

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

This information collection request (ICR) seeks approval for a revision 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 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 also established, under Code section 9816, ERISA section 716, and PHS Act section 2799A-1, 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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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.

July 2021 and October 2021 Interim Final Rules

To implement these No Surprises Act 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 build on the July 2021 interim final rules and implement the Federal IDR process. The October interim final rules also include HHS-only provisions implementing the 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.

The July 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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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, 2022.¹ The July and 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 rules apply to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022.

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.

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 issued the August 2022 final rules² published as a joint rule in the Federal Register 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 requirement for the certified IDR entity to provide a written decision. The August 2022 final rules also specify 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.

The August 2022 final rules also included amendments to remove from the regulations the language vacated by the United States District Court for the Eastern District of Texas (District Court) in *TMA I* and *LifeNet*, as described in the following section.

¹ 86 FR 36872 (July 13, 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.
² 87 FR 52618 (August 26, 2022).

Litigation

On February 23, 2022 and July 26, 2022, the District Court, 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. On February 6, 2023, the District Court issued an opinion and order in *Texas Medical Association, et al. v. United States Department of Health and Human Services, et al.*, Case No. 6:22-cv-372 (E.D. Tex.) (*TMA II*) that vacated portions of the August 2022 final rules. Later, the District Court in *Texas Medical Association, et al. v. United States Department of Health and Human Services, et al.*, No. 6:23-cv-00059-JDK (E.D. Tex. Aug. 3, 2023) (*TMA IV*) and *Texas Medical Association, et al. v. United States Department of Health and Human Services, et al.*, Case No. 6:22-cv-450-JDK (E.D. Tex. Aug. 24, 2023) (*TMA III*) vacated additional portions of the October 2021 interim final rules and July 2021 interim final rules, respectively, among other guidance documents.

2023 Notice of Proposed Rulemaking

The Federal Independent Dispute Resolution Notice of Proposed Rulemaking (2023 proposed rules) relate to certain provisions of the No Surprises Act regarding the Federal IDR process. These rules propose requirements relating to the disclosure of information that group health plans and health insurance issuers offering group or individual health insurance coverage must share along with the initial payment or notice of denial of payment for certain items and services subject to the surprise billing protections in the No Surprises Act. The 2023 proposed rules would also require plans and issuers to communicate information through the use of claim adjustment reason codes (CARCs) and remittance advice remark codes (RARCs), as specified in guidance when providing any paper or electronic remittance (the initial payment or notice of denial of payment) to an entity that does not have a contractual relationship with the plan, issuer, or FEHB carrier. The 2023 proposed rules amend certain requirements related to the open negotiation period, the initiation of the Federal IDR process, including adding a new notice requirement, and certain requirements related to dispute eligibility review and the payment and collection of administrative fees and certified IDR entity fees. The 2023 proposed rules also propose to amend requirements related to the extension of timelines due to extenuating circumstances and would amend requirements related to batched qualified IDR items and services. The 2023 proposed rules would also codify clarifications regarding the requirements for bundled payment arrangements previously set forth in guidance. Additionally, the 2023 proposed rules add new requirements related

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

to registration in the Federal IDR portal of group health plans and health insurance issuers offering group or individual health insurance coverage.

Finally, the Departments propose to amend the Federal IDR eligibility determinations process to make the Federal IDR process for eligibility reviews the responsibility of the Departments under extenuating circumstances, including when the number of initiated Federal IDR disputes becomes such that certified IDREs are unable to make timely eligibility determinations. At present, before the Departments send a dispute to a certified IDR entity, the Departments collect information needed to evaluate whether the dispute is eligible for the Federal IDR process and make a preliminary eligibility determination. These preliminary Federal IDR dispute eligibility reviews now help alleviate the burden on certified IDR entities of conducting the entire eligibility review themselves, particularly because they are not receiving certified IDR entity fees for disputes determined ineligible. Under this proposal, in certain circumstances when departmental eligibility review is in effect, the Departments, rather than the certified IDR entities, would make final eligibility determinations. The departmental eligibility review would be implemented when the Departments, in their sole discretion, determine that extenuating circumstances consistent with 26 CFR 54.9816-8T(g), 29 CFR 2590.716-8(g) and 45 CFR 149.510(g) render the application of the departmental eligibility review necessary to facilitate timely payment determinations or the effective processing of disputes under the Federal IDR process. The Departments are proposing the departmental eligibility review to relieve the burden on certified IDR entities and increase the speed at which certified IDR entities can make payment determinations.

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, the August 2022 final rules, and 2023 proposed rules associated with this ICR Revision submission, set forth 19 required components, applicable to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans)³, providers, and facilities. These requirements consist of notices necessary for the Federal IDR process, requirements associated with the certification of IDR entities, and reporting requirements for certified IDR entities.

- i. Departmental Federal IDR Eligibility Determinations.* The Departments propose to add new paragraph 26 CFR 54.9816-8T(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii) regarding Federal IDR eligibility determinations to make eligibility reviews for the Federal IDR process the responsibility of the

³ These rules also apply to FEHB carriers.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

Departments when the Departments determine that extenuating circumstances render the application of the departmental eligibility review necessary to facilitate timely payment determinations or the effective processing of disputes. Under this proposal, prior to the Departments sending a dispute to a certified IDR entity, in certain circumstances the Departments would evaluate whether the dispute is eligible for the Federal IDR process, and would make a final eligibility determination.

- ii. *Registration of Group Health Plans and Health Insurance Issuers.* The 2023 proposed rules would require plans and issuers that are subject to the Federal IDR process to register and submit certain information to the Departments. The proposed regulation also requires that plans update the information associated with their registration no later than 30 calendar days after such information changes, and confirm the accuracy of its registration annually in the fourth quarter of each calendar year. Plans and issuers would be required to provide the following information upon registration: (1) the legal business name (if any) of the group health plan, issuer, or FEHB carrier, and, if applicable, the legal business name of the group health plan sponsor; (2) whether the plan or coverage is a self- or fully-insured ERISA group health plan, individual health insurance coverage, an FEHB plan, a self- or fully-insured non-Federal governmental plan, or a self- or fully-insured church plan; (3) the state(s) in which the plan or coverage is subject to a specified state law for any items or services to which the protections against balance billing under the No Surprises Act apply; (4) the state(s) in which the plan or coverage is subject to an All Payer Model Agreement under section 1115A of the Social Security Act for any items or services to which the protections against balance billing under the No Surprises Act apply; (5) for self-insured group health plans not otherwise subject to state law, any state(s) in which the group health plan has properly effectuated an election to opt in to a specified state law, if that state allows a plan not otherwise subject to the state law to opt in; and, for FEHB plans that adopt a specified state law as a term of coverage, any state(s) in which they have made such an adoption; (6) contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service. (7) the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier has not been assigned, the 5-digit HIOS identifier, or if no HIOS identifier is available, the plan or plan sponsor's Employer Identification Number (EIN) and the plan's plan number (PN), if a PN is available, or for FEHB carriers, the applicable contract number(s) and plan code(s); (8) additional information needed to identify the plan, issuer, or FEHB carrier, and the applicable Federal and State requirements for determining

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

appropriate out-of-network payment rates for items or services to which the protections against balance billing apply, as specified by the Departments in guidance, or such additional information needed with respect to FEHB carriers as specified by the OPM Director in guidance; and (9) additional information needed for purposes of administrative fee collection, as specified by the Departments in guidance, or such additional information needed with respect to FEHB carriers as specified by the OPM Director in guidance.

- iii. Open Negotiation Notice.* Before accessing the Federal IDR process to determine the out-of-network rate for a qualified IDR 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). In order to engage in open negotiation, a party must send the other party an “Open Negotiation Notice.” Under the 2023 proposed rules, the open negotiation notice must be provided to the other party and to the Departments through the Federal IDR portal to initiate the open negotiation period. The 2023 proposed rules also amend the content elements of the open negotiation notice and add additional elements that must be included in the open negotiation notice. With respect to the item or service subject to the open negotiation notice, information about the item or service and the parties including: (1) information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or air ambulance provider to the plan, issuer, or FEHB carrier, and the National Provider Identifier (NPI); (2) information sufficient to identify the plan, issuer, or FEHB carrier, such as the plan’s or issuer’s registration number, as required under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, if the plan, issuer, or FEHB carrier is registered under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, or an attestation from the party submitting the open negotiation notice that the plan, issuer, or FEHB carrier was not registered prior to the date it submitted the notice; the legal business name of the plan, issuer, or FEHB carrier as well as the current contact information (name, email address, phone number, and mailing address) of the plan, issuer, or FEHB carrier as provided with the initial payment or notice of denial of payment; and if the party submitting the open negotiation notice is a plan, issuer, or FEHB carrier, the plan type (for example, self-insured or fully-insured); (3) the name and contact information (including legal business, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation; (4) information sufficient to identify the item or service, such as: the date(s) the

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

item or service was furnished and, if the party submitting the open negotiation notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for the item or service from the plan, issuer, or FEHB carrier; the type of item or service (specifically, whether the item or service is an emergency service as defined in 26 CFR 54.9816-4T(c)(2)(i) or (ii), 29 CFR 2590.716-4(c)(2)(i) or (ii), 45 CFR 149.110(c)(2)(i) or (ii) non-emergency items and services as described in 26 CFR 54.9816-5T(b), 29 CFR 2590.716-5(b), 45 CFR 149.120(b) or an air ambulance service as defined in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, 45 CFR 149.30); whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location where the item or service was furnished (such as, place of service code or bill type code); (5) the initial payment amount (including \$0 if, for example, payment is denied); (6) the qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the party submitting the open negotiation notice is a plan, issuer, or FEHB carrier; (7) an offer of an out-of-network rate for each item or service; (8) if the party submitting the open negotiation notice is a plan, issuer, or FEHB carrier, the amount of cost sharing imposed for the item or service, if any; (9) if the party submitting the open negotiation notice is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i); (10) a statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished; (11) general information listed in the standard open negotiation notice developed by the Secretary describing the open negotiation period and the Federal IDR process; and (12) a copy of the initial payment or notice of denial of payment or other remittance that is required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service.

- iv. *Open Negotiation Response Notice.* The Departments propose that the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice that is provided to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period. The Departments proposed a standard notice that the parties would be required to use to satisfy the open negotiation response notice requirement. The proposed open negotiation response notice would be required to include: (1) information sufficient to identify the provider, facility, or provider of air

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address) as provided with the claim form submitted by the provider, facility, or provider of air ambulance services to the plan, issuer, or FEHB carrier, and the NPI; (2) information sufficient to identify the plan, issuer, or FEHB carrier such as the plan's or issuer's registration number, as required under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, if the plan, issuer, or FEHB carrier is registered under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, or an attestation from the party submitting the open negotiation response notice that the plan, issuer, or FEHB carrier was not registered prior to the date it submitted the notice; the legal business name of the plan, issuer, or FEHB carrier, as well as the current contact information (name, email address, phone number, and mailing address) of the plan, issuer, or FEHB carrier as provided with the payment remittance or notice of denial of payment; and if the party submitting the open negotiation response notice is a plan, issuer, or FEHB carrier, the plan type (for example, self-insured or fully-insured); (3) the name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the party submitting the open negotiation response notice, and an attestation that the third party has the authority to act on behalf of the party it represents in the open negotiation; (4) information sufficient to identify the item or service included in the open negotiation notice including the date(s) the item or service was furnished, and if the party submitting the open negotiation response notice is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan, issuer, or FEHB carrier, and the claim number; (5) if the party in receipt of the open negotiation notice is a plan, issuer, or FEHB carrier, a statement as to whether the party in receipt of the open negotiation notice agrees that the initial payment amount (including \$0 if, for example, payment is denied) and the qualifying payment amount reflected in the open negotiation notice is accurate for the item or service, and if not, or if the open negotiation notice indicates that the initial payment amount or qualifying payment amount was not communicated by the plan, issuer, or FEHB carrier in connection with the initial payment or notice of denial of payment or other remittance, the initial payment amount (including \$0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the qualifying payment amount); (6) if the party in receipt of the open negotiation notice is a plan, issuer, or FEHB carrier, the amount of cost sharing imposed for the item or service; (7) a counteroffer for an out-of-network rate for the item or service or an acceptance of the other party's offer; (8) if the party in

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

receipt of the open negotiation notice is a provider or facility, a statement that the patient who received the item or service did not receive notice and did not provide consent as described in 45 CFR 149.410(b) or § 149.420(c) through (i) to be treated by a nonparticipating provider or nonparticipating emergency facility; (9) with respect to each item or service, either a statement and supporting documentation that explains why the item or service is not subject to the Federal IDR process or a statement agreeing that the item or service is subject to the Federal IDR process; (10) a statement as to whether any of the information provided in the open negotiation notice is inaccurate and the basis for the statement, as well as supporting documentation; and (11) a statement confirming that the payment remittance or notice of denial of payment or other remittance provided by the party submitting the open negotiation notice is accurate, and if inaccurate, a copy of the accurate payment remittance or notice of denial of payment or other remittance with respect to the item or service.

- v. *Notice of IDR Initiation.* Under the 2023 proposed rules, the notice of IDR initiation would be required to include, with respect to the item or service subject to the notice, information about the item or service and the parties including: (1) information sufficient to identify the provider, facility, or provider of air services, such as the name and current contact information (including legal business name, email address, phone number, and mailing address), and the NPI; and if the initiating party is a provider, facility, or provider of air ambulance services, the Tax Identification Number (TIN); (2) information sufficient to identify the plan, issuer, or FEHB carrier; such as the plan's or issuer's registration number, as required under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 if the plan, issuer, or FEHB carrier is registered under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, or an attestation from the initiating party that the plan, issuer, or FEHB carrier was not registered prior to the date that it submitted the notice; the legal business name of the plan, issuer, or FEHB carrier as well as the current contact information (name, email address, phone number, and mailing address) of the plan, issuer, or FEHB carrier as provided with the initial payment remittance or notice of denial of payment; and if the party submitting the notice of IDR initiation is a plan, issuer, or FEHB carrier, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor); (3) the name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process; (4) information sufficient to identify if the dispute is being initiated as batched or bundled qualified IDR items or services as described in 26 CFR 54.9816-8(c)(4), 29 CFR 2590.716-8(c)(4), and

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

45 CFR 149.510(c)(4); (5) information sufficient to identify the qualified IDR item or service that is the subject of the notice of IDR initiation, including the date(s) the qualified IDR item or service was furnished; if the initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan, issuer, or FEHB carrier; the date the open negotiation period began; the type of item or service; whether the service is a professional service or facility-based service; the State where the item or service was furnished; the claim number; the service code; and information to identify the location the item or service was furnished (including place of service code or bill type code); (6) the initial payment amount (including \$0 if, for example, payment is denied); (7) the qualifying payment amount, if provided with the initial payment or notice of denial of payment or if the initiating party is a plan, issuer, or FEHB carrier; (8) if the initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or § 149.420(c) through (i); (9) a statement that the provider, facility, or provider of air ambulance services was a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services on the date the item or service was furnished; (10) attestation that the item or service under dispute is a qualified IDR item or service, and the basis for the attestation; (11) general information listed in the standard notice of IDR initiation developed by the Secretary describing the Federal IDR process (including a description of the purpose of the Federal IDR process and key deadlines in the Federal IDR process); (12) a copy of the initial payment or notice of denial of payment or other remittance that is required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1), with respect to the item or service; (13) preferred certified IDR entity; and (14) a statement describing the key aspects of the claim, such as patient acuity or level of training of the provider, facility, or provider of air ambulance services that furnished the qualified IDR item or service, discussed by the parties during open negotiation that relate to the payment for the disputed claim, whether the reasons for initiating the Federal IDR process are different from the aspects of the claim discussed during the open negotiation period, and an explanation of why the party is initiating the Federal IDR process, including any of the permissible considerations that serve as the party's basis for initiating the Federal IDR process.

- vi. *Notice of IDR Initiation Response.* The Departments propose that, to initiate the Federal IDR process, the initiating party must submit a written notice of IDR initiation to the non-initiating party and to the Departments (using the standard

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

form developed by the Departments) during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The Departments also propose that the non-initiating party must submit a written response to the notice of IDR initiation to the initiating party and to the Departments (using the standard form developed by the Departments) during the 3-business-day period beginning on the day after the Notice of IDR Initiation is received by the Departments. The proposed notice of IDR initiation response must include: (1) information sufficient to identify the provider, facility, or provider of air ambulance services, including the name and current contact information (including the legal business name, email address, phone number, and mailing address), the NPI, and if the initiating party is a provider, facility, or provider of air ambulance services, the TIN; (2) information sufficient to identify the plan, issuer, or FEHB carrier, including the plan's or issuer's registration number, as required under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530, if the plan, issuer, or FEHB carrier is registered under proposed 26 CFR 54.9816-9, 29 CFR 2590.716-9, and 45 CFR 149.530 or an attestation from the non-initiating party that the plan, issuer, or FEHB carrier was not registered prior to the date that it submitted the notice; the legal business name of the plan, issuer, or FEHB carrier, as well as the current contact information (name, email address, phone number, and mailing address) of the plan, issuer, or FEHB carrier as provided with the initial payment remittance or notice of denial of payment; and if the party submitting the notice of IDR initiation response is a plan, issuer, or FEHB carrier, the plan type (for example, self-insured or fully-insured) and TIN (or, in the case of a plan that does not have a TIN, the TIN of the plan sponsor); (3) the name and contact information (including the legal business name, email address, phone number, and mailing address) for any third party representing the non-initiating party, and an attestation that the third party has the authority to act on behalf of the party it represents in the Federal IDR process; (4) information sufficient to identify each item or service included in the notice of IDR initiation, including the date(s) the item or service was furnished. If the non-initiating party is a provider, facility, or provider of air ambulance services, the date(s) that the provider, facility, or provider of air ambulance services received the initial payment or notice of denial of payment for such item or service from the plan, issuer, or FEHB carrier, and the claim number; (5) if the non-initiating party is a plan, issuer, or FEHB carrier, a statement as to whether the non-initiating party agrees that the initial payment (including \$0 if, for example payment is denied) and the qualifying payment amount reflected in the notice of IDR initiation is accurate for the item or service that is the subject to the dispute, and if not, the initial payment amount (including \$0 if, for example, payment is denied) and/or qualifying payment amount it believes to be correct, and documentation to support the statement (for example, the remittance advice confirming the

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

qualifying payment amount); (6) if the non-initiating party is a plan, issuer, or FEHB carrier, the amount of cost sharing imposed for the item or service; (7) if the non-initiating party is a provider or facility, a statement that the items and services do not qualify for the notice and consent exception described at 45 CFR 149.410(b) or 149.420(c) through (i); (8) with respect to each item or service that is the subject of the dispute, either an attestation that the item or service is a qualified IDR item or service, or for each item or service that the non-initiating party asserts is not a qualified IDR item or service, an explanation and documentation to support the statement; (9) a statement confirming that the initial payment or notice of denial of payment or other remittance provided by the initiating party at proposed 26 CFR 54.9816-8(b)(1)(ii)(A)(12), 29 CFR 2590.716-8(b)(1)(ii)(A)(12), and 45 CFR 149.510(b)(1)(ii)(A)(12) is accurate, and if inaccurate, a copy of the accurate initial payment or notice of denial of payment or other remittance required to include the disclosures under 26 CFR 54.9816-6T(d)(1), 29 CFR 2590.716-6(d)(1), and 45 CFR 149.140(d)(1) with respect to the item or service; (10) a statement as to whether any of the information provided in the notice of IDR initiation is inaccurate and the basis for the statement as well as any supporting documentation; and (11) a statement as to whether the non-initiating party agrees or objects to the initiating party's preferred certified IDR entity. If the non-initiating party objects to the initiating party's preferred certified IDR entity, the notice of IDR initiation response must include the name of an alternative preferred certified IDR entity and, if applicable, an explanation of any conflict of interest with the initiating party's preferred certified IDR entity.

- vii. *Certified IDR Entity Selection.* The parties to the Federal IDR process may jointly select a certified IDR entity not later than 3 business days after the date of IDR initiation. The initiating party chooses a preferred certified IDR entity, which is named on the notice of IDR initiation. If the non-initiating party agrees or fails to object to the initiating party's preferred certified IDR entity within 3 business days after the date of IDR initiation, the initiating party's preferred certified IDR entity would be considered jointly selected by the parties. However, if on the notice of IDR initiation response the non-initiating party objects to the initiating party's preferred certified IDR entity, the non-initiating party must designate an alternative preferred certified on that form within the 3-business-day timeframe after the date of IDR initiation. If the non-initiating party objects in this manner, the initiating party is required to agree or object to the alternative preferred certified IDR entity using the notice of certified IDR entity selection. If the initiating party has not responded to the non-initiating party's alternative preferred certified entity within 3 business days after the date of IDR initiation, then the alternative preferred certified IDR entity would be considered jointly

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

selected by the parties. However, if the non-initiating party submits the notice of IDR initiation response with an alternative preferred certified IDR entity and the initiating party does not agree to that alternative preferred certified IDR entity on the same day, the parties would have failed to jointly select a certified IDR entity. The 2023 proposed rules allow the parties to go back and forth in selecting and responding to a selection of an alternative preferred certified IDR entity within the 3-business-day period after IDR initiation. All of this is submitted through the Federal IDR portal. The data elements contained in the notice of IDR initiation and notice of IDR initiation response inform this process in the communication. However, if there is disagreement after that communication and before the 3-business-day period after IDR initiation, the parties would use the notice of certified IDR entity selection. The information required in that notice are: (1) a statement indicating the party's agreement with or objection to the other party's alternative preferred certified IDR entity; (2) if applicable, a statement explaining any conflicts of interest that have contributed to the party's objection to the selected alternative preferred certified IDR entity; and (3) the name of another alternative preferred certified IDR entity.

- viii. *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, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the dispute number, a statement of the out-of-network rate for the qualified IDR item or service (that is, the total payment amount, including both cost sharing and the total plan or coverage payment), an allocation of how the parties agree to pay certified IDR entity fee (if the parties choose not to evenly split the fee), and signatures from an authorized signatory for each party.
- ix. *Withdrawal.* A dispute may be withdrawn from the Federal IDR process by the initiating party, the Departments, or a certified IDR entity before a payment determination is made if one of the following conditions met: (1) the initiating party provides notification through the Federal IDR portal to the Departments and the certified IDR entity (if selected) that both parties agree to withdraw the dispute from the Federal IDR process without agreement on an out-of-network rate; the notification must include the dispute number, a statement about both parties' agreement to withdraw and signatures from authorized signatories for both parties; (2) the initiating party provides notification through the Federal IDR portal to the Departments, the certified IDR entity (if selected), and the non-

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

initiating party of its request to withdraw the dispute through the Federal IDR portal and the non-initiating party notifies the Departments, certified IDR entity (if selected), and initiating party of its agreement to withdraw through the Federal IDR portal within 5 business days of the initiating party's request. If the non-initiating party fails to respond within 5 business days of the initiating party's request, the non-initiating party will be considered to have agreed to the withdrawal, and the dispute will be withdrawn; (3) the certified IDR entity or the Departments cannot determine eligibility because both parties are unresponsive to any requests for additional information to determine eligibility; or (4) the certified IDR entity cannot make a payment determination because both parties have failed to submit an offer.

- x. *Notice of Offer.* Not later than 10 business days after the date of the certified IDR entity final selection (or, under the 2023 proposed rules, not later than 10 business days after the qualified IDR items and services are determined to be eligible for the Federal IDR process when the departmental eligibility review process is in effect), 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. 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, issuer, or FEHB carrier 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). The offer must include the QPA for the applicable year for the same or similar items or services. 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 may also submit any additional information relating to the offer for the payment

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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 Federal IDR portal collects this information as part of the offer submission process, such that certified IDR entities will not have to directly request this information.

- xi. IDR Payment Determination.* Not later than 30 business days after the selection of the certified IDR entity (or, under the 2023 proposed rules, not later than 30 business days if the Departments determine that extenuating circumstances necessitate extension of timeframes as set forth under proposed 26 CFR 54.9816-8T(g), 29 CFR 2590.716-8(g), and 45 CFR 149.510(g)), 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 identify which of the parties' offers the certified IDR entity selected to be the appropriate out-of-network rate for the qualified IDR item or service. The certified IDR entity must provide an explanation of the decision that includes 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 information submitted by a party in compliance with the rules. For batched payment determinations, the certified IDR entity's written decision must identify for each qualified IDR item or service which of the parties' offers is selected to be the appropriate out-of-network rate for the item or service. In addition, the certified IDR entity should indicate which party prevails in the overall payment determination, which will be the party with the higher number of determinations in its favor, should each party receive at least one favorable determination. If each party prevails in an equal number of determinations, neither party will be considered the prevailing party.
- xii. 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. Under the 2023 proposed rules, the Departments could also provide an extension of the time periods if they identify unforeseen or good cause delays on a case-by-case basis, as opposed to solely

relying on one of the parties to submit an extension request. The Departments may detect these issues before either party would and could immediately grant the necessary extension without having to wait for the submission of a formal request. As under the current rules, the certified IDR entity or either party may request an extension by submitting a request for an extension due to extenuating circumstances to the Departments through the Federal IDR portal including an explanation of the extenuating circumstances and why the extension is needed. The party requesting the extension must identify and attach all relevant documentation to support the reasons for requesting the extension, and 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 under the circumstances. Under the 2023 proposed rules, the Departments may extend applicable time periods (other than the timing of the payments following a final determination or settlement) when the Departments determine that the parties or certified IDR entity cannot meet applicable timelines due to systematic delays in processing disputes under the Federal IDR process, such as an unforeseen volume of disputes or Federal IDR portal system failures.

- xiii. IDR Certification.* The October 2021 interim final rules provide that an IDR entity must 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 set forth in 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.
- xiv. 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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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.

- xv. *Administrative Fee.* Under Code section 9816(c)(8), ERISA section 716(c)(8), PHS Act section 2799A-1(c)(8), and the October 2021 interim final rules, each party to a determination must pay an administrative fee for participating in the Federal IDR process. Previously, the certified IDR entity collected the administrative fee directly from the parties at the time such certified IDR entity was selected. Under the 2023 proposed rules, the Departments propose to collect the administrative fee due from each party for participating in the Federal IDR process directly. The Departments also propose to require the initiating party to pay the administrative fee within 2 business days of the date of preliminary selection of certified IDR entity pursuant to proposed 26 CFR 54.9816-8(c)(1)(iii), 29 CFR 2590.716-8(c)(1)(iii), and 45 CFR 149.510(c)(1)(iii). The Departments further propose that the non-initiating party must pay the administrative fee within 2 business days of the date of notice that an eligibility determination for the Federal IDR process has been reached by either the certified IDR entity or the Departments, if the departmental eligibility review applies as proposed in 26 CFR 54.9816-8(c)(2)(ii), 29 CFR 2590.716-8(c)(2)(ii), and 45 CFR 149.510(c)(2)(ii).
- xvi. *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.

A 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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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).

- xvii. *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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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.

- xviii. *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, issuer, or FEHB carrier, 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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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.

- xix. *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 Notices of IDR Initiations submitted to the certified IDR entity that pertain to air ambulance services during the immediately preceding month; the number of such notices 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, specified by 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, issuer, or FEHB carrier 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.

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, the August 2022 final rules, and 2023 proposed 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. However, under the 2023 proposed rules, these notices, along with the proposed “Open Negotiation Response Notice” and “Notice of IDR Initiation Response” would be required to be submitted electronically through the Federal IDR portal using the standard forms developed by the Departments. The Departments have established the Federal IDR portal to administer the Federal IDR Process, available at <https://www.nsa-idr.cms.gov>.

Additionally, use of the Federal IDR portal would also be required to satisfy various other requirements, including, selection of the certified IDR entity, the submission of offers, and notification to the Departments and certified IDR entity (if selected) of an agreement by the parties to an out-of-network rate for the qualified IDR item or service after providing the notice of IDR initiation to the Departments. The Departments are of the view that mandatory use of the Federal IDR portal would better ensure that certified IDR entities and the Departments can satisfy the timeline and process requirements of the Federal IDR process.

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 No Surprises Act, October 2021 interim final rules, and August 2022 final rules amend and add provisions to existing rules under the PHS Act, ERISA, and the Code.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

The 2023 proposed rules would further amend such rules. 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 need to satisfy requirements under the October 2021 interim final rules and August 2022 final rules, and if the 2023 proposed rules are implemented, the requirements under such 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;⁴ 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. The 2023 proposed rules would permit additional flexibility in batching by adding, in addition to the existing batching policy, two new ways to batch multiple qualified IDR items and services: 1) if they were furnished during a single patient encounter; and 2) for anesthesiology, radiology, pathology, and laboratory qualified IDR items and services, items and services

⁴This requirement from the October 2021 interim final rules was vacated by *Texas Medical Association, et al. v. United States Department of Health and Human Services, et al.*, No. 6:23-cv-00059-JDK (E.D. Tex. Aug. 3, 2023).

would be considered to relate to the treatment of similar conditions when they are furnished to one or more patients and were billed under service codes belonging to the same Category I CPT code ranges..

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, August 2022 final rules, and 2023 proposed rules, if finalized, 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.

Under the 2023 proposed rules, the Departments propose creating a single registry of plans and issuers subject to the Federal IDR process. Initial registration would be required to be completed by the later of [the date that is 30 business days after the effective date of the final rule,] the date that is 30 business days after the registry becomes available, or the date the group health plan or health insurance issuer begins

offering a group health plan or individual health insurance coverage subject to the Federal IDR process. A plan, issuer, or FEHB carrier would be required to report to the Departments changes to the information required under this section within 30 calendar days after the information changes and confirm the accuracy of its registration annually in the fourth quarter of each calendar year. Not implementing this requirement, or requiring plans and issuers subject to the Federal IDR process to update information any less frequently would undermine efforts by the Departments to mitigate communication challenges between disputing parties, including avoiding preventable instances of misdirected correspondence.

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.

In addition to requesting public comment on the proposed regulation, the NPRM solicits public comment on the paperwork burden of the proposed regulation. The Office of Management and Budget has 60 days to review the information, but must allow at least 30 days for public comment. Therefore, the PRA section of the proposed rule requests the public to send comments within 30 days to ensure their consideration. (5 CFR 1320.11(c); 5 CFR 1320.11(e)).

- 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, August 2022 final rules, and 2023 proposed 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, August 2022 final rules, and 2023 proposed 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 following wage rates were used in this analysis: \$132.38 (general or operations manager), \$63.45 (clerical worker), \$134.93 (compensation and benefits manager), and \$208.07 (physician).⁵

Departmental Federal IDR Eligibility Determinations

The Departments anticipate no change or nominal change in burden related to the proposed preliminary Federal IDR dispute eligibility determinations. The same type and quantity of information would continue to be collected from disputing parties to determine eligibility under this proposed rule. When the departmental eligibility review is in effect, the Department would be collecting information related to Federal IDR dispute eligibility. When the departmental eligibility review is not in effect, the Department and the certified IDR entities would be collecting this information. Therefore, the Department is of the view that there is no change in burden associated with changing to whom the parties are submitting eligibility information.

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

The Departments estimate that 420,000 claims will be submitted annually as part of the Federal IDR process each year.

The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. Accordingly, the Departments estimate that 560,000 claims will go through open negotiation.⁶ The Departments estimate that, on average, it will take a compensation and benefit manager 2 hours to write each “Open Negotiation Notice” and a clerical worker 15 minutes to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$286. For all 560,000 claims subject to the interim final rules going through the Federal IDR process, the annual burden would be 1,260,000 hours,

⁵ Internal DOL calculation based on 2023 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>.

⁶ This is calculated $420,000 / (1 - 0.25) = 560,000$.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

with an associated equivalent cost of \$160 million.⁷ 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, issuer, or FEHB carrier regarding such item or service.

The Departments propose to require the party to provide an open negotiation notice and supporting documentation to the other party and the Departments to initiate the open negotiation period. Furthermore, the party in receipt of the open negotiation notice would be required to provide a response to the open negotiation notice that is provided to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period. The Departments estimate that it would take a compensation and benefits manager 30 minutes and an office clerk 15 minutes on average to prepare and submit the additional information for open negotiation for each plan, issuer, or FEHB carrier and provider or facility initiating open negotiation. This results in a cost of \$83 per party per open negotiation notice. Similarly, the Departments estimate that it would take a compensation and benefits manager 30 minutes and an office clerk 15 minutes on average to prepare and submit the proposed open negotiation response notice for each party in receipt of the open negotiation notice, resulting in a cost of \$83 per party per open negotiation response notice. Accordingly, the Departments estimate that 560,000 initiating parties to prepare and submit the additional materials proposed for the open negotiation notice and 560,000 non-initiating parties to prepare and submit the additional materials proposed for the open negotiation notice response notice. For the 1,120,000 claims, this results in a total annual hour burden of 840,000 hours, with an annual equivalent cost estimate of \$93.3 million.⁸

The Departments also propose to collect one new information collection element in the Federal IDR portal associated with the administrative fee. The Departments propose to require the initiating party to attest (for example, by checking a box) in the portal that no offer made by either party during open negotiation exceeded a predetermined threshold, in order to determine if the parties should be charged the reduced administrative fee for low-dollar disputes. The Departments are of the view that checking this box will take a *de minimis* amount of time in the context of the total time it takes for the initiating party to initiate a dispute.

7 The burden is estimated as follows: 560,000 claims x 2 hours + 560,000 claims x 0.25 hour = 1,260,000 hours. A labor rate of \$134.93 is used for a compensation and benefit manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 560,000 claims x 2 hours x \$134.93 + 560,000 claims x 0.25 hours x \$63.45 = \$160,004,600. Labor rates are EBSA estimates.

8 The burden is estimated as follows: 1,120,000 claims x 0.5 hours + 1,120,000 claims x 0.25 hours = 840,000 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor 1are applied in the following calculation: 1,120,000 claims x 0.5 hours x \$134.93 + 1,120,000 claims x 0.25 hours x \$63.45 = \$93,326,800. Labor rates are EBSA estimates.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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 2 hours for a compensation and benefit manager to write the “Notice of IDR Initiation” and 15 minutes for a clerical worker to prepare and send the initiating notice. The burden for each plan, issuer, FEHB carrier, provider, and facility would be 2.25 hours, with an equivalent cost of approximately \$286. For the 420,000 claims initiating the Federal IDR process, the annual burden would be 945,000 hours, with an annual equivalent cost estimate of \$120 million.⁹

The Departments propose that, to initiate the Federal IDR process, the initiating party must submit a written notice of IDR initiation to the non-initiating party and to the Departments (using the standard form developed by the Departments) during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The Departments also propose that the non-initiating party must submit a written response to the notice of IDR initiation to the initiating party and to the Departments (using the standard form developed by the Departments) during the 3-business-day period beginning on the day after the notice of IDR initiation is received by the Departments. Further, the Departments propose to collect the taxpayer identification number of the disputing parties on the Notice of IDR Initiation or written response to the notice of IDR initiation. The Departments are of the view that it would take a *de minimis* amount of time to include the taxpayer identification number on the notice of initiation from the initiating party and the written response to the notice of IDR initiation from the non-initiating party, which would be required to link debts owed by the disputing parties to the Departments.

The Departments estimate that it would take a compensation and benefits manager 30 minutes and an office clerk 15 minutes on average to prepare and submit the additional statements proposed for the notice of IDR initiation for each initiating party, resulting in a cost of \$83 per party per notice of IDR initiation. Similarly, the Departments estimate that it would take a compensation and benefits manager 30 minutes and an office clerk 15 minutes on average to prepare and submit the proposed IDR initiation response notice for each non-initiating party, resulting in a cost of \$83 per party per IDR initiation response notice. The Departments estimate that 420,000 disputes would be initiated, requiring

⁹ The burden is estimated as follows: 420,000 claims x 2 hours + 420,000 claims x 0.25 hours = 945,000 hours. A labor rate of \$134.93 is used for a compensation and benefit manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 420,000 claims x 0.25 hours x \$134.93 + 420,000 claims x 2 hours x \$63.45 = \$120,003,450. Labor rates are EBSA estimates.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

work by 840,000 disputing parties. For the 840,000 claims associated with additional materials proposed for the Notice of IDR Initiation, the annual hour burden would be 630,000 hours, with an equivalent cost estimate of \$70 million for 420,000 disputes annually.¹⁰

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 compensation and benefit manager 30 minutes to write each agreement and a clerical worker 15 minutes to submit the agreement to the Federal IDR portal. The burden for each plan, issuer, FEHB carrier, provider, and facility would be 45 minutes, with an equivalent cost of approximately \$83. For the 4,200 payment determinations resolved in this manner, the annual burden would be 3,150 hours, with an associated equivalent cost of \$0.3 million.¹¹

Under the 2023 proposed rules, this information collection would be limited to those disputes in which either party does not agree to the other party's preferred alternative certified IDR entity. For this subset of disputes, the initiating party would be required to submit the notice of certified IDR entity selection to indicate agreement or objection to the non-initiating party's alternate preferred certified IDR entity selection as indicated in the notice of IDR initiation response, and both parties would have the ability to submit the notice back-and-forth during the 3-business-day period after the date of IDR initiation until an agreed upon entity is identified or the parties fail to jointly agree. The content of the collection would be revised to only require a party to indicate their agreement or objection and if applicable an explanation of the conflict of interest, and identification of an alternate preferred certified IDR entity and thus the Departments anticipate that it

10 The burden is estimated as follows: 840,000 claims x 0.5 hours + 840,000 claims x 0.25 hours = 630,000 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 840,000 claims x 0.5 hours x \$134.93 + 840,000 claims x 0.25 hours x \$63.45 = \$69,995,100. Labor rates are EBSA estimates.

11 The burden is estimated as follows: 420,000 claims x 1 percent x 0.5 hours + 420,000 claims x 1 percent x 0.25 hours = 3,150 hours. A labor rate of \$134.93 is used for a compensation and benefit manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 420,000 claims x 1 percent x 0.5 hours x \$134.93 + 420,000 claims x 1 percent x 0.25 hours x \$63.45 = \$349,976. Labor rates are EBSA estimates.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

would take a respondent much less time to submit this information than previously estimated.

Based on internal data, in approximately 29 percent of disputes, the non-initiating party objects to the certified IDR entity selected by the initiating party. Further, out of the 29 percent of disputes in which the non-initiating party objected to the certified IDR entity selected by the initiating party, the majority of those disputes (93 percent, or 27 percent of all disputes) the initiating party agreed to the alternate preferred certified IDR entity selected by the non-initiating party. In a very small percentage (approximately 2 percent) of disputes, the non-initiating party and initiating party engage in a back-and-forth by objecting to each other's preferred certified IDR entities multiple times. Based on the number of disputes submitted as of summer 2023, the Departments estimate that approximately 113,400 disputes would require the initiating party to submit a notice of certified IDR entity selection form a single time. The Departments estimate that it would take a clerical worker 30 minutes on average to prepare and submit the notice indicating agreement or objection to the alternate preferred certified IDR entity and selecting an alternative entity, if applicable. This would result in a cost of \$31.73 per dispute. For the approximately 113,400 disputes that would require this collection, the total annual hourly burden would be 56,700 hours, with an equivalent annual cost of approximately \$3.6 million.¹²

In addition, the Departments expect that, for a small proportion of disputes, the initiating party and the non-initiating party would exchange the notice of certified IDR entity selection multiple times within the proposed timeframe before reaching agreement and jointly selecting or defaulting to random selection. To reflect the additional burden associated with disputes requiring multiple notices, the Departments conservatively estimate that approximately 8,400 disputes would require the provision of total rounds of notice exchange¹³ by the initiating party and non-initiating party before either jointly selecting a certified IDR entity or defaulting to selection by the Departments. This would result in a cost of \$63.45 per dispute, and a total annual hourly burden of 8,400 hours with an equivalent cost of \$0.5 million.¹⁴

Additionally, no later than 10 business days after the date of selection of the certified IDR

12 The burden is estimated as follows: 113,400 claims x 0.5 hours = 56,700 hours. A labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 113,400 claims x 0.5 hours x \$63.45 = \$3,597,615.

13 Internal data show that the highest number of times a certified IDR entity was selected for a single dispute was five. Since the 2023 proposed rules would amend the frequency of use of the notice of certified IDR entity selection by transferring one of the selection instances to the notice of IDR initiation, five unique selections would correspond to four exchanges of the notice of certified IDR entity selection.

14 The burden is estimated as follows: 8,400 claims x 1 hour = 8,400 hours. A labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 8,400 claims x 1 hour x \$63.45 = \$532,980.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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. With the information requested by the certified IDR entity, the parties must include: (A) the coverage area of the plan, issuer, or FEHB carrier and the relevant geographic region for purposes of the QPA; (B) whether the coverage is fully insured, or fully or partially self-insured, as applicable; and (C) the QPA. The parties may also submit to the certified IDR entity any information relating to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, except that the information may not include information on factors described in paragraph 26 CFR 54.9816-8T(c)(4)(v), 29 CFR 2590.716-8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). The Departments estimate that for providers, issuers, providers, and facilities it will take an average of 2.5 hours for a compensation and benefit manager to write the offer and 30 minutes for a clerical worker to prepare and send the offer. The burden for each plan, issuer, and FEHB carrier would be 3 hours, with an equivalent cost of approximately \$369. For the 420,000 payment determinations that will go through submission of offer, the annual burden would be 2,520,000 hours, with an annual equivalent cost estimate of \$310 million.¹⁵

Finally, the Departments propose to establish a process for disputes to be withdrawn from the Federal IDR process. The proposed withdrawal process would require the creation of a new collection of information and increase burden on the initiating and non-initiating parties required to submit the proposed notice. The 2023 proposed rules would require the initiating party to submit a withdrawal request to the Departments and the non-initiating party through the Federal IDR portal. The non-initiating party would then be required to provide a response within 5 business days indicating agreement or objection to the request for withdrawal. Each dispute would therefore require a collection from both the initiating (requesting) and the non-initiating (responding) parties in order to withdraw. If the non-initiating party fails to respond, the non-initiating party would be considered to have agreed to the dispute's withdrawal. The Departments expect that dispute withdrawals would be relatively rare: Based on internal data, the Departments anticipate that approximately 4 percent of disputes (or 16,800 disputes) would be withdrawn annually.

The Departments estimate that it would take a compensation and benefits manager

¹⁵ The burden is estimated as follows: $(420,000 \text{ claims} \times 2.5 \text{ hours} + 420,000 \text{ claims} \times 0.5 \text{ hours}) + (420,000 \text{ claims} \times 2.5 \text{ hours} + 420,000 \text{ claims} \times 0.5 \text{ hours}) = 2,520,000 \text{ hours}$ for providers and issuers. A labor rate of \$134.93 is used for a compensation and benefit manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: $(420,000 \text{ claims} \times 2.5 \text{ hours} \times \$134.93 + 420,000 \text{ claims} \times 0.5 \text{ hours} \times \$63.45) + (420,000 \text{ claims} \times 2.5 \text{ hours} \times \$134.93 + 420,000 \text{ claims} \times 0.5 \text{ hours} \times \$63.45) = \$310,002,000$. Labor rates are EBSA estimates.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

approximately 15 minutes and a clerical worker approximately 15 minutes on average for the initiating party to prepare and submit the notice of request for withdrawal to the non-initiating party and the Departments through the Federal IDR portal, resulting in a cost of \$49.60 per dispute for the initiating party. For the anticipated 16,800 withdrawn disputes annually, initiating parties would incur a total of 8,400 burden hours with an equivalent cost burden of \$833,196 to submit withdrawal requests annually.¹⁶ Because the notice of withdrawal response would have fewer data elements and would require a lower amount of time and labor burden to submit, the Departments estimate that it would take an office clerk approximately 15 minutes on average for the non-initiating party to submit the notice of withdrawal response to the initiating party and the Departments through the Federal IDR portal, resulting in a cost of \$15.86 per response. For the anticipated 16,800 withdrawn disputes annually, the non-initiating party would incur a total of 4,200 burden hours or an equivalent cost burden of \$266,490 to submit withdrawal responses annually.¹⁷ This results in a total estimated annual burden of 12,600 hours or an equivalent cost burden of \$1.1 million across both the initiating and non-initiating parties.¹⁸

Summary

The total hour burden associated with the Federal IDR process for nonparticipating provider and nonparticipating facility claims, excluding nonparticipating providers of air ambulance services, is 6,275,850 hours with an equivalent cost of \$758,912,207.

Half of the burden associated with the Federal IDR process for hospital and emergency departments is estimated to be allocated to health care plans, issuers, and FEHB carriers, and the other half is estimated to be allocated to health care providers and facilities. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, DOL and the Department of the Treasury will each account for 25 percent of the burden, and OPM will account for 5 percent of the burden.

The hour burden associated with DOL requirements is estimated to be approximately 1,568,963 hours at an equivalent cost of \$189,728,052.

16 The burden is estimated as follows: (16,800 claims x 0.25 hours) + (16,800 claims x 0.25 hours) = 8,400 hours. The labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculations: (16,800 claims x 0.25 hours x \$134.93) + (16,800 claims x 0.25 hours x \$63.45) = \$833,196.

17 The burden is estimated as follows: 16,800 claims x 0.25 hours = 4,200 hours. A labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculations: 16,800 claims x 0.25 hours x \$63.45 = \$266,490.

18 This is calculated as follows: 8,400 total initiating party burden hours + 4,200 total non-initiating party burden hours = 12,600 total burden hours. \$833,196 total initiating party cost + \$266,490 total non-initiating party cost = \$1,099,686 total cost across both parties.

Request of Extension of Time Periods for Extenuating Circumstances

Under the October 2021 interim final rules the Departments may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause, such as due to a natural disaster that prevents certified IDR entities, providers, facilities, providers of air ambulance services, plans, or issuers from complying with an applicable time period. Under the 2023 proposed rules, the Departments, or at the request of a certified IDR entity or a party, would determine whether an extension is necessary because the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of the certified IDR entity or one or both parties, or for other good cause.

The Departments anticipate that codifying the ability of certified IDR entities to submit case-by-case extension requests in the same manner as parties would slightly increase the estimated burden associated with collecting requests for extensions. In general, the Departments maintain the expectation that requests for extensions due to extenuating circumstances would be relatively limited, and do not expect that certified IDR entities would submit a high volume of requests for extensions, particularly since the 2023 proposed rules also propose to codify the Departments' ability to grant case-by-case extensions of their own initiative without a prior request from certified IDR entities or parties. Based on internal data, the Departments anticipate that certified IDR entities would submit approximately 20 such requests for extensions annually.

The Departments estimate that it would take a clerical worker approximately 15 minutes on average to prepare and submit the Request for Extension due to Extenuating Circumstances form. Based on internal data reflecting the number of extension requests submitted by certified IDR entities, the Departments estimate that approximately 20 extensions requests would be submitted by certified IDR entities annually. Accordingly, the Departments estimate that the burden associated with the submission of the extension request notice by certified IDR entities would result in a total annual burden of 5 hours with an equivalent cost of approximately \$317¹⁹ across all certified IDR entities in addition to the existing burden estimate for extension requests submitted by plans, issuers, FEHB carriers, providers, facilities, and air ambulance services providers.

Summary

The total hour burden associated with requests for extension is 5 hours with an equivalent

¹⁹ The burden is estimated as follows: 20 annual requests x 0.25 hours = 5 hours. A labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: 20 annual requests x 0.25 hours x \$63.45 hourly rate = \$317.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

cost of \$317. Half of the burden is estimated to be allocated to health plans, issuers, FEHB carriers, or TPAs, and the other half is estimated to be allocated to health care providers, facilities, and providers of air ambulance services. The burden is assumed to be shared by the Departments and OPM. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, DOL and the Department of the Treasury will each account for 25 percent of the burden, and OPM will account for 5 percent of the burden.

The hour burden associated with DOL requirements is estimated to be approximately 1 hour at an equivalent cost of \$79.

ICRs Regarding Registration of Group Health Plans and Health Insurance Issuers

The 2023 proposed rules would require plans and issuers that are subject to the Federal IDR process to register and submit certain information to the Departments.

The Departments assume that TPAs would provide this information on behalf of self-insured plans. The Departments estimate that a total of 1,705 issuers and TPAs would incur a burden to comply with this provision. The Departments estimate that for each issuer and TPA, an administrative assistant would spend 8 hours, a compensation and benefits manager would spend 2 hours (at an hourly rate, and a lawyer 2 hours to prepare the registration and provide the necessary information. The estimated total burden for each issuer or TPA would be 12 hours with an equivalent cost of approximately \$1,096. The estimated total first year cost for initial registration and submission of information would be 17,050 hours, with an equivalent cost of \$1.9 million.²⁰

The proposed rule also requires that plans update the information associated with their registration no later than 30 days after such information changes or at least annually. The Departments estimate that for each issuer and TPA, an administrative assistant would spend 30 minutes, and a compensation and benefits manager would spend 15 minutes to update information in a timely way when such information changes. The estimated total burden for each issuer or TPA would be 0.75 hours with an equivalent cost of approximately \$65.46. The Departments estimate that updating information in a timely way would incur an annual total cost for all issuers and TPAs of approximately 1,279 hours with an equivalent cost of approximately \$0.1 million.²¹

20 The burden is estimated as follows: (1,705 issuers and TPAs x 2 hours) + (1,705 issuers and TPAs x 2 hours) + (1,705 issuers and TPAs x 8 hours) = 17,050 hours. A labor rate of \$159.34 is used for a lawyer, a labor rate of \$134.93 is used for a compensation and benefits manager, and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: (1,705 issuers and TPAs x 2 hours x \$159.34) + (1,705 issuers and TPAs x 2 hours x \$134.93) + (1,705 issuers and TPAs x 8 hours x \$63.45) = \$1,868,918. Labor rates are EBSA estimates.

21 The burden is estimated as follows: (1,705 issuers and TPAs x 0.5 hours) + (1,705 issuers and TPAs x 0.25

Summary

The total hour burden in the first year associated with the registration of group health plans and health plan issuers is 21,739 hours with an equivalent cost of \$1,980,524. The total hour burden in subsequent years associated with the registration of group health plans and health plan issuers is 1,279 hours with an equivalent cost of \$111,605. The three-year average hour burden associated with the registration of group health plans and health plan issuers is 8,099 hours with an equivalent cost of \$734,578.

The burden associated with this additional information is assumed to be shared by the Departments. HHS is assumed to cover 50 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden.

For DOL, the total hour burden in the first year associated with the registration of group health plans and health plan issuers is 5,435 hours with an equivalent cost of \$495,131. The total hour burden in subsequent years associated with the registration of group health plans and health plan issuers is 320 hours with an equivalent cost of \$27,901. The three-year average hour burden associated with the registration of group health plans and health plan issuers is 2,025 hours with an equivalent cost of \$183,644.

Total Hour Burden Summary

In the first year, the total annual hour burden associated with the Federal IDR process is 10,052,080 hours with an equivalent cost burden of \$1,079,900,719. In subsequent years, the total annual hour burden associated with the Federal IDR process is 10,031,620 hours with an equivalent cost burden of \$1,078,031,800. Thus, the 3-year average hour burden associated with the Federal IDR process is 10,038,440 hours with an equivalent cost burden of \$1,078,654,773.

The Departments assume that half of the burden associated with the required notices will be allocated to plans, issuers, and FEHB carriers and the other half of the burden will be allocated to providers, facilities, and providers of air ambulance services. The burden of the plans, issuers, and FEHB carriers will be allocated toward the hour burden of DOL, the Department of the Treasury, and OPM, and the burden of the providers, facilities, and providers of air ambulance services will be allocated toward the hour burden of HHS. The burden of the certified IDR entities will be fully allocated toward the cost burden in

hours) = 1,279 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: (1,705 issuers and TPAs x 0.5 hours x \$134.93) + (1,705 issuers and TPAs x 0.25 hours x \$63.45) = \$111,605. Labor rates are EBSA estimates.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

Question 13.

For DOL requirements, the total hour burden in the first year associated with the Federal IDR process is 1,574,399 hours with an equivalent cost burden of \$190,223,262. In subsequent years, the total hour burden associated with the Federal IDR process is 1,569,284 hours with an equivalent cost of \$189,756,032. Thus, the 3-year average hour burden associated with the Federal IDR process for DOL is 1,570,989 hours with an equivalent cost burden of \$189,911,775.

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							
Compensation and benefits managers write the Open Negotiation Notice	140,000	1	140,000	2	280,000	\$134.93	\$37,780,400
Clerical workers prepare and send Open Negotiation Notice	140,000	1	140,000	0.25	35,000	\$63.45	\$2,220,750
Compensation and benefits managers prepare and submit the additional materials proposed for the Open Negotiation Notice	280,000	1	280,000	0.5	140,000	\$134.93	\$18,890,200
Clerical	280,000	1	280,000	0.25	70,000	\$63.45	\$4,441,500

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

workers prepare and submit the additional materials proposed for the Open Negotiation Notice							
Compensation and benefits manager write the Notice of IDR Initiation	105,000	1	105,000	2	210,000	\$134.93	\$28,335,300
Clerical workers prepare and send Notice of IDR Initiation	105,000	1	105,000	0.25	26,250	\$63.45	\$1,665,563
Compensation and benefits managers prepare and submit the additional materials proposed for the Notice of IDR Initiation	210,000	1	210,000	0.5	105,000	\$134.93	\$14,167,650
Clerical workers prepare and submit the additional materials proposed for the Notice of IDR Initiation	210,000	1	210,000	0.25	52,500	\$63.45	\$3,331,125
Clerical workers prepare and send the	28,350	1	28,350	0.5	14,175	\$63.45	\$899,404

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

Notice of Selection of Certified IDR Entity a single time							
Clerical workers prepare and exchange the Notice of Selection of Certified IDR Entity multiple times	2,100	1	2,100	1	2,100	\$63.45	\$133,245
Compensation and benefits managers write the Notice of Agreement on an Out-of-Network Rate	1,050	1	1,050	0.5	525	\$134.93	\$70,838
Clerical workers prepare and send Notice of Agreement on an Out-of-Network Rate	1,050	1	1,050	0.25	263	\$63.45	\$16,656
Compensation and benefits manager writes the Offer	210,000	1	210,000	2.5	525,000	\$134.93	\$70,838,250
Clerical workers prepare and submit the Offer	210,000	1	210,000	0.5	105,000	\$63.45	\$6,662,250
Compensation and benefits	4,200	1	4,200	0.25	1,050	\$134.93	\$141,677

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

managers prepare Notice of IDR Withdrawal Request							
Clerical workers prepare Notice of IDR Withdrawal Request	4,200	1	4,200	0.25	1,050	\$63.45	\$66,623
Clerical workers prepare response to Notice of IDR Withdrawal Request	4,200	1	4,200	0.25	1,050	\$63.45	\$66,623
Request for Extension							
Clerical workers prepare and submit the Request for Extension	5	1	5	0.25	1	\$63.45	\$79
Registration of Group Health Plans and Health Insurance Issuers							
Clerical workers provide information for initial registration (first year cost)	426	1	426	8	3,410	\$63.45	\$216,365
Compensation and benefit managers provide information for initial registration (first year cost)	426	1	426	2	853	\$134.93	\$115,028
Lawyers update	426	1	426	2	853	\$159.34	\$135,837

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

registration information for initial registration (first year cost)							
Clerical workers update registration information	426	1	426	0.50	213	\$63.45	\$13,523
Compensation and benefit managers update registration information	426	1	426	0.25	107	\$134.93	\$14,378
Total (3-year Average) ***	420,438	-	1,086,174		1,570,989		\$189,911,775

Note:

* The total number of respondents was calculated in the following manner: 420,000 (Federal IDR process for items and services relating to nonparticipating providers or nonparticipating emergency facilities and air ambulance providers) + 7 (Certified IDR Entity) + 5 (Request for Extension) + 426 (Registration of Group Health Plans and Health Insurance Issuers) = 420,438.

**The total number of responses in the first year and subsequent years was calculated in the following manner: 1,085,700 (Federal IDR Process for Services relating to nonparticipating providers or nonparticipating emergency facilities and air ambulance providers) +5 (Request for Extension) + 43 (Certified IDR Entity) + 426 (Registration of Group Health Plans and Health Insurance Issuers) =1,086,174.

***The three-year average burden has been reported. There are some activities which are incurred only in the first year.

- 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, August 2022 final rules, and 2023 proposed rules consistent with the court orders in *TMA I, II, III, and IV*.

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 Departments estimate that 420,000 claims will be submitted as part of the Federal IDR process each year. The Departments estimate that 25 percent of disputes will be resolved in open negotiation before entering the Federal IDR process. Accordingly, the Departments estimate that 560,000 claims will go through open negotiation.²² The

²² This is calculated $420,000 / (1 - 0.25) = 560,000$.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

Departments assume that 5 percent of these notices would be mailed by the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$19,880.²³

The Departments propose to require the party to provide an open negotiation notice and remittance advice documentation to the other party and the Departments to initiate the open negotiation period. Furthermore, the party in receipt of the open negotiation notice would be required to provide an open negotiation response notice and supporting documentation to the open negotiation notice that is provided to the other party and the Departments no later than the 15th business day of the 30-business-day open negotiation period. The Departments estimate that 453,333 initiating parties to prepare and submit the additional materials proposed for the open negotiation notice and 453,333 non-initiating parties to prepare and submit the additional materials proposed for the open negotiation notice response. For the 1,120,000 claims, the mailing cost is estimated to be \$39,760.²⁴

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 initiating party may furnish 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; The Departments assume that 5 percent of these notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$14,190.²⁵

The Departments propose that, to initiate the Federal IDR process, the initiating party must submit a written notice of IDR initiation to the non-initiating party and to the Departments (using the standard form developed by the Departments) during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The Departments also propose that the non-initiating party must submit a written notice of IDR initiation response to the initiating party and to the Departments (using the standard form developed by the Departments) during the 3-business-day period beginning on the day after the notice of IDR initiation is received by the Departments. If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility select a certified IDR entity, or if they fail to select a

23 This is calculated $560,000 \times 0.05 \times (\$0.05 + \$0.66) = \$19,880$.

24 This is calculated $1,120,000 \times 0.05 \times (\$0.05 + \$0.66) = \$39,760$.

25 This is calculated $420,000 \times 0.05 \times (\$0.05 + \$0.66) = \$14,910$.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

certified IDR entity, they must notify the Departments no later than 1 business day after such 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 assume that 5 percent of these notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$29,820.²⁶

Under the 2023 proposed rules, when either party does not agree to the other party's preferred alternative certified IDR entity, the initiating party would be required to submit the notice of certified IDR entity selection to indicate agreement or objection to the non-initiating party's alternate preferred certified IDR entity selection as indicated in the notice of IDR initiation response, and both parties would have the ability to submit the notice back-and-forth during the 3 day period after IDR initiation until an agreed upon entity is identified or the parties fail to jointly agree. The content of the collection would be revised to only require a party to indicate their agreement or objection and if applicable an explanation of the conflict of interest, and identification of an alternate preferred certified IDR entity and thus the Departments anticipate that it would take a respondent much less time to submit this information than previously estimated.

Based on internal data, in approximately 29 percent of disputes, the non-initiating party objects to the certified IDR entity selected by the initiating party. Further, out of the 29 percent of disputes in which the non-initiating party objected to the certified IDR entity selected by the initiating party, the majority of those disputes (93 percent, or 27 percent of all disputes) the initiating party agreed to the alternate preferred certified IDR entity selected by the non-initiating party. In a very small percentage (approximately 2 percent) of disputes, the non-initiating party and initiating party engage in a back-and-forth by objecting to each other's preferred certified IDR entities multiple times. Based on the number of disputes submitted as of summer 2023, the Departments estimate that approximately 113,400 disputes would require the initiating party to submit a notice of certified IDR entity selection form a single time. For these 91,800 claims, the Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$4,026.²⁷

In addition, the Departments expect that, for a small proportion of disputes, the initiating party and the non-initiating party would exchange the notice of certified IDR entity selection multiple times within the proposed timeframe before jointly selecting or failing to select. To reflect the additional burden associated with disputes requiring multiple

²⁶ This is calculated $840,000 \times 0.05 \times (\$0.05 + \$0.66) = \$29,820$.

²⁷ This is calculated $113,400 \times 0.05 \times (\$0.05 + 0.66) = \$4,026$.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

notices, the Departments conservatively estimate that approximately 8,400 disputes would require the provision of total rounds of notice exchange²⁸ by the initiating party and non-initiating party before either jointly selecting a certified IDR entity or failing to select thereby requiring random selection by the Departments. For these 8,400 claims, the Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$298.²⁹

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. In addition to the information requested by the certified IDR entity, the parties must also include: (A) for providers and facilities, information on the size of the provider's practice or of the facility; (B) for providers and facilities, information on the practice specialty or type (C) for plans and issuers, the coverage area of the plan, issuer, or FEHB carrier and the relevant geographic region for purposes of the QPA; (D) whether the coverage is fully insured, or fully or partially self-insured, as applicable; and (E) the QPA. The parties may also submit to the certified IDR entity any information relating to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, except that the information may not include information on factors described in paragraph 26 CFR 54.9816-8T(c)(4)(v), 29 CFR 2590.716-8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). For the 340,000 payment determinations that will go through submission of offer, the Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$29,820.³⁰

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.³¹ The Departments estimate that, on average, it will take a physician and medical billing specialist 0.5 hours to prepare the payment determination notice at a composite wage rate of \$147.97.³² The burden for each certified IDR entity would be 0.5 hours, with an

28 Internal data show that the highest number of times a certified IDR entity was selected for a single dispute was five. Since the 2023 proposed rules would amend the frequency of use of the notice of certified IDR entity selection by transferring one of the selection instances to the notice of IDR initiation, five unique selections would correspond to four exchanges of the notice of certified IDR entity selection.

29 This is calculated $8,400 \times 0.05 \times (\$0.05 + 0.66) = \$298$.

30 This is calculated $(420,000 \times 0.05 \times (\$0.05 + \$0.66)) + (420,000 \times 0.05 \times (\$0.05 + \$0.66)) = \$29,820$.

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

32 The Department of Labor uses a composite wage rate because different professionals will review different types

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

equivalent cost of approximately \$74. Thus, the total cost burden for all certified IDR entities to prepare this notice for Federal IDR claims will be \$31.1 million.³³

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. For the maintenance and recordkeeping of 420,000 claims, the annual cost burden on the certified IDR entity would be \$13.3 million.³⁴

Finally, the Departments propose to establish a process for disputes to be withdrawn from the Federal IDR process. The proposed withdrawal process would require the creation of a new collection of information and increase burden on the initiating and non-initiating parties required to submit the proposed notice. The 2023 proposed rules would require the initiating party to submit a withdrawal request to the Departments and the non-initiating party through the Federal IDR portal. The non-initiating party would then be required to provide a response within 5 business days indicating agreement or objection to the request for withdrawal. Each dispute would therefore require a collection from both the initiating (requesting) and the non-initiating (responding) parties in order to withdraw. If the non-initiating party fails to respond, the non-initiating party would be considered to have agreed to the dispute's withdrawal. The Departments expect that dispute withdrawals would be relatively rare: Based on internal data, the Departments anticipate that approximately 4 percent of disputes (or 16,800 disputes) would be withdrawn annually. For the 13,600 disputes that the initiating party must prepare and submit the

of claims and groups of individuals. The wage rate of a physician is \$208.07, and the wage rate of a medical billing specialist is \$117.92. (Internal DOL calculation based on 2023 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: $(\$208.07 \times (1/3) + \$117.92 \times (2/3)) = \$147.97$

$33 \ 420,000 \text{ claims} \times 0.5 \text{ hours} \times \$147.97 \text{ as the composite wage rate for a physician and medical billing specialist} = \$31,073,700.$

$34 \text{ The burden is estimated as follows: } (420,000 \text{ claims} \times 30 \text{ minutes}) = 8,667 \text{ hours for providers and issuers. A labor rate of } \$63.45 \text{ is used for a clerical worker. The labor rates are applied in the following calculation: } (420,000 \text{ claims} \times 30 \text{ minutes} \times \$63.45) = \$13,324,500. \text{ Labor rates are EBSA estimates.}$

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

notice the request for withdrawal to the non-initiating party and the 16,800 disputes that non-initiating party must submit the notice of withdrawal response to the initiating party, Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$596.³⁵

Summary

The total cost associated with the Federal IDR process for the plans, issuers, FEHB carriers, the nonparticipating providers, and nonparticipating emergency facilities, excluding nonparticipating providers of air ambulance services, is \$44,567,279.

Half of the burden associated with the Federal IDR process for nonparticipating provider and nonparticipating facility claims, excluding nonparticipating providers of air ambulance services, is estimated to be allocated to health care plans, issuers, and FEHB carriers, and the other half is estimated to be allocated to nonparticipating providers and facilities. HHS, DOL, the Department of the Treasury, and OPM share jurisdiction. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, DOL and the Department of the Treasury will each account for 25 percent of the burden, and OPM will account for 5 percent of the burden. The total cost burden associated with DOL requirements is estimated to be \$11,141,820.

Request of Extension of Time Periods for Extenuating Circumstances

Under the October 2021 interim final rules the Departments may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause, such as due to a natural disaster that prevents certified IDR entities, providers, facilities, providers of air ambulance services, plans, or issuers from complying with an applicable time period. Under the 2023 proposed rules, the Departments, or at the request of a certified IDR entity or a party, would determine whether an extension is necessary because the parties or certified IDR entity cannot meet applicable timeframes due to matters beyond the control of the certified IDR entity or one or both parties, or for other good cause. The Departments anticipate that codifying the ability of certified IDR entities to submit case-by-case extension requests in the same manner as parties would slightly increase the estimated burden associated with collecting requests for extensions. In general, the Departments maintain the expectation that requests for extensions due to extenuating circumstances would be relatively limited, and do not expect that certified IDR entities would submit a high volume of requests for extensions, particularly since these 2023 proposed rules also propose to codify the Departments' ability to grant case-by-case extensions of their own initiative without a

³⁵ This is calculated $(16,800 \text{ claims} \times 0.05 \times (\$0.05 + \$0.66)) + (16,800 \text{ claims} \times 0.05 \times (\$0.05 + \$0.66)) = \596 .

prior request from certified IDR entities or parties. Based on internal data, the Departments anticipate that certified IDR entities would submit approximately 20 such requests for extensions annually. The Departments expect these requests to be submitted through the Federal IDR portal, and therefore have not estimated an associated mailing cost.

IDR Entity Certification and Certified IDR Entity Monthly Reporting

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.³⁶

To be certified as a certified IDR entity, the entity will need to submit an application through the Federal IDR portal demonstrating that it meets the requirements described in the interim final rules. An IDR entity must provide written documentation to the Departments regarding general company information (such as contact information, TIN, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. The IDR entity must have (directly or through contracts or other arrangements) sufficient arbitration and claims administration, managed care, billing and coding, medical, legal, and other expertise, and sufficient staffing. The IDR entity must also establish processes to ensure against conflicts of interest, including to attesting that such conflicts do not exist, as defined under the interim final rules. The IDR entity will also need to demonstrate its financial stability and integrity. The corresponding paperwork (including 3 years of financial statements) will be submitted through the Federal IDR portal. Finally, each IDR entity that the Departments certify must enter into an agreement with the Departments.

The Departments estimate that, on average, it will take a compensation and benefits manager 5.10 hours and a clerical worker 15 minutes to satisfy these requirements for certifications. The burden for each IDR entity would be 5.35 hours, with an equivalent cost of approximately \$704. For the 13 IDR entities that will go through certification, this results in a cost burden of \$9,152 in the first year.³⁷

Certified IDR entities are required to be recertified every 5 years. The Departments

³⁶ According to Center for Medicare and Medicaid Services, there are 13 certified IDR entities. “List of Certified Independent Dispute Resolution Entities.”

<https://www.cms.gov/nosurprises/Help-resolve-payment-disputes/certified-IDRE-list>

³⁷ The burden is estimated as follows: (13 IDR entities x 5.10 hours) + (13 IDR entities x 0.25 hours) = 59 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: (13 IDR entities x 5.10 hours x \$134.93) + (13 IDR entities x 0.25 hours x \$63.45) = \$9,152.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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 compensation and benefits manager 2.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each certified IDR entity would be 2.35 hours, with an equivalent cost of approximately \$299. For the 3 certified IDR entities³⁸ that will go through recertification annually, this results in a cost burden of \$778 in subsequent years.³⁹

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 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 petitioner must use the standard petition notice issued by the Departments and submit any supporting documentation for consideration by the Departments.

The Departments do not have substantial data on how often such a petition will occur; however, the Departments assume that such a petition will be an unusual occurrence. The Departments assume that there will be 5 petitions each year, and it will take, on average, a compensation and benefits manager services manager 2 hours and a clerical worker and 15 minutes to prepare the petition. The burden for each entity submitting petition is estimated to be 2.25 hours, with an equivalent cost of approximately \$286. For the 5 petitions, this results in a cost burden of \$1,429.⁴⁰

For each month, certified IDR entities will be required to report information on their activities to the Departments. The required information will include the number of Notices of IDR Initiation submitted to the certified IDR entity under the Federal IDR process during the immediately preceding month; the number of such Notices of IDR

38 The Departments estimate that, on average, one-fifth of certified IDR entities will need to be recertified each year. Thus, 13 certified entities x 1/5 = 3 certified IDR entities.

39 The burden is estimated as follows: (2 IDR entities x 2.1 hours) + (2 IDR entities x 0.25 hours) = 5 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: (2 IDR entities x 2.1 hours x \$134.93) + (2 IDR entities x 0.25 hours x \$63.45) = \$778.

40 The burden is estimated as follows: (5 petitions x 2 hours) + (5 petitions x 0.25 hours) = 11.3 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: (5 petitions x 2 hours x \$134.93) + (5 petitions x 0.25 hours x \$63.45) = \$1,429.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

Initiation with respect to which a final determination was made; the size of the provider practices and the size of the facilities submitting Notices of IDR Initiation; the number of times the payment amount determined or agreed to exceeded the QPA, specified by items and services; and the total amount of certified IDR entity fees paid to the certified IDR entity.

Additionally, for each notice of IDR initiation for qualified IDR items and services that are not air ambulance services, the certified IDR entity must provide a description of the qualified IDR items and services included with respect to the notice of IDR initiation, 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, issuer, or FEHB carrier (as applicable) and by the provider or facility (as applicable) 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, issuer, or FEHB carrier (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 (as applicable) involved in furnishing each qualified IDR item or service; the identity for each plan, issuer, or FEHB carrier, and provider or facility, with respect to the determination; and for each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

For each month, certified IDR entities will be required to report information on their activities to the Departments relating to air ambulance services. The certified IDR entities will be required to provide 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 "Notices of IDR Initiation" 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 entity 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 certified IDR entity must also provide 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 dollar amount and a percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by such plan, issuer, or FEHB carrier or by the provider or facility; the amount of the offer so selected expressed as a dollar amount and

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

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 determination; and the number of business days elapsed between selection of the certified IDR entity and the determination of the payment amount by the certified IDR entity.

For each month, certified IDR entities will be required to report the information on their activity 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. The burden for each certified IDR entity would be 1.25 hours, with an equivalent cost of approximately \$151. For the 156 certified IDR entities,⁴¹ the annual burden would be 195 hours, with an equivalent cost burden of \$23,524 each year.⁴²

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, issuer, or FEHB carrier; 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 compensation and benefits 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. The burden for each certified IDR entity would be 1.75 hours, with an equivalent cost of approximately \$217. The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.66 for postage. Thus, the mailing cost is estimated to be \$0.11.⁴³ For the 3 certified IDR entities, this results in a cost burden of \$703 each year.⁴⁴

Summary

41 13 IDR entities x 12 months = 156 IDR entities

42 The burden is estimated as follows: (13 IDR entities x 1 hour x 12 reports annually) + (13 IDR entities x 0.25 hours x 12 reports annually) = 195 hours. A labor rate of \$134.93 is used for a compensation and benefits manager and a labor rate of \$63.45 is used for a clerical worker. The labor rates are applied in the following calculation: (13 IDR entities x 1 hour x 12 reports x \$134.93) + (13 IDR entities x 0.25 hours x 12 reports x \$63.45) = \$23,524.

43 This is calculated 3 x 0.05 x (\$0.05 + \$0.66) = \$0.11

44 The burden is estimated as follows: (3 certified IDR entities x 1 hour) + (3 certified IDR entities x 0.75 hour) = 5 hours. A labor rate of \$134.94 is used for a compensation and benefits manager and a labor rate of \$132.38 is used for a general and operations manager. The labor rates are applied in the following calculation: (3 certified IDR entities x 1 hour x \$134.94) + (3 certified IDR entities x 0.75 hours x \$132.38) = \$703.

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

In the first year, the total cost burden associated with the IDR entity certification process is \$34,807. In subsequent years, the total cost burden associated with the IDR entity certification process is \$26,433. The 3-year average cost burden associated with the IDR entity certification is \$29,224.

The burden associated with the IDR entity certification is shared by HHS, DOL, the Department of the Treasury, and OPM. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, DOL and the Department of the Treasury will each account for 25 percent of the burden, and OPM will account for 5 percent of the burden.

The cost burden associated with DOL requirements is \$8,702 in the first year and \$6,608 in subsequent years. The 3-year average cost burden associated with DOL is \$7,306.

Total Cost Burden Summary

The total cost burden in the first year associated with the Federal IDR process is \$45,020,911. In subsequent years, the total cost burden associated with the Federal IDR process is \$45,012,536. Thus, the 3-year average cost burden is \$45,015,328.

The Departments classify the burden borne by IDR entities and certified IDR entities as a cost burden. For certification, re-certification, and monthly reporting requirements, 45 percent of the burden will be allocated toward the cost burden of HHS, while DOL and the Department of the Treasury will each be allocated 25 percent of the burden, and OPM will be allocated 5 percent of the burden.

The total cost burden associated with the DOL requirements in the first year is estimated to be \$11,150,522 and in subsequent years, the total cost burden associated with DOL requirements is estimated to be \$11,148,428. Thus, the 3-year average cost burden associated with DOL requirements is \$11,149,126.

- 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, to employ a contractor to assist with eligibility determinations, and to implement and

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

administer the Federal IDR process. The annual costs associated with the Federal IDR portal and administering the Federal IDR process are estimated to be \$1 million annually.

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

The Departments have updated the number of the IDR disputes that would be submitted annually as part of the Federal IDR process from 22,000 disputes to 420,000 disputes. Therefore, the hour burden has significantly increased.

In addition, the Departments have removed the hour burden for the additional information to be shared with the initial payment or notice of denial of payment, as this burden will now be included in HHS OMB Control Number 0938-1401.

The Departments have also removed the following forms, as they will be included in the following HHS PRA package, “Patient Provider Dispute Resolution Requirements Related to Surprise Billing: Part II (CMS-10853)”:

- Standard Form: Patient-Provider Dispute Resolution (PPDR) Dispute Initiation Form
- Standard Form: Online PPDR Initiation Form
- Standard Notice: Ineligible for PPDR or Additional Information Needed
- Patient-Provider SDR Entity Certification Application Data Elements
- Independent Dispute Resolution and PPDR; Vendor Management Data Elements.
- PPDR Process Data Elements
- Standard Notice: SDR Determination Notice to Parties Provided Under the No Surprises Act
- Standard Notice: SDR Entity Notification to Health Care Providers and Facilities and Uninsured (or Self-Pay) Individuals
- Standard Notice: Uninsured (or Self-Pay) Individual and Provider or Facility Settle on a Payment Amount After Initiating Patient Provider Dispute Resolution.
- Standard Notice: SDR Entity Notification to Health Care Provider or Facility and Uninsured (or Self-Pay) Individual Confirming Receipt of Dispute Settlement and Action
- Standard Notice: Uninsured (or Self-Pay) Individual, Provider or Facility’s Notification to Secretary of Health and Human Services

The Departments have also removed the form, “Good Faith Estimates Template Notice,” as the form has been included in HHS OMB Control Number 0938-1433.

Furthermore, 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 cost burden for the requirement that certified IDR entities collect the administrative fee on behalf of the Departments, as the Departments propose to require each party participating in the Federal IDR process to pay the administrative fee directly to the Departments. The Departments have also added the hour burden for the registration of group health plans and health insurance issuers.

Finally, the Departments have updated the wage rates and postage costs. As a result, the number of responses has increased by 922,628 responses, the hour burden has increased by 1,481,469 hours, and the cost burden has increased by \$10,592,979.

- 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.**

The No Surprises Act requires that the Departments make publicly available certain information on the Federal IDR process for each calendar quarter. The Departments have published reports that are a partial fulfillment of that requirement for the first three calendar quarters of operation for the Federal IDR portal – that is, from April 15, 2022, through December 31, 2022. The Departments intend to issue a complete report for these quarters and each calendar quarter in a subsequent year.

The reports include information on the number of disputes initiated; the number of disputes closed; the types of parties engaged in disputes; the types of services under dispute; and the states in which disputed items and services were provided. The reports also include information on expenditures and administrative fees collected for the Federal IDR process.

- 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.**

The OMB expiration date will be published in the Federal Register following OMB approval. The OMB Control Number will be on the homepage of the portal.

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

Independent Dispute Resolution Process
OMB Control No. 1210-0169
Expiration Date: 06/30/2025

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

There are no statistical methods used in this information collection.