount of the offer so selected expressed as a dollar amount and a percentage of the QPA; the rationale for the certified IDR entity's decision; the air ambulance vehicle type; the identity of the plan, issuer, FEHB carrier, or provider of air ambulance services with respect to such notification; and the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity. The calculation of these statistics will be a tabulation of the monthly reports submitted by certified IDR entities.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable.

18. Explain each exception to the certification statement identified in Item 19.

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

Not applicable.