

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

This Information Collection Request (ICR) seeks approval of a new 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 a 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 for initial payments for emergency services. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A-1 to establish a Federal independent dispute resolution (Federal 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 services. More specifically, the Federal IDR provisions may be used to determine the out-of-network rate for certain emergency services, nonemergency items and services furnished by nonparticipating providers at participating health care facilities, where an All-Payer Model Agreement or specified state law does not apply. Section 105 of the No Surprises Act created Code section 9817, ERISA section 717, and PHS Act section 2799A-2 which contain limitations on cost sharing and requirements for initial payments for air ambulance services, and allow plans and issuers and providers of air ambulance services to access the Federal IDR process. CAA provisions that apply to health care providers and facilities, and providers of air ambulance services, such as requirements around cost sharing, prohibitions on balance billing for certain items and services, and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in a new part E.

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The OPM interim final rules amend existing 5 CFR 890.114(a) to include references to the Department of Treasury (Treasury), Department of Labor (DOL), and Department of Health and Human Services (HHS) interim final rules to clarify that pursuant to 5 U.S.C. 8902(p), FEHB carriers are also subject to the Federal IDR process set forth in those regulations with respect to an item or service eligible for determination through open negotiation or 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. Through new 5 CFR 890.114(d), OPM adopts the Departments' interim final rules as conformed by terms unique to the FEHB Program. In 5 CFR 890.114(d), OPM adopts the Departments' rules as necessary to properly integrate with existing FEHB Program structure and sets forth circumstances in which OPM will enforce these rules as applied to FEHB carriers. The OPM interim final rules require carrier notice to the OPM Director (herein, the Director) of a carrier's intent to initiate, or receipt of a provider's notice to initiate, the Federal IDR process. The Director will coordinate with the Departments in matters regarding FEHB carriers requiring resolution under the Federal IDR process and with respect to oversight of certified IDR entities' reports regarding FEHB carriers. As discussed in the July 2021 interim final rule, all out-of-network rate determinations regarding IDR items or services eligible for determination through open negotiation or the Federal IDR process under the No Surprises Act with respect to FEHB plans or carriers that are not resolved by open negotiation are subject to the Federal IDR process unless OPM contracts with FEHB carriers include terms that adopt state law as governing for this purpose.

The Departments of Labor, Health and Human Services and the Treasury (Departments) and OPM have each submitted a request for a new ICR containing the information collection requirements for the Federal IDR process created by the No Surprises Act to be processed as an Emergency Clearance Request in accordance with section 5 CFR 1320.13 of the Paperwork Reduction Act, Emergency Processing. The Emergency processing request under the PRA is being requested on the same basis that good cause was found by the Departments and the OPM to issue these interim final rules. The Departments and OPM have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until after a full public notice and comment process has been completed. Although this effective date may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions in the No Surprises Act, this timeframe would not provide sufficient time for the regulated entities to implement the requirements.

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 information requirements of the interim final rules have 10 components, described below. 8 of the requirements consist of notices necessary for the Federal IDR process, 2 of the requirements are associated with the certification of IDR entities, and the remaining requirement is a reporting requirement for certified IDR entities. These notices also apply to FEHB carriers.

- i. Open Negotiation Notice.* Before accessing the Federal IDR process to determine the out-of-network rate for a qualified item or service, the parties must engage in a 30-business-day open negotiation period to attempt to reach an agreement regarding the total out-of-network rate (including any cost sharing). To initiate the open negotiation period, the initiating party must provide notice to the other party within 30 business days of the receipt of initial payment or notice of denial of payment for the qualified item or service. The open negotiation notice must include information sufficient to identify the items or services subject to negotiation, including the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer for the out-of-network rate, and contact information of the party sending the open negotiation notice.
- ii. Notice of IDR Initiation.* When the parties do not reach an agreed upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process by submitting the Notice of IDR Initiation to the other party and to the Departments during the 4-business day period beginning on the 31st business day after the start of the open negotiation period. An FEHB carrier must in addition notify the Director OPM. The Notice of IDR Initiation must include: (1) information sufficient to identify the qualified IDR items or services (and whether the qualified IDR items or services are designated as batched items and services), including the dates and location of the items or services, the type of qualified IDR items or services (such as emergency services, post-stabilization services, professional services, hospital-based services), corresponding service and place-of-service codes, the amount of cost sharing allowed and the amount of the initial payment made by the plan or issuer for the qualified IDR items or services, if applicable; (2) the names and contact information of the parties involved, including email addresses, phone numbers, and mailing addresses; (3) the state where the qualified IDR items or services were furnished; (4) the commencement date of the open negotiation period; (5) the preferred certified IDR entity; (6) an attestation that the items or services are

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qualified IDR items and services within the scope of the Federal IDR process; (7) the qualifying payment amount (QPA); (8) information about the QPA as described in 26 CFR 54.9816-6T(f)(1)(v)(C), 29 CFR 2590.716-6(f)(1)(v)(C), and 45 CFR 149.140(f)(1)(v)(C);¹ and (9) general information describing the Federal IDR process.

- iii. *Notice of Certified IDR Entity Selection.* The parties to the Federal IDR process may jointly select a certified IDR entity not later than 3 business days following the date of initiation of the Federal IDR process. The initiating party must notify the Departments by electronically submitting the notice of the certified IDR entity selection or failure to select (as applicable), no later than 1 business day after the end of the 3-business-day period (or, in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal. In addition, in instances where the non-initiating party believes that the Federal IDR process is not applicable, they must notify the Departments through the Federal IDR portal on the same timeframe that the notice of selection (or failure to select) is required and provide information regarding the lack of applicability. If the parties have agreed on a certified IDR entity, the notice of the certified IDR entity selection must include the following information: (1) the name of the certified IDR entity; (2) the certified IDR entity number; and (3) an attestation by both parties (or by the initiating party if the other party did not respond) that the selected certified IDR entity does not have a conflict of interest.
- iv. *Notice of Agreement on an Out-of-Network Rate.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing a Notice of IDR Initiation to the Departments, but before the certified IDR entity has made its payment determination, the initiating party must send a notification to the Departments and to the certified IDR entity (if selected) electronically in a form and manner specified by the Departments in guidance, such as through the Federal IDR portal, as soon as possible but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate (that is, the total payment amount, including both cost sharing and the total plan or coverage payment) and signatures from an authorized signatory for each party.
- v. *Notice of Offer.* Not later than 10 business days after the selection of the certified IDR entity, the plan, issuer, or FEHB carrier and the nonparticipating provider

¹ To satisfy the requirement to provide information about the QPA, the parties should attach the information on the QPA provided under 26 CFR 54.9816-6T(f)(1)(v)(C), 29 CFR 2590.716-6(f)(1)(v)(C), and 45 CFR 149.140(f)(1)(v)(C).

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nonparticipating emergency facility or provider of air ambulance services must each submit a written offer to the certified IDR entity. This offer must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, to facilitate the certified IDR entity reporting the offer as a percentage of the QPA to the Departments. Where batched items and services have different QPAs, the parties should provide these different QPAs and may provide different offers for these batched items and services, provided that the same offer should apply for all items and services with the same QPA. Parties to the IDR process must also submit information requested by the certified IDR entity relating to the offer. This information must, at a minimum, include the information described in 26 CFR 54.9816-8T(c)(4)(i)(A)(2), 29 CFR 2590.716-8(c)(4)(i)(A)(2), and 45 CFR 149.510(c)(4)(i)(A)(2). The provider must specify whether the provider practice or organization has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. Providers and facilities must also provide information on the practice specialty or type, respectively (if applicable). Plans and issuers must provide the coverage area of the plan or issuer, the relevant geographic region for purposes of the QPA, and, for group health plans, whether they are fully-insured, or partially or fully self-insured (or an FEHB carrier, if the item or service relates to FEHB coverage). Parties may also submit any information relating to the offer submitted by either party 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 governmental rates. The Departments intend for the Federal IDR portal to collect this information as part of the offer submission process, such that certified IDR entities will not have to directly request this information.

- vi. *IDR Payment Determination Notice.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must notify the plan, issuer, or FEHB carrier and the provider, facility, or provider of air ambulance services of the selection of the offer and provide the written decision to the parties and the Departments. If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on certain allowable considerations outlined in the rules.
- vii. *Request of Extension of Time Periods for Extenuating Circumstances.* The time

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periods specified in these interim final rules (other than the timing of the payments including, if applicable, to the provider, provider of air ambulance services, or facility) may be extended in the case of extenuating circumstances at the Departments' discretion 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. Parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, including an explanation about the extenuating circumstances that require an extension and why the extension is needed. The party requesting the extension must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable.

- viii. *IDR Certification.* The interim final rules provide that an IDR entity must provide written documentation to the Departments that demonstrates the entity satisfies certain standards and procedures outlined in the 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 how the documentation will be reviewed for certification. The required certification documentation will be submitted by IDR entities through an application on the Federal IDR portal. An IDR entity that satisfies the standards in the interim final rules and guidance issued by the Departments will be provided a certified IDR entity number and will be certified for a 5-year period. IDR entities will need to be recertified every 5 years.
- ix. *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 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 may use the standard petition notice issued by the Departments and submit any supporting documentation for consideration by the Departments. The Departments will make public the list of IDR entities seeking certification, as well as the list of certified IDR entities, to help facilitate the petition process.
- x. *Administrative Fee.* Under Code section 9816(c)(8), ERISA section 716(c)(8), PHS Act section 2799A-1(c)(8), and these interim final rules, each party to a

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determination must pay an administrative fee for participating in the Federal IDR process. The interim final rules require each party to pay the administrative fee to the certified IDR entity at the time the certified IDR entity is selected, regardless of whether that certified IDR entity was selected by the parties or by the Departments.

- xi. Breach Notification.* Following the discovery of a breach of individually-identifiable health information (IIHI), a certified IDR entity must notify 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 notification must include, to the extent possible, the identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach; a brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known; a description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved); a brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address. A certified IDR entity must submit the notification in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.
- xii. Recordkeeping Requirements.* A certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for 6 years. This recordkeeping requirement will help ensure that state and Federal oversight agencies are able to audit past determinations of certified IDR entities and that parties are able to obtain records of the determinations. Certified IDR entities must make these records available for examination by all parties to the dispute, except when disclosure would violate state or Federal privacy laws and regulations, as well as to state or Federal oversight agencies upon request for oversight purposes.
- xiii. Monthly IDR Entity Reporting Requirements.* Within 30 business days of the close of each month beginning on or after January 1, 2022, each certified IDR entity must report certain data and information in a form and manner specified by the Departments. Certified IDR entities must report the number of Notices of

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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 and, in instances where the provider or facility submits the Notice of Initiation, the size of the provider practices or facilities submitting notifications. The certified IDR entity must report the number of written Notices of IDR Initiation for which a final determination was made by the certified IDR entity. 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 items and services with respect to which the Notice of IDR Initiation was provided. Certified IDR entities must also report, for each determination, the offers submitted by the disputing parties expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, and whether the offer selected by the certified IDR entity was submitted by the plan or issuer, or the provider or facility. Where batched items and services have multiple QPAs, the certified IDR entities must report the offer as a percentage of each QPA that applied 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 determined exceeded the QPA. For each determination, the certified IDR entity must also report the practice specialty or type of each provider or facility involved in furnishing the items and services at issue as well as each party's name and address. For each determination, the certified IDR entity must also report the number of business days between the selection of the certified IDR entity and the payment determination. Finally, the certified IDR entity must report the total amount of certified IDR entity fees paid to the certified IDR entity during the preceding month. 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. With respect to claims involving air ambulance services, the certified IDR entity must report the number of written notifications submitted to the certified IDR entity that pertain to air ambulance services during the preceding month; the number of such notifications with respect to which a final determination was made; the number of times the out-of-network rate determined (or agreed to) exceeded the QPA for air ambulance services; and the total amount of certified IDR. With respect to each Notice of IDR Initiation, the certified IDR entity must provide a description of each air ambulance service, including the relevant billing and service codes and point of pick-up (as defined in 42 CFR 414.605) for the services 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

percentage of the QPA; whether the offer selected by the certified IDR entity was the offer submitted by the plan or issuer or by the provider of air ambulance services; and the amount of the offer so selected, expressed as a percentage of the QPA. The certified IDR entity must report the rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria listed under 26 CFR 54.9817-2T(b)(2), 29 CFR 2590.717-2(b)(2), and 45 CFR 149.520(b)(2). 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, 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 IDR entity fees paid to the certified IDR entity for the preceding month. This total amount of IDR entity fees should not include amounts refunded by the certified IDR entity to prevailing parties. 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.

- 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 interim final rules do not restrict plans, or issuers, (or FEHB carriers) from using electronic technology to provide notices. Parties may provide the Open Negotiation Notice and the Notice of IDR Initiation to the other party electronically if the initiating party has a good faith belief that the electronic method is readily accessible by the other party, and the notice is provided in paper form free of charge upon request. Additionally, many of the requirements described above, including notices, petitions, and reporting will be shared electronically through the IDR portal.

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 Department of Labor 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.**

These interim final rules and the No Surprises Act amend and add provisions to existing rules under the PHS Act, ERISA and the Code. Several states already have their own 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 Department of Labor 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 this regulation 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. 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 will need to satisfy the same requirements under the interim final rules; however, these costs are scalable to the number of Federal IDR process payment determinations an entity is involved in. These interim final rules permit multiple items and services to be batched together in a single arbitration proceeding to encourage efficiency. Batched items and services must be billed by the same provider or group of providers or facility or same provider of air ambulance services; payment for the items and services must be made by the same group health plan or health insurance issuer; the items and services must be the same or similar items or services; and all the items and services must have been furnished within the same 30-business-day period. By batching similar claims, these 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, costs are likely to be lower for smaller providers and entities.

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

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

As the Federal IDR process depends on the sending and receiving of notices; discontinuing or reducing the frequency of these notices will not be possible in the process. 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, ensures that certified IDR entities meet 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 interim final rules would 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 IDR processes as closely, which could harm individuals, plans, issuers, providers, facilities, and providers of air ambulance services, and could cause harms to the wider health care market. This would also affect the ability of the Departments to report certain information on their public websites as is required under the No Surprises Act.

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

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and 2 copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The interim 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 description 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 interim final rule requires the parties utilizing the Federal IDR process to provide certain notices to the parties and to the Departments. Such information is required to efficiently conduct the Federal IDR process within the timeframes allowed by statute.

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

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

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

The Departments will be requesting approval of the emergency review requests by the effective date of the interim final rules. The Departments will be seeking approval for the ICR for 180 days, the maximum allowed for an ICR approved using an emergency

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review. As part of the emergency review request, the Departments will be requesting that OMB waive the notice requirement set forth in 5 CFR 1320.13(d). Once the emergency submission is approved, the Departments will initiate an ICR Revision, the process required under the PRA to seek up to three (3) years of approval for the information collections. As part of the process, the Departments will open a 60-day and 30-day comment period on the ICR.

The Departments have conducted stakeholder meetings and received letters from stakeholders to obtain their reviews regarding these interim final rules.

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 individually identifiable health information 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.**

Note: To give a fair overview of the burden imposed by this ICR the estimated annual burden of this ICR is shown during the calculations. As the ICR is being submitted as an emergency with a requested approval for 180 day the costs for the first 180 days is reported in the summary sections and in parentheses in the table at the end of this question.

Group health plans, health insurance issuers, FEHB carriers, providers, providers of air ambulance services, and facilities are responsible for ensuring compliance with the interim final rules. Accordingly, in the discussion below, the Departments refer to costs for plans, issuers, and FEHB carriers. However, it is expected that most self-insured group health plans will work with a third-party administrator (TPA) to meet the requirements of these interim final rules.

The Departments recognize the potential that some of the largest self-insured plans may seek to meet the requirements of these interim 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

The Departments estimate that 17,333 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. The Departments request data or comments on this assumption. Accordingly, the Departments estimate that 23,111 claims will go through open negotiation.² The Departments estimate that it will take, on average, a medical and health services manager 2 hours to write each notice of open negotiation and

² This is calculated $17,333 / (1 - 0.25) = 23,111$.

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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 \$224. For all 23,111 claims subject to these interim final rules proceeding through the Federal IDR process, the annual burden would be 51,999 hours, with an associated equivalent cost of \$5.2 million.³ The open negotiation notice must be sent within 30 business days beginning on the day the provider or facility receives an initial payment or a notice of denial of payment from the plan or issuer regarding such item or service.

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. The Departments estimate that it will take 2 hours for a legal professional 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, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. For the 17,333 claims initiating the Federal IDR process, the annual burden would be 38,999 hours, with an annual equivalent cost estimate of \$3.9 million.⁴

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 it will take, on average, a medical and health services manager 30 minutes to write each notice of open negotiation and a clerical worker 15 minutes to submit the notice to the Federal IDR portal. The burden for each

³ The burden is estimated as follows: 23,111 claims x 2 hours + 23,111 claims x 0.25 hour = 51,999 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 23,111 claims x 2 hours x \$105.01 + 23,111 claims x 0.5 hour x \$55.23 = \$5,172,803. Labor rates are EBSA estimates.

⁴ The burden is estimated as follows: 17,333 claims x 2 hours + 17,333 claims x 0.25 hours = 38,999 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 17,333 claims x 0.25 hours x \$105.01 + 17,333 claims x 2 hours x \$55.23 = \$3,879,602. Labor rates are EBSA estimates.

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plan, issuer, and FEHB carrier would be 45 minutes, with an equivalent cost of approximately \$66. For the 173 payment determinations resolved in this manner, the annual burden would be 130 hours, with an associated equivalent cost of \$11,472.⁵

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 certified IDR entity, they must notify the Departments of their selection 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 estimate that in 75 percent of IDR payment determinations, a certified IDR entity will be selected by the disputing parties. Additionally, the Departments assume that it will take 1 hour for a legal professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 1.25 hours, with an equivalent cost of approximately \$119. For the 13,000 claims that will have a certified IDR entity selected by the disputing parties, the annual burden would be 16,250 hours, with an annual equivalent cost estimate of \$1.5 million.⁶

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

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 provider or facility and the plan or issuer must submit to the certified IDR entity an offer

5 The burden is estimated as follows: 17,300 claims x 1 percent x 0.5 hours + 17,300 claims x 1 percent x 0.25 hours = 130 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 17,300 claims x 1 percent x 0.5 hours x \$105.01 + 17,300 claims x 1 percent x 0.25 hours x \$55.23 = \$11,472. Labor rates are EBSA estimates.

6 The burden is estimated as follows: (13,000 claims x 75 percent x 1 hour) + (13,000 claims x 75 percent x 0.25 hours) = 16,250 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (13,000 claims x 75 percent x 0.25 hours x \$105.01) + 13,000 claims x 75 percent x 1 hours x \$55.23 = \$1,544,628. Labor rates are EBSA estimates.

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for a payment amount for the qualified IDR item or service furnished by such provider or facility through the Federal IDR portal. The Departments estimate for providers and issuers, it will take an average of 2.5 hours for a medical and health services 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 \$290. For the 17,333 payment determinations that will go through submission of offer, the annual burden would be 103,998 hours, with an annual equivalent cost estimate of \$10.1 million.⁷

After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier of the payment determination and the reason for such determination, in a form and manner specified by the Departments.⁸ The cost of preparing and delivering this notice is assumed to be included in the certified IDR entity fee paid by the plan or issuer, or provider or facility, to conduct the review.⁹

If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the permitted considerations, with respect to the qualified IDR item or service. 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. When determining the out-of-network rate, the certified IDR entity must consider the QPA and must consider the other statutory factors when a party presents credible information relating to those factors clearly demonstrating the QPA is materially different from the appropriate out-of-network rate, or where the offers are equally distant from the QPA but in opposing directions.

Additionally, the selected certified IDR entity must provide the payment determination and the reasons for such to 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.

7 The burden is estimated as follows: $(17,333 \text{ claims} \times 2.5 \text{ hours} + 17,333 \text{ claims} \times 0.5 \text{ hours}) + (17,333 \text{ claims} \times 2.5 \text{ hours} + 17,333 \text{ claims} \times 0.5 \text{ hours}) = 103,998 \text{ hours}$ for providers and issuers. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: $(17,333 \text{ claims} \times 2.5 \text{ hours} \times \$105.01 + 17,333 \text{ claims} \times 0.5 \text{ hours} \times \$55.23) + (17,333 \text{ claims} \times 2.5 \text{ hours} \times \$105.01 + 17,333 \text{ claims} \times 0.5 \text{ hours} \times \$55.23) = \$10,057,993$. Labor rates are EBSA estimates.

8 IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

9 Under Section 103 of the No Surprises Act, the party whose offer was not chosen by the certified IDR entity is responsible for paying the IDR entity's fee.

Summary

The total hour burden associated with the Federal IDR process for hospital and emergency department claims is 211,376 hours with an equivalent cost of \$20,666,498. The total cost associated with the Federal IDR process for hospital and emergency claims is \$481,294.

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 be allocated to health care providers and facilities. 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. OPM will account for 5 percent of the burden.

The hour burden associated with DOL requirements is estimated to be approximately 52,844 hours at an equivalent cost of \$5,166,624. During the first six months, the hour burden associated with DOL requirements is approximately 26,422 hours at an equivalent cost of \$2,583,312 each.

Federal IDR Process for Air Ambulance

According to the March 2019 Health Insurance Coverage Bulletin, in 2018, 213.2 million individuals had private health insurance.¹⁰ In 2017, HCCI estimated that, on average, there were 33.3 air ambulance uses per 100,000 people,¹¹ and the GAO estimated that approximately 69 percent of air transports resulted in an out-of-network bill.¹² The Departments do not have data on what percent of out-of-network bills will proceed to the Federal IDR process; however, given the nature of air ambulance services, the Departments assume that the percentage will be substantially higher than for hospital or emergency department claims. The Departments assume that 10 percent of out-of-network claims for air transport will end up in the Federal IDR process.

10 Employee Benefits Security Administration. “Health Insurance Coverage Bulletin.” (March 2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>.

11 Hargraves, John and Aaron Bloschichak. “Air Ambulances-10-Year Trends in Costs and Use.” Health Care Cost Institute. (2019). <https://healthcostinstitute.org/emergency-room/air-ambulances-10-year-trends-in-costs-and-use>.

12 Government Accountability Office. “Air Ambulance: Available Data Show Privately-Insured Patients are at Financial Risk.” (2019). <https://www.gao.gov/assets/gao-19-292.pdf>.

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Accordingly, the government estimates there will be 4,899 air ambulance service claims submitted to the Federal IDR process each year.¹³ In these interim final rules, air ambulance services are subject to the same requirements for hospital and emergency services in 26 CFR 54.9816-8T, 29 CFR 2590.716-8, and 45 CFR 149.510 (as applicable), except that the items and services for which the requirements of (b)(1) of that section apply shall be understood to be out-of-network air ambulance services, and “qualified IDR items and services” are understood to be air ambulance services.

The Departments estimate that 4,899 air transport disputes will be handled by the Federal IDR process each year, but 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 6,532 transport payment determinations will enter into open negotiation.¹⁴ The Departments estimate that it will take an average of 2 hours for a medical and health services manager to write each open negotiation notice and 15 minutes for a clerical worker 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 \$224. For the 6,532 payment determinations that will enter into open negotiation, the annual burden would be 14,696 hours, with an annual equivalent cost estimate of \$1.5 million.¹⁵ The open negotiation notice must be sent within 30 business days beginning on the day the provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan, issuer, or FEHB carrier regarding such item or service.

For the estimated 4,899 payment determinations that are submitted to the Federal IDR process, the Departments estimate that it will take 2 hours for a legal professional 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, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. For the 4,899 payment determinations that will have selected a certified IDR entity, the annual burden would be 11,022 hours, with an annual equivalent cost estimate of \$1.1 million.¹⁶

13 The Departments estimate that of the 213.2 million individuals with employer-sponsored health insurance, there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The Departments assume that 10 percent of the out-of-network bills will end up in IDR. $(213,200,000 \times 0.000333 \times 0.69 \times 0.1 = 4,899)$.

14 This is calculated as $4,899 / (1 - 0.25) = 6,532$.

15 The burden is estimated as follows: $6,532 \text{ claims} \times 2 \text{ hours} + 6,532 \text{ claims} \times 0.25 \text{ hours} = 14,696 \text{ hours}$. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: $6,532 \text{ claims} \times 0.25 \text{ hours} \times \$105.01 + 6,532 \text{ claims} \times 2 \text{ hours} \times \$55.23 = \$1,461,951$. Labor rates are EBSA estimates.

16 The burden is estimated as follows: $4,899 \text{ claims} \times 2 \text{ hours} + 4,899 \text{ claims} \times 0.25 \text{ hours} = 11,022 \text{ hours}$. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical

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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, 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 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 it will take, on average, a medical and health services manager 30 minutes to write each notice of open negotiation and a clerical worker 15 minutes to submit the notice to the Federal IDR portal. The burden for each plan, issuer, and FEHB carrier would be 45 minutes, with an equivalent cost of approximately \$66. For the 49 payment determinations resolved in this manner, the annual burden would be 37 hours, with an associated equivalent cost of \$3,249.¹⁷

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services select or fail to select a certified IDR entity, they must notify the Departments of their selection or failure to select a certified IDR entity no later than 1 day after such selection or failure. The Departments estimate that in 75 percent of payment determinations, a certified IDR entity will be selected. Additionally, the Departments assume that it will take one hour for a legal professional to write the notice and 15 minutes for a clerical worker to prepare and send the notice. The burden for each plan, issuer, and FEHB carrier would be 1.25 hours, with an equivalent cost of approximately \$119. Due to the tight turnaround, the Departments assume this notice will be sent electronically through the Federal IDR portal. For the 3,674 payment determinations that will have a selected a certified IDR entity, the annual burden would be 4,593 hours, with an annual equivalent cost estimate of \$0.4 million.¹⁸

worker. The labor rates are applied in the following calculation: $4,899 \text{ claims} \times 0.25 \text{ hours} \times \$105.01 + 4,899 \text{ claims} \times 2 \text{ hours} \times \$55.23 = \$1,096,463$. Labor rates are EBSA estimates.

17 The burden is estimated as follows: $4,899 \text{ claims} \times 1 \text{ percent} \times 0.5 \text{ hours} + 4,899 \text{ claims} \times 1 \text{ percent} \times 0.25 \text{ hours} = 37 \text{ hours}$. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: $4,899 \text{ claims} \times 1 \text{ percent} \times 0.5 \text{ hours} \times \$105.01 + 4,899 \text{ claims} \times 1 \text{ percent} \times 0.25 \text{ hours} \times \$55.23 = \$3,249$. Labor rates are EBSA estimates.

18 The burden is estimated as follows: $(4,899 \text{ claims} \times 75 \text{ percent} \times 1 \text{ hour}) + (4,899 \text{ claims} \times 75 \text{ percent} \times 0.25 \text{ hours}) = 4,593 \text{ hours}$. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: $(4,899 \text{ claims} \times 75 \text{ percent} \times 0.25 \text{ hours} \times \$105.01) + (4,899 \text{ claims} \times 75 \text{ percent} \times 1 \text{ hours} \times \$55.23) = \$436,535$. Labor rates are EBSA estimates.

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If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method. The range of certified IDR entity fees and the administrative fee paid to the Departments by the plan, issuer, or FEHB carrier and the provider of air ambulance services will be addressed in later guidance by the Departments. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider of air ambulance services, plan, issuer, or FEHB carrier must submit to the certified IDR entity: (1) an offer for a payment amount for the qualified IDR item or 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; the relevant geographic region for purposes of the QPA; (B) whether the coverage is fully-insured self-insured, or mixed funded), if applicable; and (C) the QPA. The parties may also submit to the certified IDR entity any information relating to the offer submitted by either party, 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 for providers of air ambulance services, issuers, plans, and FEHB carriers, it will take an average of 2 hours for a medical and health services manager to write the offer and 15 minutes for a clerical worker to prepare and send the offer. The burden for each plan, issuer, and FEHB carrier would be 2.25 hours, with an equivalent cost of approximately \$224. For the 4,899 claims that will go through submission of offers, the annual burden would be 22,044 hours, with an annual equivalent cost estimate of \$2.2 million.¹⁹

After the certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination.²⁰ The cost of preparing and delivering this notice is included in

¹⁹ The burden is estimated as follows: (4,899 claims x 2 hours + 4,899 claims x 0.25 hours) + (4,899 claims x 2 hours + 4,899 claims x 0.25 hours) = 22,044 hours for providers and issuers. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (4,899 claims x 2 hours x \$105.01 + 4,899 claims x 0.25 hours x \$55.23) + (4,899 claims x 2 hours x \$105.01 + 4,899 claims x 0.25 hours x \$105.01) = \$2,192,926. Labor rates are EBSA estimates.

²⁰ IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

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the \$25 administrative fee paid by the provider of air ambulance services, plan, issuer, or FEHB carrier to conduct the review.

Certified IDR entities also need to notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination and the written decision explaining such determination. If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA amount was materially different from the appropriate out-of-network rate, based on the required considerations, with respect to the qualified IDR item or service.

Summary

The total hour burden associated with the Federal IDR process for air ambulance services is 52,392 hours with an equivalent cost of \$5,191,124. Half of the burden associated with the Federal IDR process for air ambulance services is estimated to be allocated to health plans, issuers, or TPAs, and the other half is estimated be allocated to health care providers. The burden associated with the Federal IDR process for air ambulance services is assumed to be shared by the Departments and OPM. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden.

The hour burden associated with DOL requirements is estimated to be approximately 13,089 hours at an equivalent cost of \$1,297,781. During the first six months, the hour burden associated with DOL is approximately 6,549 hours at an equivalent cost of \$648,891.

Request of Extension of Time Periods for Extenuating Circumstances

The Departments do not have data on how often entities will request an extension; however, the Departments are of the view that extenuating circumstances will be rare. The Departments assume that 100 plans, issuers, FEHB carriers, health care or air ambulance service providers, or facilities will annually request an extension starting in 2022 by completing the "Request for Extension due to Extenuating Circumstances" form and attesting that prompt action will be taken to ensure the payment determination under this section is made as soon as administratively practical. The Departments estimate that it will take a clerical worker 15 minutes to prepare and send the notice. The annual

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burden would be 25 hours, with an associated equivalent cost of \$1,381.²¹

Summary

The total hour burden associated with requests for extension is 25 hours with an equivalent cost of \$1,381. Half of the burden is estimated to be allocated to health plans, issuers, 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. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden.

The hour burden associated with DOL requirements is estimated to be approximately 6 hours at an equivalent cost of \$345 each. During the first six months, the hour burden associated with DOL is approximately 3 hours at an equivalent cost of \$173.

Total Hour Burden Summary

The total hour burden in the first six months associated with the Federal IDR process is 3,400,460 hours with an equivalent cost burden of \$366,082,073. The total annual hour burden associated with the Federal IDR process is 4,972,056 hours with an equivalent cost burden of \$518,688,160.

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 will be allocated toward the hour burden of HHS. The burden of IDR entities will be fully allocated toward the cost burden.

For DOL requirements, the total annual hour burden in the first six months associated with the Federal IDR process is estimated to be estimated to be 32,974 hours with an equivalent cost of \$3,232,375. The total annual hour burden associated with the Federal IDR process for DOL is 65,948 hours with an equivalent cost burden of \$6,464,751.

²¹ The burden is estimated as follows: 100 requests x 0.25 hour = 25 hours. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: 100 requests x 0.25 hours x \$55.23 = \$1,381. Labor rates are EBSA estimates.

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Estimated Annualized Respondent Cost and Hour Burden

Note: The six month burden and number of responses has been included below in parenthesis.

Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Total Burden Cost
Federal IDR Process for Services relating to Nonparticipating Providers or Nonparticipating Emergency Facilities							
Medical Billing Specialist write the notice for Open Negotiation	5,778	1	5,778 (2,889)	2	11,555 (5,778)	\$105.01	\$1,213,426 (\$606,713)
Clerical workers prepare and send notice for Open Negotiation	5,778	1	5,778 (2,889)	15/60	1,444 (722)	\$55.23	\$79,775 (\$39,888)
Medical Billing Specialist write the Notice for General Initiation of Independent Dispute Resolution Process in the Case of Failed Negotiation	4,333	1	4,333 (2,167)	2	8,667 (4,334)	\$105.01	\$910,069 (\$455,035)
Clerical workers prepare and send Notice for General Initiation of Independent Dispute Resolution Process in the Case of Failed Negotiation	4,333	1	4,333 (2,167)	15/60	1,083 (542)	\$55.23	\$59,831 (\$29,916)
Medical Billing Specialist write the notice for Notice of Agreement on an Out-of-Network Rate	43	1	43 (22)	30/60	22 (11)	\$105.01	\$2,271 (\$1,135)
Clerical workers prepare and send notice for Notice of Agreement on an Out-of-Network Rate	43	1	43 (22)	15/60	11 (5)	\$55.23	\$597 (\$299)
Medical Billing Specialist write the	3,250	1	3,250 (1,625)	1	3,250 (1,625)	\$105.01	\$341,283

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notice for selecting IDR entity							(\$170,641)
Clerical workers prepare and send the notice for write the notice for selecting IDR entity	3,250	1	3,250 (1,625)	15/60	813 (406)	\$55.23	\$44,874 (\$22,437)
Medical Billing Specialist write the offer	8,667	1	8,667 (4,33)	2.5	21,667 (10,833)	\$105.01	\$2,275,173 (\$1,137,586)
Clerical workers prepare and submit the offer	8,667	1	8,667 (4,333)	0.5	4,333 (2,166)	\$55.23	\$239,326 (\$119,663)
Federal IDR Process for Air Ambulance Services							
Medical Billing Specialist write the notice for Open Negotiation	1,633	1	1,633 (816)	2	3,266 (1,633)	\$105.01	\$342,941 (\$171,471)
Clerical workers prepare and send notice for Open Negotiation	1,633	1	1,633 (816)	0.25	408 (204)	\$55.23	\$22,546 (\$11,273)
Medical Billing Specialist write the Notice for General Initiation of Independent Dispute Resolution Process in the Case of Failed Negotiation	1,225	1	1,225 (612)	2	2,449 (1,225)	\$105.01	\$257,206 (\$128,603)
Clerical workers prepare and send Notice for General Initiation of Independent Dispute Resolution Process in the Case of Failed Negotiation	1,225	1	1,225 (612)	15/60	306 (153)	\$55.23	\$16,910 (\$8,455)
Medical Billing Specialist write the notice for Notice of Agreement on an Out-of-Network Rate	12	1	12 (6)	30/60	6 (3)	\$105.01	\$643 (\$322)
Clerical workers prepare and send notice for Notice of Agreement on an Out-of-Network Rate	12	1	12 (6)	15/60	3 (1.5)	\$55.23	\$169 (\$85)

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Medical Billing Specialist write the notice for selecting IDR entity	919	1	919 (459)	1	919 (459)	\$105.01	\$96,452 (\$48,226)
Clerical workers prepare and send the notice for write the notice for selecting IDR entity	919	1	919 (459)	15/60	230 (115)	\$55.23	\$12,683 (\$6,341)
Medical Billing Specialist write the offer	2,449	1	2,449 (1,225)	2	4,899 (2,449)	\$105.01	\$514,412 (\$257,206)
Clerical workers prepare and submit the offer	2,449	1	2,449 (1,225)	15/60	612 (306)	\$55.23	\$33,819 (\$16,909)
Request for Extension							
Clerical workers prepare and submit the offer	25	1	25 (13)	15/60	6 (3)	\$55.23	\$345 (\$173)
Total (3-year average)	22,257*	1.647825	36,675** (18,338)	1.7982	65,948 (32,974)	-	\$6,464,751 (\$3,232,375)

* The total number of respondents was calculated in the following manner: 17,333 (Federal IDR Process for Services relating to Nonparticipating Providers or Nonparticipating Emergency Facilities) + 4,899 (Federal IDR Process for Air Ambulance Services) + 25 (IDR Entity) = 22,257.

**The total number of responses in the first year was calculated in the following manner: 27,487 (Federal IDR Process for Services relating to Nonparticipating Providers or Nonparticipating Emergency Facilities) + 8,993 (Federal IDR Process for Air Ambulance Services) + 25 (Request for Extension) + 176 (IDR Entity) = 36,682. The total number of responses in the subsequent years was calculated in the following manner: 27,487 (Federal IDR Process for Services relating to Nonparticipating Providers or Nonparticipating Emergency Facilities) + 8,993 (Federal IDR Process for Air Ambulance Services) + 25 (Request for Extension) + 166 (IDR Entity) = 36,672. Thus, the three-year average number of responses is 36,675 ((36,682 + 36,672 + 36,672)/3).

***Please note that the numbers in the table are rounded.

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

- The cost estimate should be split into 2 components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of

capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

- If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.
- Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

Group health plans, health insurance issuers, FEHB carriers, providers, facilities, and providers of air ambulance services are responsible for ensuring compliance with these interim final rules. Accordingly, in the discussion below, the Departments refer to costs on plans, issuers, and carriers. However, it is expected that most self-insured group health plans will work with a TPA to meet the requirements of the rules. As such, issuers and TPAs are assumed to incur this cost and burden for most group health plans, and only the largest self-insured plans may incur this cost directly.

Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities

The Departments estimate that 17,333 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 23,111 claims will go through open negotiation.²² The Departments assume that five percent of these notices would be mailed and will incur a printing cost of \$0.05 per page

²² This is calculated $17,333 / (1 - 0.25) = 23,111$.

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and \$0.55 for postage. Thus, the mailing cost is estimated to be \$693.²³

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. 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 five percent of these notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$520.²⁴

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 certified IDR entity, they must notify the Departments of their selection 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 estimate that in 75 percent of IDR payment determinations, a certified IDR entity will be selected by the disputing parties. For the 13,000 claims that will have a certified IDR entity selected by the disputing parties, the Departments assume that five percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$390.²⁵

If the plan, issuer, or FEHB carrier and the nonparticipating provider or nonparticipating emergency facility fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

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 provider or facility and the plan or issuer must submit to the certified IDR entity an offer

²³ This is calculated $23,111 \times 0.05 \times (\$0.05 + \$0.55) = \693 .

²⁴ This is calculated $17,333 \times 0.05 \times (\$0.05 + \$0.55) = \520 .

²⁵ This is calculated $13,000 \times 0.05 \times (\$0.05 + \$0.55) = \390 .

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for a payment amount for the qualified IDR item or service furnished by such provider or facility through the Federal IDR portal. For the 17,333 payment determinations that will go through submission of offer, the Departments assume that five percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$1,040.²⁶

After the selected certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier of the payment determination and the reason for such determination, in a form and manner specified by the Departments.²⁷ The cost of preparing and delivering this notice is assumed to be included in the certified IDR entity fee paid by the plan or issuer, or provider or facility, to conduct the review.²⁸

If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the permitted considerations, with respect to the qualified IDR item or service. 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. When determining the out-of-network rate, the certified IDR entity must consider the QPA and must consider the other statutory factors when a party presents credible information relating to those factors clearly demonstrating the QPA is materially different from the appropriate out-of-network rate, or where the offers are equally distant from the QPA but in opposing directions.

Additionally, the selected certified IDR entity must provide the payment determination and the reasons for such to 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 these 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.

²⁶ This is calculated $(17,333 \times 0.05 \times (\$0.05 + \$0.55)) + (17,333 \times 0.05 \times (\$0.05 + \$0.55)) = \$1,040$.

²⁷ IDR Payment Determination Notification (ERISA 716(c)(5)(A))

²⁸ Under Section 103 of the No Surprises Act, the party whose offer was not chosen by the certified IDR entity is responsible for paying the IDR entity's fee.

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For the maintenance and recordkeeping of 17,333 claims, the annual cost burden would be \$0.5 million.²⁹

Summary

The total cost associated with the Federal IDR process for hospital and emergency claims is \$481,294.

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. 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. OPM will account for 5 percent of the burden.

The total cost burden associated with DOL requirements is estimated to be \$120,324. During the first six months, the cost burden associated with DOL requirements is approximately \$60,162.

Federal IDR Process for Air Ambulance

The Departments estimate that 6,532 transport payment determinations will enter into open negotiation.³⁰ The open negotiation notice must be sent within 30 business days beginning on the day the provider of air ambulance services 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 assume that five percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$196.³¹

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. 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

29 The burden is estimated as follows: (17,333 claims x 30 minutes) = 8,667 hours for providers and issuers. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (17,333 claims x 30 minutes x \$55.23) = \$478,651. Labor rates are EBSA estimates.

30 This is calculated as 4,899 / (1 - 0.25) = 6,532.

31 This is calculated 6,532 x 0.05 x (\$0.05 + \$0.55) = \$196.

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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 five percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$147.³²

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services select or fail to select a certified IDR entity, they must notify the Departments of their selection or failure to select a certified IDR entity no later than 1 day after such selection or failure. The Departments estimate that in 75 percent of payment determinations, a certified IDR entity will be selected. Due to the tight turnaround, the Departments assume this notice will be sent electronically through the Federal IDR portal. For the 3,674 payment determinations that will have a selected a certified IDR entity, the Departments assume that five percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$110.³³

If the plan, issuer, or FEHB carrier and the nonparticipating provider of air ambulance services fail to select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity costs (or has received approval from the Departments to charge a fee outside of the allowed range) through a random selection method. The range of certified IDR entity fees and the administrative fee paid to the Departments by the plan, issuer, or FEHB carrier and the provider of air ambulance services will be addressed in later guidance by the Departments. The Departments estimate that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties.

Additionally, no later than 10 business days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider of air ambulance services, plan, issuer, or FEHB carrier must submit to the certified IDR entity: (1) an offer for a payment amount for the qualified IDR item or 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; the relevant geographic region for purposes of the QPA; (B) whether the coverage is fully-insured self-insured, or mixed funded), if applicable; and (C) the QPA. The parties may also submit to the certified IDR entity any information relating to the offer submitted by either party, except that the information may not include information on factors described

³² This is calculated $4,899 \times 0.05 \times (\$0.05 + \$0.55) = \147 .

³³ This is calculated $3,674 \times 0.05 \times (\$0.05 + \$0.55) = \110 .

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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 4,899 claims that will go through submission of offers, the Departments assume that five percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$294.³⁴

After the certified IDR entity has reviewed the offer, the certified IDR entity must notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination.³⁵ The cost of preparing and delivering this notice is included in the \$25 administrative fee paid by the provider of air ambulance services, plan, issuer, or FEHB carrier to conduct the review.

Certified IDR entities also need to notify the provider of air ambulance services and the plan, issuer, or FEHB carrier of the payment determination and the written decision explaining such determination. If the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA amount was materially different from the appropriate out-of-network rate, based on the required considerations, with respect to the qualified IDR item or service.

Additionally, the certified IDR entity must provide the payment determination and the reasons for such determination to 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 of air ambulance services, 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 make such records available for examination by the plan, issuer, FEHB carrier, provider of air ambulance services, or state or Federal oversight agency upon request, except where such disclosure would violate state or Federal privacy laws. The Departments assume it will take 30 minutes for a clerical worker to establish the records for each determination under the Federal IDR process necessary to meet the requirements. The cost burden for each certified IDR entity would be 30 minutes, with an equivalent cost of approximately \$28. For the maintenance and recordkeeping of 4,899 claims, the annual cost burden would be \$0.1 million.³⁶

³⁴ This is calculated $(4,899 \times 0.05 \times (\$0.05 + \$0.55)) + (4,899 \times 0.05 \times (\$0.05 + \$0.55)) = \294 .

³⁵ IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

³⁶ The burden is estimated as follows: $(4,899 \text{ claims} \times 30 \text{ minutes}) = 2,449 \text{ hours}$ for providers and issuers. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: $(4,899 \text{ claims} \times 30 \text{ minutes} \times \$55.23) = \$135,278$. Labor rates are EBSA estimates.

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Summary

The total cost burden associated with the Federal IDR process for air ambulance services is \$136,025. Half of the burden associated with the Federal IDR process for air ambulance services is estimated to be allocated to health plans, issuers, or TPAs, and the other half is estimated to be allocated to health care providers. The burden associated with the Federal IDR process for air ambulance services is assumed to be shared by the Departments and OPM. HHS is assumed to cover 45 percent of the burden, while DOL and the Department of the Treasury will each cover 25 percent of the burden and OPM will cover 5 percent of the burden.

The total cost burden associated with DOL requirements is estimated to be \$34,006. During the first six months, the cost burden associated with DOL requirements is approximately \$17,003.

Request of Extension of Time Periods for Extenuating Circumstances

The Departments assume that 100 plans, issuers, FEHB carriers, health care or air ambulance service providers, or facilities will annually request an extension starting in 2022 by completing the “Request for Extension due to Extenuating Circumstances” form and attesting that prompt action will be taken to ensure the payment determination under this section is made as soon as administratively practical. The Departments expect these requests to be submitted through the Federal IDR portal, and therefore have not estimated an associated mailing cost.

IDR Entity Certification and 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 50 entities that seek IDR certification.

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 these 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

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defined under these 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. That agreement will include a number of provisions encompassed by these interim final rules.

The Departments estimate that on average it will take a medical and health services manager 5.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each IDR entity would be 5.35 hours, with an equivalent cost of approximately \$548. For the 50 IDR entities that will go through certification, this results in a cost burden of \$27,468 in the first year.³⁷

Upon selection of a certified IDR entity, the certified IDR entity must submit the administrative fee to the Departments on behalf of patient and the provider or facility. The Departments estimate that the time required to complete the information collection is estimated to average a clerical worker 18 hours annually, including the time to review instructions, search existing data resources, gather required data, and complete and review information collection. This results in a cost burden of \$49,707.³⁸

Certified IDR entities are required to be recertified every 5 years. The Departments estimate that on average one-fifth of certified IDR entities will need to be recertified each year. Similar to the initial certification process, the IDR entities must ensure the processes are established and complete the corresponding paperwork, including the certification agreement, through the Federal IDR portal. The Departments estimate that, on average, it will take a medical and health services manager 2.10 hours and a clerical worker 15 minutes to satisfy the requirement. The burden for each certified IDR entity would be 2.35 hours, with an equivalent cost of approximately \$224. For the 10 certified IDR entities that will go through recertification, this results in a cost burden of \$2,238 in subsequent years.³⁹

37 The burden is estimated as follows: (50 IDR entities x 5.10 hours) + (50 IDR entities x 0.25 hours) = 268 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 IDR entities x 5.10 hours x \$105.01) + (50 IDR entities x 0.25 hours x \$55.23) = \$27,468.

38 The burden is estimated as follows: (18 hours x \$55.23) = \$994.14 each IDR entity. A labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 x 18 hours x \$55.23) = \$49,707. Labor rates are EBSA estimates.

39 The burden is estimated as follows: (50 IDR entities x 1/5 x 2.1 hours) + (50 IDR entities x 1/5 x 0.25 hours) = 24 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (50 IDR entities x 1/5 x 2.1 hours x \$105.01) + (50 IDR entities x 1/5 x 0.25 hours x \$55.23) = \$2,343.

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These interim final rules permit an individual, provider, facility, provider of air ambulance services, or group health plan, health insurance issuer offering group or individual health insurance coverage, or FEHB carrier to petition for a denial of a certification or a revocation of a certification with respect to an IDR entity seeking certification or certified IDR entity for failure to meet certain requirements set forth in the interim final rules. The Departments do not have data on how often such a petition might occur; however, the Departments assume that such a petition will be a rare occurrence. The Departments assume that there will be 3 petitions each year, and it will take on average a medical and health services manager 2 hours and a clerical worker 15 minutes to prepare the petition. The burden for each IDR entity seeking certification or certified IDR entity would be 2.25 hours, with an equivalent cost of approximately \$224. For the three petitions, this results in a cost burden of \$560.⁴⁰

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 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, 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 or issuer (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 or issuer (as applicable) or by the provider or facility (as applicable); the amount of the selected offer expressed as a dollar amount and a percentage of the QPA; the rationale for the certified IDR entity's decision; the practice specialty or type of each provider or facility (as applicable) involved in furnishing each qualified IDR item or service; the identity for each plan or issuer, 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.

⁴⁰ The burden is estimated as follows: (3 IDR entities x 2 hours) + (3 IDR entities x 0.25 hours) = 6 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (3 IDR entities x 2 hours x \$105.01) + (3 IDR entities x 0.25 hours x \$55.23) = \$560.

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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 a percentage of the QPA, including 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 \$118. For the 600 IDR entities, the annual burden would be 750 hours, with an equivalent cost burden of \$71,291 each year.⁴¹

The certified IDR entities are required, following the discovery of a breach of unsecured IIHI, to notify of the breach the provider, facility, or provider of air ambulance services; the plan or issuer; the Departments; and each individual whose unsecured IIHI has been,

⁴¹ The burden is estimated as follows: (50 IDR entities x 1 hour x 12 reports annually) + (50 IDR entities x 0.25 hours x 12 reports annually) = 750 hours. A labor rate of \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (200 IDR entities x 1 hour x 12 reports x \$105.01) + (200 IDR entities x 0.25 hours x 12 reports x \$55.23) = \$71,291.

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or is reasonably believed to have been, subject to the breach, to the extent possible. The Departments estimate that three certified IDR entities will have a breach each year. In addition, the Departments estimate that it will take a medical and health services manager 1 hour, on average, to handle the initial breach and follow the required protocols, and that it will take a general and operations manager 45 minutes, on average, to ensure the protocol is executed and adapt policies accordingly. The burden for each certified IDR entity would be 1.75 hours, with an equivalent cost of approximately \$197. For the three certified IDR entities, this results in a cost burden of \$591 each year.⁴² The Departments assume that 5 percent of notices would be mailed and will incur a printing cost of \$0.05 per page and \$0.55 for postage. Thus, the mailing cost is estimated to be \$0.09.⁴³

Summary

In the first year, the total cost burden associated with the IDR entity certification process is \$149,616. In subsequent years, the total cost burden associated with the IDR entity certification process is \$124,491. The three-year average cost burden associated with the IDR entity certification is \$132,866.

The burden associated with the IDR entity certification is shared by HHS, DOL, the Department of the Treasury, and OPM. It is estimated that 45 percent of the burden will be accounted for by HHS, 25 percent of the burden will be accounted for by DOL and the Department of the Treasury each, and 5 percent will be accounted for by OPM.

The cost burden associated with DOL requirements is \$37,404 in the first year and \$31,123 in subsequent years. The three-year average cost burden associated with DOL is \$33,217 each.

Total Cost Burden Summary

The total cost burden in the first six months associated with the Federal IDR process is \$610,675. The total cost burden in the first year associated with the Federal IDR process is \$1,206,242. In subsequent years, the total cost burden associated with the Federal IDR process is \$1,143,314. Thus, the 3-year average cost burden is \$1,164,290.

The Departments classify the burden born by IDR entities and certified IDR entities as a cost burden. For certification, re-certification, and monthly reporting requirements, 45

⁴² 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 \$105.01 is used for a medical and health services manager and a labor rate of \$55.23 is used for a clerical worker. The labor rates are applied in the following calculation: (3 certified IDR entities x 1 hour x \$105.01) + (3 certified IDR entities x 0.75 hour x \$122.55) = \$591.

⁴³ This is calculated 3 x 0.05 x (\$0.05 + \$0.55) = \$0.09

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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.

For DOL requirements, the total cost burden associated with the Federal IDR process in the first six months is \$99,300. The total cost burden in the first year is estimated to be \$191,734 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be \$185,452. Thus, the 3-year average cost burden associated with DOL requirements is \$187,546.

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

The Federal government will incur costs to build and maintain the federal IDR portal and to implement and administer the patient-provider dispute resolution process. The costs associated with the Federal IDR portal are estimated to be a one-time cost of \$6 million in 2021 and annual costs of \$1 million going forward.

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

This is a new collection of information.

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

For each calendar quarter in 2022 and each calendar quarter in a subsequent year, the Departments will publish information regarding the Federal IDR process on a public website.

The information will include aggregate statistics, such as the number of notifications submitted; the size of the provider practices and facilities submitting notifications; the number of notifications for which a determination was made; the information basis for such a determination; the number of times the payment amount determined under this

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subsection exceeds the qualifying payment amount, by items and services; the amount of expenditures made by the Departments during such calendar quarter to carry out the Federal IDR process; the total amount of fees paid; and the total amount of compensation paid to certified IDR entities.

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

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

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

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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.

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

Not applicable.